Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2114136	12/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
United Bioscience, Llc	901 W Leuda St Suite B, Fort Worth, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Based upon the onsite survey conducted 12/17/2018 - 12/19/2018 this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed. 493.1240 Pre-Analytic Systems 493.1250 Analytic Systems 493.1409 Technical Consultant 493.1441 Laboratory Director, (high complexity) 493.1447 Technical Supervisor 493.1459 General Supervisor
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the CMS 209, personnel records, proficiency testing (PT) records, and in interview with staff, the laboratory failed to ensure PT samples were tested by personnel who routinely perform Allergy testing on the Hitachi CLA - 1 test method for 2 of 3 testing events in 2017 (2017-B, 2017-C) and 2 of 3 testing events in 2018 (2018-A, 2018-B). Findings included: 1. Review of the CMS 209 form listed two testing persons (TP-1 and TP-2) who perform high complexity testing, that included allergy testing on the Hitachi CLA-1. Review of personnel records revealed TP-1 hire date was 07/10/2017 and TP-2 hire date was 08/10/2017. Training documentation for allergy testing for both TP's was in 07/2017 and 08/2017. 2. Review of PT records for allergy testing for 2017 and 2018 revealed the following events were all tested by TP-1: 2017 Event SE-B testing date was 09/01/2017 2017 Event SE-C testing date was 12 /07/2017 2018 Event SE-A testing date was 04/09/2018 2018 Event SE-B testing date

	was 08/23/2018 The laboratory did not ensure PT samples were tested by personnel who routinely perform Allergy testing on the Hitachi CLA - 1 test method. 3. During an interview on 12/17/2018 at 12:30 pm, TS (who was also TP-1) reviewed the above findings and stated TP-2 helps set-up the PT samples for testing. The did not ensure PT samples were tested by TP-2, who routinely performs Allergy testing on the Hitachi CLA - 1 test method. Word Key: SE - southeastern (southeastern inhalants)
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: I. Based on direct observation, review of laboratory records and confirmed in interview, the laboratory failed to retain package inserts for 6 of 12 sets of urine toxicology control material. Findings included: 1. Observed in the laboratory refrigerator on 12/18/2018 at 1540 hours were the following urine toxicology quality control materials in use: a. MAS DOA Total Control One vial of Level 2 MAS DOA Total Control Lot number DAT18122A/Expiration Date 2018-12-31 One vial of Level 3 MAS DOA Total Control Lot number DAT18123A/Expiration Date 2018-12-31 One vial of Level 4 MAS DOA Total Control Lot number DAT18124A/Expiration Date 2018-12-31 One vial of Level 5 MAS DOA Total Control Lot number DAT18125A/Expiration Date 2018-12-31 b. MGC Select XTC Control: One vial of Low Level MGC Select XTC Control Lot number 730233349/Expiration Date 2020 /01 One vial of High Level MGC Select XTC Control Lot number 730233350 /Expiration Date 2020/01 c. DRI Hydrocodone Assay Control: One vial of Low Level DRI Hydrocodone Assay Control Lot number 73122350/Expiration Date 2019/08 One vial of Low Level DRI Hydrocodone Assay Control Lot number 73122351 /Expiration Date 2019/08 d. CEDIA Buprenorphine Control One vial of Low Level CEDIA Buprenorphine Control Lot number 73008237/Expiration Date 2019/08 One vial of High Level CEDIA Buprenorphine Control Lot number 73008238/Expiration Date 2019/08 e. Creatinine Detect Control: One vial of Creatinine Detect 1.3 Control Lot number 73079519/Expiration Date 2018/12 One vial of Creatinine Detect 7.5 Control Lot number 73079520/Expiration Date 2018/12 One vial of Creatinine Detect 23.0 Control Lot number 73079543/Expiration Date 2018/12 f. DRI General Oxidant-Detect Control One vial of Low Level DRI General Oxidant-Detect Control Lot number 73181372/Expiration Date 2019/09 One vial of High Level DRI General Oxidant-Detect Control Lot number 73181373/Expiration Date 2019/09 2. Review of laboratory records revealed a document titled "Lots Used for Toxicology Validation 7-10-16" listed the following urine toxicology control material lot numbers: MAS DOA Total L2; Lot number DAT17072A; Expiration date 7-31-17 MAS DOA Total L3; Lot number DAT18023A; Expiration date 2-28-18 MAS DOA Total L4; Lot number DAT17074A; Expiration date 7-31-17 MAS DOA Total L5; Lot number DAT17075A; Expiration date 7-31-17 MGC Select DAU Control Set; Lot number 72371641; Expiration date 11-30-17 MGC Select DAU High Control; Lot number 72371649; Expiration date 11-30-17 DRI Hydrocodone Low Control; Lot number 72329751; Expiration date 5-31-2017 DRI Hydrocodone High Control; Lot number 72329745; Expiration date 5-31-2017 Cedia Buprenorphine Low Control; Lot number 72428405; Expiration date 9-30-17 Cedia Buprenorphine High Control; Lot number 72428406; Expiration date 9-30-17 Creatinine Detect 1.3 mg/dl Control; Lot number

72363194; Expiration date 1-31-17 Creatinine Detect 7.5 mg/dl Control; Lot number 72363192; Expiration date 1-31-17 Creatinine Detect 23.0 mg/dl Control; Lot number 72363190; Expiration date 1-31-17 DRI General Oxidant Detect Negative Control; Lot number 72372818; Expiration date 5-31-17 DRI General Oxidant Detect Positive Control; Lot number 72372822; Expiration date 5-31-17 3. During an interview on 12 /18/2018 at 1540 hours, the laboratory manager was asked to provide package inserts for previous lot numbers of urine toxicology control material. He stated the current lots of control material were in use when he started working at the facility and he was not aware of any past lot numbers that were utilized. After reviewing the document titled "Lots Used for Toxicology Validation 7-10-16", the laboratory manager confirmed the package inserts for the above reagents were not retained. This confirmed the above findings. 40420 Surveyor: 40420 II. Based on review of laboratory records and confirmed in interview, the laboratory failed to ensure instrument print outs (thermal paper) from the Hitachi analyzer were properly retained for quality control (QC) for 5 of 5 days in 2017 (08/2017, 09/2017 random sampling) and 9 of 9 patient test results in 2017 and 2018 (10/2017, 10/2018 random sampling). Findings: 1. Review of the Hitachi analyzer instrument print outs (thermal paper) for quality control and patient test results revealed the laboratory failed to ensure the thermal paper remained legible. The following is a random sampling for 2017 and 2018: Southeastern inhalants, test date 08/18/2017 (from planner sheet) Positive control lot #K4K34895, Exp. Date 01/31/2019, test date and time were illegible on the thermal paper Negative control lot #A1273-156K, Exp. Date 02/28/2019, test date and time were illegible on the thermal paper Southeastern inhalants, test date 09/01/2017 (from planner sheet) Positive control lot # unknown (it was not documented), test date and time were illegible on the thermal paper Negative control lot # unknown (it was not documented), test time was illegible on the thermal paper Moderate food, test date 09/01/2017 (from planner sheet) Negative control lot # unknown (it was not documented), test time was illegible on the thermal paper Moderate food, test date 09 /13/2017 (from planner sheet) Positive control lot #K4K34895, Exp. Date 01/2019, test year, test time, analyte # 24 LU value and name, apple analyte LU value, and analyte #26 LU value and name were illegible on the thermal paper Negative control lot #A1273-156K, Exp. Date 02/2019, test year, test time, analytes #25 and 26 names were illegible on the thermal paper Southeastern inhalants, test date 09/13/2017 (from planner sheet) Positive control lot #K4K34895, Exp. Date 01/2019, test date and time were illegible on the thermal paper Negative control lot #A1273-156K, Exp. Date 02 /2019, test date, test time and name of analyte #36 were illegible on the thermal paper Patient 180917001 tested for inhalants on 10/23/18 (from planner sheet), year of testing was illegible on the thermal paper only month and day (Oct 23) Patient 181008007 tested for inhalants on 10/23/18 (from planner sheet), day of testing was illegible on the thermal paper only month and year (Oct 2018) Patient 181008005 tested for inhalants on 10/23/18 (from planner sheet), day of testing was illegible on the thermal paper only month and year (Oct 2018) Patient 181008001 tested for inhalants on 10/23/18 (from planner sheet), day of testing was illegible on the thermal paper only month and year (Oct 2018) Patient 181008002 tested for inhalants on 10/23 /18 (from planner sheet), day of testing was illegible on the thermal paper only month and year (Oct 2018) Patient 180904010 tested for food on 10/23/18 (from planner sheet), month and year of testing were illegible on the thermal paper Patient 170929003 tested for inhalants on 10/04/2017, test time and name of analyte #36 were illegible on the thermal paper Patient 170929002 tested for inhalants on 10/04/2017, analyte #36 Penicillium LU value was illegible on the thermal paper Patient 170929004 tested for inhalants on 10/07/17 (from planner sheet), date of testing, analytes #35 and 36 names and LU values were illegible on the thermal paper only month and year (Oct 2018) The laboratory failed to ensure instrument print outs

	(thermal paper) from the Hitachi analyzer were properly retained for QC and patient test results. 2. During the exit interview on 12/19/2018 at 12:32 pm, Testing Person-1 and Testing Person-2 confirmed the above findings.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of Proficiency Testing (PT) records and in interview with staff, the laboratory failed to retain all PT documents for allergy testing for 1 of 3 testing events in 2017 (2017-A). Findings included: 1. Review of PT records from 2017 for allergy testing performed on the Hitachi CLA-1 analyzer revealed the laboratory did not retain the instrument printouts for PT samples tested for 2017 Event SE-A. PT samples (SE-01, SE-02, SE-03, SE-04, SE-05) were tested/reported for southeastern inhalants and raw data was not retained. Testing date was not available and attestation was signed/dated 05/24/2017 by a prior testing person. 2. During an interview on 12 /17/2018 at 12:30 pm, the technical supervisor reviewed the above findings and was unable to provide. The laboratory did not retain all PT records, as required.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: I. Based on review of CMS 209 form, personnel records, and in interview with staff, the laboratory failed to establish and follow written policies to assess consultant competency for 1 of 1 technical consultant (TC), technical supervisor (TS), and general supervisor (GS) in 2018 (01/2018). Findings included: 1. Review of the CMS 209 form included one individual listed as the TC, TS, and GS to provide oversight of chemistry testing, urine drug screen testing on AU480 analyzer, and allergy testing on the Hitachi CLA-1 analyzer. 2. Personnel records for the TC/TS/GS revealed hire date was 07/10/2017 and initial training was documented in 07/2017 for testing on the AU480 and Hitachi CLA-1. There was no documentation of competency assessment at least semi-annually during the first year the individual was employed and testing. There were no policies/procedures established for assessing TC/TS/GS competency and no written delegated duties as specified by the laboratory director (Refer to D6103 and D6107). The laboratory did not ensure competency assessment was performed and documented for the TC/TS/GS individual. 3. During an interview on 12 /17/2018 at 11:10 am, the TS was unable to provide the above requested documentation. II. Based on review of laboratory policy, laboratory record, and personnel records, the laboratory failed to include allergy testing in their personnel competency assessment policy. Findings included: 1. Review of the laboratory's policy "Personnel Competency Check" only included the specialty chemistry in their personnel assessment policy/procedure (approval by laboratory director date: 02/05 /2016). 2. According to records, the laboratory implemented allergy testing by Hitachi CLA-1 method 02/2017. The annual volume was 42,000 allergy tests performed. 3.

	Review of personnel records revealed the technical supervisor had not evaluated and documented competency assessment for TP-2 at least semiannually (02/2018). Refer to D6127. The laboratory's policy did not include allergy testing (Immunology) in their personnel competency assessment policy.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: I. Based on review of College of American Pathologist (CAP) proficiency testing (PT) records, laboratory's procedure manual, and in interview with staff, the laboratory failed to at least twice annually verify accuracy of drug analytes and adulterants tested on the AU480 not included in subpart I of this part and not covered by the PT company in 2017 and 2018. Findings included: 1. Review of CAP PT records for urine drug screen testing on the AU480 revealed ecstasy was only included in 1 of 3 testing events in 2017 (2017 Event -A). The laboratory did not ensure ecstasy was verified for accuracy at least twice annually in 2017. 2. Review of CAP PT record for urine drug screen testing on the AU480 revealed hydrocodone was not included in 3 of 3 testing events in 2017 and 2018. During an interview on 12/17/2018 at 12:30 pm, the TS stated split sample testing was performed with another laboratory to cover hydrocodone. Documentation was provided and revealed the split sample testing with the other laboratory was done 12/10/2018 (this included hydrocodone). The laboratory did not ensure hydrocodone was verified for accuracy at least twice annually in 2017. Hydrocodone was verified for accuracy only once in 2018, not twice. 3. Review of CAP PT records for urine drug adulterants testing on the AU480 revealed creatinine was only included in 1 of 2 testing events in 2018 (2018 Event - A). There was no PT records or other twice annual verification of accuracy documentation in 2017 for creatinine. The laboratory did not ensure creatinine was verified for accuracy at least twice annually in 2017 and 2018. 4. Review of the laboratory's procedure manual did not include a policy/procedure for split sample testing for analytes not covered in the subpart I of this part (non-regulated analytes) to verify accuracy. Refer to D5403. 5. During an interview on 12/17/2018 at 12:30 pm, the TS reviewed and confirmed the above findings. II. Based on review of laboratory's allergy panels, proficiency testing (PT) records, and in interview with staff, the laboratory failed to at least twice annually verify accuracy of all allergy subgroups tested on the Hitachi CLA-1 not included in subpart I of this part and not covered by the PT company in 2017 and 2018. Findings included: 1. Review of laboratory's records revealed Hitachi CLA-1 analyzer was implemented 02/2017. Subgroups Southeastern Inhalants and Moderate Food allergy panels were tested. 2. Review of proficiency testing (PT) records from 2017 and 2018 for Allergy testing revealed not all subgroups were covered in PT to ensure verification of accuracy, at least twice annually, as follows: 2017 Event SE-A analyzed Southeastern Inhalants and not Moderate Food 2017 Event SE-B analyzed Southeastern Inhalants and not Moderate Food 2018 Event SE-A analyzed Southeastern Inhalants and not Moderate Food 2018 Event SE-B analyzed Southeastern Inhalants and not Moderate Food 2018 Event SE-C analyzed Southeastern Inhalants and not Moderate Food The laboratory failed to ensure verification of accuracy, at least twice annually for Moderate Food allergy panel subgroup. 3. During an interview on 12/17/2018 at 2:13 pm, the Technical Supervisor (TS) was asked whether the laboratory had any other documentation of verification of

	accuracy for Allergy testing, he stated he had sent a sample to Allos (laboratory affiliated with manufacturer) but was having problems with it. The TS was asked whether sending a sample to Allos was sent on a defined frequency/schedule, he stated no. There was no written policy for this practice.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, laboratory policies, a random review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03/2017 through 12/12/2018, manufacturer's instructions, patient test reports, client services manual, test requsitions, Thermo Scientific DRI urine assay manufacturer's instructions, laboratory's documents, and confirmed in interview, the laboratory failed to meet the requirements of the condition of preanalytical systems as evidenced by: 1. The laboratory failed to ensure the test requisitions solicited the tests to be performed for 8 of 29 requisitions. Refer to D5305. 2. The laboratory failed to follow its own written policy and manufacturer instructions for testing specimens for urine toxicology analytes within the specified stability requirements for 13 of 67 patients from 03/03/2017 through 12/12/2018. Refer to D5311, I. 3. The laboratory failed to ensure the correct specimen storage, preservation and conditions for transportation, according to manufacturer's instructions for 11 of 11 specimens in 2017 (random sampling). Refer to D5311, II. 4. The laboratory failed to establish a policy for the rejection of hemolyzed specimens used in allergy testing. Refer to D5311, III. 5. The laboratory failed to document the time 67 of 67 patient specimens were received into the laboratory for processing and testing. Refer to D5313, I. 6. The laboratory failed to document the received time of specimens that were received from outside clients for 60 of 60 patients in 2017 (06/2017, 07/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 10 of 10 patients 2018 (08/2018, 09/2018, 10/2018) for allergy testing. Refer to D5313, II. 7. The laboratory failed to ensure all components for proper handling of urine specimens were included in their client services document. Refer to D5317, I. 8. The laboratory failed to ensure the client services manual was consistent with manufacturer's instructions for specimen handling for allergy specimens that were received from clients. Refer to D5317, II.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The

	source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of laboratory policy, a random review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03/2017 through 12/12/2018, and staff interview, the laboratory failed to ensure the test requisitions solicited the tests to be performed for 8 of 29 requisitions. Findings included: 1. The laboratory policy titled "Patient Test Management - Specimen Accessioning and Processing" (approved by the Laboratory Director 10/05/2016) stated, "Select the laboratory tests or profiles requested by the physician for which appropriate samples have been received." 2. Review of patient test requisitions revealed the following requisitions with NO tests requested: Date 03/03/2017; Patient Number 170303001 Date 07/11 /2017; Patient Number 170711001 Date 07/11/2017; Patient Number 170711002 Date 11/16/2017; Patient Number 171116001 Date 10/26/2018; Patient Number 181026001 Date 10/26/2018; Patient Number 181026002 Date 10/26/2018; Patient Number 181026003 Date 12/11/2018; Patient Number 181211002 3. The above findings were confirmed in an interview by the laboratory staff on 12/18/2018 at 1550 hours in the conference room.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of the laboratory policy, manufacturer's instructions, review of laboratory records, review of patient test reports, and confirmed in staff interview, the laboratory failed to follow its own written policy and manufacturer instructions for testing specimens for urine toxicology analytes within the specified stability requirements for 13 of 67 patients from 03/03/2017 through 12/12/2018. Findings included: 1. Review of the laboratory policies for Barbiturates, Buprenorphine, Cannabinoid, Ethyl Alcohol, Opiate, and Hydrocodone approved by the laboratory director on 10/5/2016 specified the following in the section titled "Specimen Collection and Handling": a. Barbiturates "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 7 days." b. Buprenorphine "Specimens kept at room temperature that do not receive initial test within 8 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 30 days." c. Cannabinoid "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 4 weeks (28 days)." d. Ethyl

Alcohol "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months." e. Hydrocodone "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months." f. Opiate "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months." 2. The manufacturer's instructions (Thermo Scientific DRI assays) for Barbiturates, Buprenorphine, Cannabinoid, Ethyl Alcohol, Opiate, and Hydrocodone specified the following in the section titled "Specimen Collection and Handling": a. Barbiturates (0353-12-EN 2017 11) "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8 C (Celsius) for up to 7 days." b. Buprenorphine (10007988-13-EN 2018 01) "Specimens kept at room temperature that do not receive initial test within 8 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 30 days." c. Cannabinoid (0142-10-EN 2017 12) "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 4 weeks (28 days)." d. Ethyl Alcohol (0318-11-EN 2017 12) "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months." e. Hydrocodone (10020160-1 2017 07) "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months." f. Opiate (0140-13-EN 2017 07) "Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months." 3. Review of the laboratory records revealed the laboratory failed to establish performance specification studies for specimen collection and handling when the laboratory modified the manufacturer's stated specimen collection and handling requirements. The laboratory was asked to provide documentation of performing the studies. No documentation was provided. Refer to D5423 II 5. Review of patient test reports from 03/03/2017 through 12/12/2018 revealed the following urine toxicology analytes were tested for each patient sample: Amphetamine Barbiturate Benzodiazepine Buprenorphine Cannabinoid Cocaine Ethyl Alcohol Ecstasy Methadone Hydrocodone Opiates Oxycodone Phencyclidine Propoxyphene 4. Further review of patient test reports from 03/03/2017 through 12/12 /2018 revealed the laboratory failed to follow its own policy and Thermo Scientific DRI assay manufacturer's instructions for specified stability requirements for the following 13 of 67 patients tested: Patient 170303001 Collection Date: 02/20/2017 Receive Date: 03/03/2017 Test Date: 03/08/2017 Days Elapsed from collection to testing=16 days Specimen Tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 17071200 Collection Date: 04/25/2017 Receive Date: 04/25/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing =78 Days; Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Specimen tested for Buprenorphine beyond the manufacturer's specified 30 days. Specimen tested for Cannabinoid beyond the manufacturer's specified 28 days. Specimen tested for Ethyl Alcohol beyond the manufacturer's specified 2 months. Specimen tested for Hydrocodone beyond the manufacturer's specified 2 months. Specimen tested for Opiates beyond the manufacturer's specified 2 months. Patient 170712001 Collection Date: 05/25/2017 Receive Date: 07/12/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing = 48 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Specimen tested for Buprenorphine beyond the

manufacturer's specified 30 days. Specimen tested for Cannabinoid beyond the manufacturer's specified 28 days. Patient 170711002 Collection Date: 06/20/2017 Receive Date: 06/20/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing= 22 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 170711003 Collection Date: 06/20/2017 Receive Date: 06/20/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing= 22 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 170711004 Collection Date: 06/19/2017 Receive Date: 06/19/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing= 23 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 170711001 Collection Date: 06/22/2017 Receive Date: 06/22/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing= 20 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 171116001 Collection Date: 11/16/2017 Receive Date: 11/16/2017 Test Date: 11/28/2017 Days Elapsed from collection to testing= 12 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 1810118002 Collection Date: 01/01/2018 Receive Date: 01/18/2018 Test Date: 01/18/2018 Days Elapsed from collection to testing= 17 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 181009002 Collection Date: 09/24/2018 Receive Date: 10/09/2018 Test Date: 10/09/2018 Days Elapsed from collection to testing= 15 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 181009004 Collection Date: 09/24/2018 Receive Date: 10/09/2018 Test Date: 10/09/2018 Days Elapsed from collection to testing= 15 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 181009001 Collection Date: 09/25/2018 Receive Date: 10/09/2018 Test Date: 10/10/2018 Days Elapsed from collection to testing= 15 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 181009003 Collection Date: 09/25/2018 Receive Date: 10/09/2018 Test Date: 10/09/2018 Days Elapsed from collection to testing= 14 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. 5. The above findings were confirmed in an interview with the laboratory staff on 12/18/2018 at 1550 hours in the conference room. 40420 II. Based on direct observation, review of manufacturer's instructions, laboratory policies, client services manual, and confirmed in interview, the laboratory failed to ensure the correct specimen storage, preservation and conditions for transportation, according to manufacturer's instructions for 11 of 11 specimens in 2017 (random sampling). Findings: 1. Review of Hitachi CLA-1 allergy analyzer manufacturer's instructions "4 Test Operation" page 4-3 stated: "Store Serum Store serum samples at 2-8 for a period of up to one week. For longer storage, samples should be frozen at -20C. Repeated freezing and thawing of serum samples should be avoided. Storage in a frost-free refrigerator may affect the long-term stability of the sample." 2. Review of laboratory policy "CLA Allergen-Specific IgE Assay" page 3 stated "Specimen Collection and Handling ...Serum samples may be stored at 2-8C for up to one week. For longer periods up to one year, store samples frozen at -20C. Repeated freezing and thawing of serum samples should be avoided." 3. Review of laboratory policy "PRE AND POST-ANALYTICAL SAMPLE PROCESSING" stated: "SPECIMEN TRANSPORT 1. Couriers will be provided with three types of specimen transport containers: a. cooler with ice packs for refrigerated specimens. b. cooler with dry ice for frozen specimens. c. plastic box or container for non-refrigerated or non-frozen specimens." 4. Review of the laboratory client services manual "BLOOD COLLECTION FOR ALLERGY TESTING" page 2 stated: "5 PUT all allergy specimens that are packaged for shipment in specimen and keep refrigerated until ready to ship. When ready to ship, place allergy specimens in a mailing cooler along with 2-3 ice packs. WARNING DO NOT FREEZE" Client services manual was not consistent with the laboratory's policy for transport. 5. During an interview on 12/18

/18 at 1:55 pm, with Testing Person-1 (TP-1) and Testing Person-2 (TP-2), the surveyor asked where specimens that were waiting to be tested were stored and TP-1 stated the freezer and pointed in the direction of the "Hot Point" frost-free refrigerator /freezer. Testing personnel were asked how the allergy specimens arrived and TP-2 stated "they come frozen on ice packs in foam coolers." TP-1 stated "2-8C is acceptable" and the specimens arrive "frozen or slushy." Testing personnel were asked how specimens were stored if they were not going to be tested the same day they were received, TP-2 stated that they would freeze them (in a "Hot Point" frost-free freezer). Testing personnel were asked if they documented the disposition of specimen arrival and TP-2 stated that it was not documented. The laboratory failed to ensure the proper storage, preservation and transportation of specimens. The freezer in which specimens were stored until testing was frost-free, this was not according to manufacturer's instructions for storage. The frost-free freezer does not maintain -20C or colder. The following are a random sampling of samples stored in the frost-free freezer; the diposition of these samples was not documented upon arrival and were not transported in conditions to ensure manufacturer's requirements were met: Patient #170726007: collection date 07/24/2017, collection time 4:00 pm, received date 07/26/207 (note received time was not documented), southeastern inhalants test date 08/02/2017, test time 14:38 Patient #170726008: collection date 07/21/2017, collection time 10:00, received date 07/26/2017 (note received time was not documented), southeastern inhalants and moderate food test date 08/02/2017, test time 14:40 (inhalants)/14:46 (food) Patient #170726009: collection date 07/19/2017, collection time 12:15, received date 07/26/2017 (note received time was not documented), southeastern inhalants test date 08/02/2017, test time 14:41 Patient #170726011: collection date 07 /21/2017, collection time 3:00, received date 07/26/2017 (note received time was not documented), southeastern inhalants test date 08/02/2017, test time 14:43 Patient #170929004: collection date 09/26/2017, collection time 3:00, received date 09/29 /2017 (note received time was not documented), southeastern inhalants test date 10/04 /2017, test time unknown due to thermal tape being illegible Patient #170929002: collection date 09/26/2017, collection time 3:00, received date 09/29/2017 (note received time was not documented), southeastern inhalants test date 10/04/2017, test time 13:49 Patient #170929003: collection date 09/22/2017, collection time 11:00 am, received date 09/29/2017 (note received time was not documented), southeastern inhalants test date 10/04/2017, test time unknown due to thermal tape being illegible Patient #171005005: collection date 10/05/2017, collection time 3:00, received date 10 /05/2017 (note received time was not documented), southeastern inhalants and moderate food test date 10/10/2017, test time unknown due to thermal tape being illegible for both inhalants and food Patient #171005006: collection date 10/05/2017, collection time 3:00, received date 10/05/2017 (note received time was not documented), southeastern inhalants and moderate food test date 10/10/2017, test time unknown due to thermal tape being illegible (inhalants)/14:46 (food) Patient #171005007: collection date 09/30/2017, collection time 12:00 pm, received date 10 /05/2017 (note received time was not documented), southeastern inhalants test date 10 /10/2017, test time unknown due to thermal tape being illegible Patient #171005009: collection date 10/03/2017, collection time 11:00, received date 10/05/2017 (note received time was not documented), southeastern inhalants test date 10/10/2017, test time unknown due to thermal tape being illegible 6. According to records the laboratory had an annual test volume of 42,000 allergy tests on the Hitachi analyzer. 7. During an interview on 12/18/19 at 1:55 pm, TP-1 stated that no studies were performed on specimens undergoing more than one freeze-thaw cycle. This confirmed the above findings. The laboratory did not follow manufacturer's instructions for correct storage of specimens upon receipt and for ensuring correct conditions during transport. The laboratory did not document disposition of specimens upon receipt to

	ensure manufacturer's instructions were met. III. Based on review of direct observation, laboratory's policy, manufacturer's instructions, test requisitions, and confirmed in interview, the laboratory failed to establish a policy for the rejection of hemolyzed specimens used in allergy testing. Findings: 1. Review of Hitachi CLA-1 allergy analyzer manufacturer's instructions "4 Test Operation" page 4-2 stated: "Collect a venous blood sample Hemolysis can adversely affect the performance of the CLA Allergy Assay." 2. Review of "PATIENT TEST MANAGEMENT-SPECIMEN ACCESSIONING AND PROCESSING" policy page 1 and 2 stated: "ACCESSIONING 5. Note on the request the number and type of specimens received and any comments peculiar to the specimen (e.g. specimen received frozen, hemolyzed)." The policy failed to define rejection criteria for hemolyzed specimens. 3. Review of the laboratory's client services manual "BLOOD COLLECTION FOR ALLERGY TESTING" page 5 stated: "COMMON CAUSES OF UNACCEPTABLE SERUM OR PLASMA SPECIMENS AND INNACCURATE TEST RESULTS: HEMOLYSIS Grossly or moderately hemolyzed specimens may be rejected and even slight hemolysis may alter certain test results." The client services manual failed to define rejection criteria for hemolyzed. 4. Review of a random sampling of test requisitions for 2017 and 2018 revealed on 06/06/2017 the laboratory received the following specimen: patient #17071008, a notation was made on the right top corner of the test requisition "Noted 6-6-17 (Initials)", "*Hemolyzed*", "6-12-17 (Initials) set up" Test records revealed the sample was analyzed on 06/14/2017. The laboratory failed to document notification to the client of hemolysis and how it can "adversely affect the performance of the CLA Allergy Assay" During an interview on 12/17/18 at 3:56 pm, Testing Person-1 (TP-1) was asked for a specimen rejection log and he stated that there was no log and they just call the clients to notify them what was done wrong. 5. During a closing interview on 12/19/18 at 12:32 pm, TP-1 and TP-2 confirmed the above mentioned patient specimen was tested and not rejected.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: I. Based on review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03/2017 through 12/12/2018, and confirmed in interview, the laboratory failed to document the time 67 of 67 patient specimens were received into the laboratory for processing and testing. 1. A random review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03/2017 through 12/12/2018 revealed the laboratory failed to document the time 67 of 67 patient specimens were received. The following is a random sample of patient specimens in which the receipt time was NOT documented: Date of Receipt: 03/03/2017 Patient Number: 170303001 Date of Receipt: 06/22/2017 Patient Number: 170711001 Date of Receipt: 06/20/2017 Patient Number: 170711002 Date of Receipt: 06/20/2017 Patient Number: 170711003 Date of Receipt: 06/19/2017 Patient Number: 170711004 Date of Receipt: 07/12/2017 Patient Number: 170712001 Date of Receipt: 04/25/2017 Patient Number: 170712004 Date of Receipt: 07/28/2017 Patient Number: 170728001 Date of Receipt: 10/18/2017 Patient Number: 171018002 Date of Receipt: 10/23/2017 Patient Number: 171023004 Date of Receipt: 11/16/2017 Patient Number: 171116001 Date of Receipt: 01/18/2018 Patient Number: 180118002 Date of Receipt: 03/27/2018 Patient Number: 180327001 Date of Receipt: 03/28/2018 Patient Number: 180328001 Date of Receipt: 04/02/2018 Patient Number: 180402001 Date of Receipt: 04/24/2018 Patient Number:

180424001 Date of Receipt: 07/17/2018 Patient Number: 180717002 Date of Receipt: 07/19/2018 Patient Number: 180719002 Date of Receipt: 10/09/2018 Patient Number: 181009001 Date of Receipt: 10/09/2018 Patient Number: 181009002 Date of Receipt: 10/09/2018 Patient Number: 181009003 Date of Receipt: 10/09/2018 Patient Number: 181009004 Date of Receipt: 10/26/2018 Patient Number: 181026001 Date of Receipt: 10/26/2018 Patient Number: 181026002 Date of Receipt: 10/26/2018 Patient Number: 181026003 Date of Receipt: 12/12/2018 Patient Number: 181212001 Date of Receipt: 12/11/2018 Patient Number: 181211002 2. The above findings were confirmed in an interview with the laboratory staff on 12/19/2018 at 1022 hours in the conference room. 40420 II. Based on review of manufacturer's instructions, patient test requisitions, final test reports, and confirmed in interview, the laboratory failed to document the received time of specimens that were received from outside clients for 60 of 60 patients in 2017 (06/2017, 07/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 10 of 10 patients 2018 (08/2018, 09/2018, 10/2018) for allergy testing. Findings: 1. Review of Hitachi analyzer manufacturer's instructions "4 Test Operation" page 4-3 stated: "Store Serum Store serum samples at 2-8 for a period of up to one week. For longer storage, samples should be frozen at -20C. Repeated freezing and thawing of serum samples should be avoided. Storage in a frost-free refrigerator may affect the long-term stability of the sample." 2. Review of patient test requisitions and final test reports, revealed that the received time was not documented on requisitions nor final test reports in 2017 and 2018 as follows: (this was a random sampling)
Patient#170925004 collection date: 09/19/17, received date: 09/22/2017
Patient#170925003 collection date: 09/19/17, received date: 09/22/2017
Patient#170925002 collection date: 09/20/17, received date: 09/22/2017
Patient#170925001 collection date: 09/20/17, received date: 09/22/2017
Patient#170929004 collection date: 09/26/17, received date: 09/29/2017
Patient#170929002 collection date: 09/26/17, received date: 09/29/2017
Patient#170929003 collection date: 09/22/17, received date: 09/29/2017
Patient#171004001, no lab requisition available, collection date: 10/02/2017 (from final test report), received date: 10/04/2017 (from final test report) Patient#170914004 collection date: 09/12/17, received date: 09/14/2017 Patient#170914003 collection date: 09/12/17, received date: 09/14/2017 Patient#170914002 collection date: 09/11 /17, received date: 09/14/2017 Patient#170824004 collection date: 08/22/17, received date: 09/14/2017 Patient#170914005 collection date: blank, collection time blank, received date: 09/12/2017 Patient#170907001 collection date: 09/01/17, received date: 09/07/2017 Patient#170907003 collection date: 09/01/17, received date: 09/07 /2017 Patient#170075002 collection date: 09/01/17, received date: 09/07/2017
Patient#170710008 collection date: 06/01/17, received date: 06/06/2017
Patient#170608020 collection date: 06/01/17, received date: 06/01/2017
Patient#17068019 collection date: 06/01/17, received date: 06/01/2017
Patient#170608018 collection date: 06/01/17, received date: 06/01/2017
Patient#17060817 collection date: 06/01/17, received date: 06/01/2017
Patient#170608016 collection date: 06/01/17, received date: 06/01/2017
Patient#170608015 collection date: 06/01/17, received date: 06/01/2017
Patient#170608014 collection date: 06/01/17, received date: 06/01/2017
Patient#170608013 collection date: 06/01/17, received date: 06/01/2017
Patient#170608012 collection date: 06/01/17, received date: 06/01/2017
Patient#170710007 collection date: 06/08/17, received date: 06/08/2017
Patient#170608022 collection date: 06/08/17, received date: 06/08/2017
Patient#170608021 collection date: 06/08/17, received date: 06/08/2017
Patient#170608023 collection date: 06/08/17, received date: 06/08/2017
Patient#170608024 collection date: 06/08/17, received date: 06/08/2017
Patient#170710011 collection date: 06/07/17, received date: 06/09/2017

	Patient#170710010 collection date: 06/08/17, received date: 06/09/2017 Patient#170710009 collection date: 06/06/17, received date: 06/09/2017 Patient#170710013 collection date: 06/05/17, received date: 06/07/2017 Patient#170726007 collection date: 07/24/17, received date: 07/26/2017 Patient#170726008 collection date: 07/21/17, received date: 07/26/2017 Patient#170726009 collection date: 07/19/17, received date: 07/26/2017 Patient#170726011 collection date: 07/21/17, received date: 07/26/2017 Patient#170801008 collection date: 07/29/17, received date: 08/01/2017 Patient#170728002 collection date: 07/25/17, received date: 07/28/2017 Patient#170816007 collection date: 08/12/17, received date: 08/12/2017 Patient#170816006 collection date: 08/12/17, received date: 08/12/2017 Patient#170824006 collection date: 08/22/17, received date: 08/24/2017 Patient#170824005 collection date: 08/22/17, received date: 08/24/2017 Patient#170831004 collection date: 08/29/17, received date: 08/31/2017 Patient#170831003 collection date: 08/26/17, received date: 08/31/2017 Patient#170831002 collection date: 08/26/17, received date: 08/31/2017 Patient#170831001 collection date: 08/26/17, received date: 08/31/2017 Patient#171005005 collection date: 10/05/17, received date: 10/05/2017 Patient#171005006 collection date: 10/05/17, received date: 10/05/2017 Patient#171005007 collection date: 09/30/17, received date: 10/05/2017 Patient#171005008 collection date: 09/30/17, received date: 10/05/2017 Patient#171005009 collection date: 10/03/17, received date: 10/05/2017 Patient#171213004 collection date: 12/12/17, received date: 12/13/2017 Patient#171213005 collection date: 12/12/17, received date: 12/13/2017 Patient#171213006 collection date: 12/12/17, received date: 12/13/2017 Patient#171213001 collection date: 12/12/17, received date: 12/13/2017 Patient#171213002 collection date: 12/12/17, received date: 12/13/2017 Patient#171213003 collection date: 12/12/17, received date: 12/13/2017 Patient#180904010 collection date: 08/30/18, received date: 09/04/2018 Patient#180913007 collection date: blank (final report 09/10/18), collection time: blank, received date: 09/13/2018 Patient#180917001 collection date: 09/13/18, received date: not stamped on requisition (final report 09/17/2018) Patient#181008007 collection date: blank (final report 09/18/18), collection time: blank, received date: 10/08/2018 Patient#181008006 collection date: blank (final report 09/17/18), collection time: blank, received date: 10/08/2018 Patient#181008005 collection date: 09/24/18, received date: 10/08/2018 Patient#181008001 collection date: blank (final report 09/26/18), collection time: blank, received date: 10/08/2018 Patient#181008002 collection date: blank (final report 09/26/18), collection time: blank, received date: 10/08/2018 Patient#181008003 collection date: blank (final report 09/20/18), collection time: blank, received date: 10/08/2018 Patient#181008004 collection date: 09/24/18, received date: 10/08/2018 The laboratory had an annual test volume of 42,000 allergy tests on the Hitachi CLA-1 analyzer. 3. During an interview on 12/19/2018 at 10:30 am, Testing Person-1 (TP-1) and Testing Person-2 (TP-2) confirmed that received time of specimens was not documented. TP-1 stated that the computer system did not allow them to document the received time. This confirmed the above findings.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

This STANDARD is not met as evidenced by:
I. Based on review of Thermo Scientific DRI urine assay manufacturer's instructions, laboratory's documents, and staff interview, the laboratory failed to ensure all components for proper handling of urine specimens were included in their client services document. Findings included: 1. Review of the Thermo Scientific DRI urine drug assay manufacturer's instructions for urine toxicology analytes specified the following in the section titled "Specimen Collection and Handling": a. Amphetamines (0138-12-EN 2017 08) "Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for several weeks. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C indefinitely ... ...Handle all urine specimens as if they were potentially infectious." b. Barbiturates (0353-12-EN 2017 11) "Collect urine specimens in plastic or glass containers. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 7 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C ... ...Handle all urine specimens as if they were potentially infectious." c. Benzodiazepine (0372-11-EN 2015 07) "Collect urine specimens in plastic or glass containers. Testing of fresh urine specimens is suggested. Specimens that do not receive an initial test within 7 days of arrival in the laboratory should be placed into secure refrigeration units. Handle all urine specimens as if they were potentially infectious." d. Buprenorphine (10007988-13-EN 2018 01) "Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed. Specimens kept at room temperature that do not receive initial test within 8 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 30 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C. Studies have shown buprenorphine analytes in urine are stable at -20C up to 85 days. ... ...Handle all urine specimens as if they were potentially infectious." e. Cannabinoid (0142-10-EN 2017 12) "Collect urine specimens in plastic or glass containers. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 4 weeks. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C ... ...Handle all urine specimens as if they were potentially infectious." f. Cocaine Metabolite (0139-9-EN 2015 10) "Collect urine specimens in plastic or glass containers. Fresh urine should be used. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units at 2 to 8C. Handle all urine specimens as if they were potentially infectious." g. Ecstasy Assay (10006188-8-EN 2015-07) "Collect urine specimens in plastic or glass containers. Testing of fresh urine is suggested. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units." h. Ethyl Alcohol (0318-11-EN 2017 12) "Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C.

Handle all urine specimens as if they were potentially infectious." i. Hydrocodone (10020160-1 2017 07) "Collect urine specimens in plastic or glass containers. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C. Handle all urine specimens as if they were potentially infectious." j. Methadone (0666-7-EN 2015-10) "Collect urine specimens in plastic or glass containers. Testing of fresh urine is suggested. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units. Handle all urine specimens as if they were potentially infectious." k. Opiate (0140-13-EN 2017 07) "Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C. Handle all urine specimens as if they were potentially infectious." l. Oxydodone (10008282-7-EN 2015 07) "Collect urine specimens in plastic or glass containers. Testing of fresh urine is suggested. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units. Handle all urine specimens as if they were potentially infectious." m. Phencyclidine (0141-12-EN 2018 01) "Collect urine specimens in plastic or glass containers. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to six months. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C. Handle all urine specimens as if they were potentially infectious." n. Propoxyphene (0229-3-EN 201408) "Collect urine specimens in plastic or glass containers. Testing of fresh urine is suggested. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units. Handle all urine specimens as if they were potentially infectious." 2. Review of the laboratory's "URINE SPECIMEN COLLECTION FOR DRUG SCREEN AND TOXICOLOGY" document revealed the following instructions: " Use the label on the specimen to write the patient name and date of birth (2 identifiers). Instruct the patient that you need a minimum of 30 milliliters of urine. Put the specimen in the bag with the absorbent sheet. Place the requisition in the back separate pouch. Seal the pouch. Specimen is now considered packaged for shipment." This document did NOT include the following components: a) Patient preparation. b) Specimen collection. c) Specimen storage and stability for each of the analytes tested. d) Conditions for specimen transportation for urine specimen. e) Specimen processing. f) Specimen acceptability and rejection. 3. The laboratory was asked to provide a more detailed client services manual. No further documents were provided. 4. The above findings were confirmed by laboratory staff on 12/18/2018 at 1550 hours in the conference room. 40420 II. Based on review of manufacturer's instructions, client services manual and test requisitions, the laboratory failed to ensure the client services manual was consistent with manufacturer's instructions for specimen handling for allergy specimens that were received from clients. Findings: 1. The laboratory failed to ensure the client services manual included manufacturer's instructions for specimen storage /stability for allergy specimens submitted from clients. Client services manual included not to freeze specimens, but that was not the lab's practice and instructions. Refer to D5311, I. 2. During an interview with Testing Person-1 (TP-1) and Testing Person-2 (TP-2) on 12/18/18 at 1:55 pm, testing personnel were asked how the allergy specimens arrived and TP-2 stated "they come frozen on ice packs in foam coolers."

	TP-1 stated "2-8C is acceptable" and the specimens arrive "frozen or slushy." 3. The laboratory had an annual test volume of 42,000 allergy tests on the Hitachi CLA-1 analyzer. 4. During the exit interview on 12/19/18 at 12:32 pm, TP-1 and TP-2 confirmed the laboratory failed to ensure the client services manual included manufacturer's instructions for specimen storage/stability for allergy specimens submitted from clients. III. Based on review of manufacturer's instructions, client services manual and confirmed in interview, the laboratory failed to ensure client services manual was consistent with manufacturer's instructions for specimen handling. Findings: 1. Review of Hitachi analyzer manufacturer's instructions "4 Test Operation" page 4-2 stated: "Invert serum; label specimen tube Gently invert the serum collection tube 3-5 times." 2. Review of the "BLOOD COLLECTION FOR ALLERGY TESTING" client services manual page 1 stated: "2 INVERT tube 7-10 times." 3. The laboratory had an annual test volume of 40,000 allergy tests on the Hitachi analyzer. 4. During the exit interview on 12/19/18 at 12:32 pm, Testing Person-1 and Testing Person-2 confirmed that the laboratory failed to ensure client services manual instructions aligned with manufacturer's instructions.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance Plan, and staff interview, it was revealed the laboratory failed to follow its written policies to assess, monitor and correct problems in preanalytic systems. Findings: 1. Review of QA policy revealed the "continuous quality improvement program will be evaluated annually." Review of laboratory records revealed that no QA was performed annually in 2017 and 2018. 2. The laboratory failed to have a mechanism in place to monitor, assess, and when indicated, correct problems identified in preanalytic systems, as follows: a) The laboratory failed to ensure the test requisitions solicited the tests to be performed for 8 of 29 requisitions. Refer to D5305. b) The laboratory failed to follow its own written policy and manufacturer instructions for testing specimens for urine toxicology analytes within the specified stability requirements for 13 of 67 patients from 03/03 /2017 through 12/12/2018. Refer to D5311, I. c) The laboratory failed to ensure the correct specimen storage, preservation and conditions for transportation, according to manufacturer's instructions for 11 of 11 specimens in 2017 (random sampling). Refer to D5311, II. d) The laboratory failed to establish a policy for the rejection of specimens used in allergy testing. Refer to D5311, III. e) The laboratory failed to document the time 67 of 67 patient specimens were received into the laboratory for processing and testing. Refer to D5313, I. f) The laboratory failed to document the received time of specimens that were received from outside clients for 60 of 60 patients in 2017 (06/2017, 07/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 10 of 10 patients 2018 (08/2018, 09/2018, 10/2018) for allergy testing. Refer to D5313, II. g) The laboratory failed to ensure all components for proper handling of urine specimens were included in their client services document. Refer to D5317, I. h) The laboratory failed to ensure the client services manual was consistent with manufacturer's instructions for specimen handling for allergy specimens that were received from clients. Refer to D5317, II.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observations, review of laboratory policies, manufacturer's instructions, Beckman Coulter AU480 urine toxicology analyzer patient test records, College of American Pathologist (CAP) proficiency testing (PT) records, laboratory's allergy panels, laboratory records, quality control (QC) records, Hitachi CLA-1 Negative Control Serum package insert, manufacturer's package inserts, United Stated Food and Drug Administration (FDA) for Clinical Laboratory Improvement Amendments (CLIA) website, verification studies for the AU 480 analyzer, patient records from 03/03/2017 through 12/12/2018, temperature logs, verification studies, performance record checks, laboratory test menu, laboratory calibration verification records for 2017 and 2018, AU 480 operator's User guide, and confirmed in interview, the laboratory failed to meet the requirements of the condition of analytic systems. Findings: 1. The laboratory failed to follow its own written policy to test the pH for 67 of 67 patients tested for urine toxicology. Refer to D5401, I. 2. The laboratory failed to follow its own written policy to confirm a positive result by another method for 14 of 15 patients with a positive result. Rerfer to D5401, II. 3. The laboratory failed to implement a written policy for split sample testing when not all analytes not included in subpart I of this part and not covered by the PT company for ensuring verification of accuracy at least twice annually for allergy and urine drug screen testing. Refer to D5403, I. 4. The laboratory failed to implement a policy for verification studies when relocating an analyzer to ensure accurate and reliable test results. Refer to D5403, II. 5. The laboratory failed to include a quality control policy for allergy testing and failed to establish the acceptability criteria for each lot of CLA positive and negative control serum for allergens on the Hitachi analyzer. Refer to D5403, III. 7. The laboratory failed to establish a calibration procedure for the Hitachi CLA-1 analyzer. Rerfer to D5403, IV. 8. The laboratory failed to follow manufacturer's instructions for documenting all required information on the "Standard Overnight Assay Planner Sheet" for 6 of 6 days in 2017 and 2 of 2 days in 2018 (random review). Refer to D5411. 9. The laboratory failed to follow manufacturer's instructions for the storage of quality control material for 53 of 62 days in 2017 and 179 of 227 days in 2018. Refer to D5413. 10. The laboratory failed to have documentation of the open date and /or the revised expiration date for the in-use Urine Toxicology quality control materials. Refer to D5415. 11. The laboratory failed to demonstrate that the Hitachi analyzer can obtain performance specifications for all allergens comparable to those established by the manufacturer in accuracy, precision, and reference intervals. Refer to D5421. 12. The laboratory failed to establish performance specifications for analytical sensitivity and analytical specificity to include interfering substances when the laboratory introduced assay reagents that were not subject to FDA clearance. Refer to D5423, I. 13. The laboratory failed to establish performance specifications for specimen collection and handling when the laboratory modified the manufacturer's stated specimen collection and handling requirements. Refer to D5423, II. 14. The laboratory failed to perform and document the calibrations at least once every 6

	months in 2018 (10/2018) for the Hitachi analyzer. Refer to D5437. 15. The laboratory failed to have documentation of performing calibration verification every six months for analytes tested on the Beckman Coulter AU 480 urine toxicology analyzer. Refer to D5439. 16. The laboratory failed to have a system in place to monitor over time the accuracy and precision of AU 480 analyzer test performance with current and accurate statistical parameters. Refer to D5441. 17. The laboratory failed to perform two levels of control each day of patient testing for 6 of 9 days reviewed in a random sampling from August 2017 through October 2018. Refer to D5447. 18. The laboratory failed to provide documentation of establishing quality control target ranges for 14 of 28 lot numbers of control material the Beckman Coulter AU 480 urine toxicology analyzer. Refer to D5469, I. 19. The laboratory failed to establish the acceptability criteria for each lot number of CLA positive and negative control serum for allergens analyzed on the Hitachi analyzer since testing began in 05 /2017. Refer to D5469, II. 20. The laboratory failed to ensure the results of QC for allergy testing were acceptable before reporting patient test results for 10 of 10 days in 2017 (06/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 1 of 1 day 2018 (10/2018). Refer to D5481. 21. The laboratory failed to document corrective action for QC failures on the Hitachi analyzer for 10 of 10 days in 2017 (06/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 1 of 1 day 2018 (10/2018). Refer to D5781. 22. The laboratory failed to document evaluation of patient test results obtained in unacceptable test runs for 68 of 68 patients tested in 2017 and 2018 (06/2017, 08/2017, 09/2017, 10/2017, 12 /2017) and 8 of 8 patients in 2018 (10/2018). Refer to D5783.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on direct observation, review of the laboratory's policies, review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03/2017 through 12/12/2018, and staff interview, the laboratory failed to follow its own written policy to test the pH for 67 of 67 patients tested for urine toxicology. Findings included: 1. A tour of the laboratory on 12/17/2018 at 1000 hours revealed a Beckman Coulter AU 480 urine toxicology analyzer (Serial Number 6040092). The following urine toxicology tests were performed on this analyzer: Amphetamines Barbiturate Benzodiazepine Buprenorphine Cannabinoid Cocaine Ethyl Alcohol Ecstasy Methadone Hydrocodone Opiates Oxycodone Phencyclidine Propoxyphene 2. Review of the laboratory policies approved by the laboratory director on 10/05/2016 in the section titled "Toxicology Screening" stated "Samples within a pH range of 3-11 are suitable for testing with this assay" for the following analytes: Barbiturate Benzodiazepine Cannabinoid Ethyl Alcohol Methadone Opiates Oxycodone Phencyclidine Propoxyphene 3. Review of Thermo Scientific DRI assay manufacturer's instructions stated "Samples within a pH range of 3-11 are suitable for testing with this assay" for the following analytes: Barbiturate Benzodiazepine Cannabinoid Ethyl Alcohol Methadone Opiates Oxycodone Phencyclidine Propoxyphene 4. A random review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03/2017 through 12/12/2018 revealed the laboratory failed to test pH for 67 of 67 patients. The following is a random sample of

those patient specimens in which the pH was NOT tested: Date of test: 03/08/2017 Patient Number: 170303001 Date of test: 07/12/2017 Patient Number: 170712004 Date of test: 07/12/2017 Patient Number: 170711004 Date of test: 07/12/2017 Patient Number: 170712001 Date of test: 07/12/2017 Patient Number: 170711002 Date of test: 07/12/2017 Patient Number: 170711003 Date of test: 07/12/2017 Patient Number: 170711001 Date of test: 07/12/2017 Patient Number: 170711004 Date of test: 07/28/2017 Patient Number: 170728001 Date of test: 10/18/2017 Patient Number: 171018002 Date of test: 10/23/2017 Patient Number: 171023004 Date of test: 11/28/2017 Patient Number: 171116001 Date of test: 01/18/2018 Patient Number: 180118002 Date of test: 03/27/2018 Patient Number: 180327001 Date of test: 03/28/2018 Patient Number: 180328001 Date of test: 04/02/2018 Patient Number: 180402001 Date of test: 04/24/2018 Patient Number: 180424001 Date of test: 07/17/2018 Patient Number: 180717002 Date of test: 07/19/2018 Patient Number: 180719002 Date of test: 10/09/2018 Patient Number: 181009003 Date of test: 10/09/2018 Patient Number: 181009002 Date of test: 10/09/2018 Patient Number: 181009004 Date of test: 10/10/2018 Patient Number: 181009001 Date of test: 10/29/2018 Patient Number: 181026001 Date of test: 10/29/2018 Patient Number: 181026003 Date of test: 10/29/2018 Patient Number: 181026002 Date of test: 12/11/2018 Patient Number: 181211002 Date of test: 12/12/2018 Patient Number: 181212001 5. The above findings were confirmed in an interview with the laboratory staff on 12/18/2018 at 1550 hours in the conference room. II. Based on direct observation, review of the laboratory's policies, random review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03/2017 through 12/12/2018, and staff interview, the laboratory failed to follow its own written policy to confirm a positive result by another method for 14 of 15 patients with a positive result. 1. A tour of the laboratory on 12/17/2018 at 1000 hours revealed a Beckman Coulter AU 480 urine toxicology analyzer (Serial Number 6040092). The following urine toxicology tests were performed on this analyzer: Amphetamines Barbiturate Benzodiazepine Buprenorphine Cannabinoid Cocaine Ethyl Alcohol Ecstasy Methadone Hydrocodone Opiates Oxycodone Phencyclidine Propoxyphene 2. Review of the laboratory policies approved by the laboratory director on 10/05/2016 in the section titled "Toxicology Screening" stated "A positive result by this assay should be confirmed by another nonimmunological method such as GC, TLC, or GC /MS" for the following analytes: Amphetamines Barbiturate Benzodiazepine Cannabinoid Cocaine Ecstasy Methadone Hydrocodone Opiates Phencyclidine Propoxyphene 3. Review of Thermo Scientific DRI assay manufacturer's instructions for the following analytes stated, "This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GS /MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used." Amphetamines Barbiturate Benzodiazepine Cannabinoid Cocaine Ecstasy Methadone Hydrocodone Opiates Phencyclidine Propoxyphene 4. A random review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03/2017 through 12/12/2018 revealed the laboratory failed to confirmed positive test results for the following 14 of 15 patients: Date of Test: 07/12/2017 Positive Analyte: Benzodiazepine Patient Number: 170711003 Date of Test: 07/12/2017 Positive Analyte: Amphetamine Patient Number: 170712004 Date of Test: 07/28/2017 Positive Analyte: Opiates Patient Number: 170728001 Date of Test: 10/18/2017 Positive Analyte: Cannabinoids Patient Number: 171018002 Date of Test: 10/23/2017 Positive Analyte: Benzodiazepine, Cannabinoids, and Methadone Patient Number: 171023004 Date of Test: 11/28/2017 Positive Analyte: Cannabinoids Patient Number: 171116001 Date of Test: 03/27/2018

	Positive Analyte: Cannabinoids Patient Number: 180327001 Date of Test: 03/28/2018 Positive Analyte: Benzodiazepine Patient Number: 180328001 Date of Test: 04/02 /2018 Positive Analyte: Hydrocodone and Opiates Patient Number: 180402001 Date of Test: 04/24/2018 Positive Analyte: Barbiturates and Opiates Patient Number: 180424001 Date of Test: 07/17/2018 Positive Analyte: Benzodiazepine Patient Number: 180717002 Date of Test: 07/19/2018 Positive Analyte: Cannabinoids Patient Number: 180719002 Date of Test: 12/11/2018 Positive Analyte: Benzodiazepine Patient Number: 181211002 Date of Test: 12/12/2018 Positive Analyte: Benzodiazepine Patient Number: 181212001 5. The above findings were confirmed in an interview with the laboratory staff on 12/18/2018 at 1550 hours in the conference room.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of laboratory's procedure manual, College of American Pathologist (CAP) proficiency testing (PT) records, laboratory's allergy panels, and in interview with staff, the laboratory failed to implement a written policy for split sample testing when not all analytes not included in subpart I of this part and not covered by the PT company for ensuring verification of accuracy at least twice annually for allergy and urine drug screen testing. Findings included: 1. Review of the laboratory's procedure manual did not include a policy/procedure for split sample testing for drug analytes and allergy subgroups not covered in the subpart I of this part (non-regulated analytes) to verify accuracy. 2. Review of CAP PT records for urine drug screen testing on the AU480 revealed ecstasy was only included in 1 of 3 testing events in 2017 (2017 Event -A). Review of CAP PT records for urine drug adulterants testing on the AU480 revealed creatinine was only included in 1 of 2 testing events in 2018 (2018 Event - A). There was no PT records or other twice annual verification of accuracy documentation in 2017 for creatinine. The laboratory did not ensure ecstasy was verified for accuracy at least twice annually in 2017 and for creatinine at least twice annually in 2017 and 2018. 3. Review of CAP PT record for urine drug screen testing on the AU480 revealed hydrocodone was not included in 3 of 3 testing events in 2017 and 2018. During an interview on 12/17/2018 at 12:30 pm, the TS stated split sample

testing was performed with another laboratory to cover hydrocodone. Documentation was provided and revealed the split sample testing with the other laboratory was done 12/10/2018 (this included hydrocodone). The laboratory did not ensure hydrocodone was verified for accuracy at least twice annually in 2017. Hydrocodone was verified for accuracy only once in 2018, not twice. The laboratory did not have a written policy of this split sample testing. 4. Review of proficiency testing (PT) records from 2017 and 2018 for Allergy testing revealed not all subgroups were covered in PT to ensure verification of accuracy, at least twice annually, as follows: 2017 Event SE-A analyzed Southeastern Inhalants and not Moderate Food 2017 Event SE-B analyzed Southeastern Inhalants and not Moderate Food 2018 Event SE-A analyzed Southeastern Inhalants and not Moderate Food 2018 Event SE-B analyzed Southeastern Inhalants and not Moderate Food 2018 Event SE-C analyzed Southeastern Inhalants and not Moderate Food The laboratory failed to ensure verification of accuracy, at least twice annually for Moderate Food allergy panel subgroup. 5. During an interview on 12/17/2018 at 2:13 pm, the Technical Supervisor (TS) was asked whether the laboratory had any other documentation of verification of accuracy for Allergy testing, he stated he had sent a sample to Allos (laboratory affiliated with manufacturer) but was having problems with it. The TS was asked whether sending a sample to Allos was sent on a defined frequency/schedule, he stated no. There was no written policy for this practice. 40420 II. Based on review of laboratory's policy, laboratory records, and confirmed in interview, the laboratory failed to implement a policy for verification studies when relocating an analyzer to ensure accurate and reliable test results. Findings: 1. Review of laboratory policies revealed that the laboratory failed to establish a policy for performance verification studies upon relocating an analyzer. 2. The facility was originally located at 1106 W Rosedale Street, Fort Worth, TX 76104, effective date 06/07/16. On 11/14/18 the laboratory relocated to 901 W Leuda St, Ste B, Fort Worth, TX 76104. 3. Review of comparison study with the Hitachi analyzer revealed one set of samples were tested at Rosedale St and the one set was then tested at Leuda St on 07/16/2018. (The study was performed on the same analyzer.) 4. During an interview on 12/17/18 at 2:23 pm, with Testing Person-1 (TP-1) he stated that the studies were performed on the same day due to the fact that he only had one hour to run the samples once the reagents were prepared. TP-1 was asked for studies when the facility permanently relocated to Leuda street on 11/14/2018 and none were provided. The laboratory did not have a policy for verification studies when relocating an analyzer to ensure accurate and reliable test results. III. Based on review of laboratory's policy, manufacturer's instructions, quality control logs (QC) and confirmed in interview, the laboratory failed to include a quality control policy for allergy testing and failed to establish the acceptability criteria for each lot of CLA positive and negative control serum for allergens on the Hitachi analyzer. Findings: 1. Review of CLA-1 procedures revealed the laboratory did not include a QC policy for allergy testing on the Hitachi analyzer. 2. Review of CLA Allergen-Specific IgE Assay package insert page 3 stated: "10 Quality Control B. IgE Positive and Negative Control Sera Hitachi Chemical Diagnostics recommends testing with two levels of serum controls ...Frequency of testing with control should be decided by each laboratory according to regulatory agencies' requirements." 3. The laboratory's written policy/procedures were written according to the manufacturer's package insert. The laboratory did not implement a policy for establishing acceptability criteria for each lot number of QC. 4. Review of the manufacturer's instructions for CLA control serum stated: "5 Expected Values ... Each laboratory should establish its own mean values and acceptable ranges and use those provided as guides." During an interview on 12/18/18 at 2:45 pm, Testing Person-1 (TP-1) was asked if the laboratory established their own QC range and he stated no and the ranges used were those provided in the package inserts. 5. During an

	interview on 12/18/2018 at 4:25pm, TP-1 stated that he only runs QC once for each new kit used and not every day of patient testing. This confirmed the above findings. IV. Based on review of the laboratory's procedure manual, manufacturer's instructions, performance check records, an in staff interview, the laboratory failed to establish a calibration procedure for the Hitachi CLA-1 analyzer. Findings: 1. Review of the laboratory's procedure manual for the Hitachi CLA-1 analyzer revealed it failed to have a procedure in place for the calibration of the analyzer every 6 months. 2. Review of the manufacturer's instructions for the Hitachi CLA-1 analyzer page 5-5 stated: "Performance Check For The CLA-1 Luminometer...HCD recommends that a CLA-1 Control scan be 1) performed three times in succession at least once every six (6) months to monitor the ongoing performance and sensitivity of the CLA-1 Luminometer." 3. During the exit interview on 12/19/2018 at 12:32 pm, Testing Person-1 and Testing Person-2 confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory records and confirmed in interview, the laboratory failed to follow manufacturer's instructions for documenting all required information on the "Standard Overnight Assay Planner Sheet" for 6 of 6 days in 2017 and 2 of 2 days in 2018 (random review). Findings: 1. Review of Hitachi analyzer operator's manual page 4-3 and 4-4 stated "Prepare Pettes ...Record kit lot numbers, panel numbers, and patient identifications on the Standard Overnight Assay Planner Sheet." Page 4-8 and 4-9 stated "Incubate Pettes ...Incubate at room temperature for 4 hours +/- 15 minutes, noting the incubation start and stop time on the Planner Sheet." 2. Review of Planner Sheets revealed the laboratory failed to document kit lot numbers, panel numbers, and incubation start and stop times in a random sampling in 2017 and 2018: 06/06/2017 Moderate food and Southeastern Inhalants: one Planner Sheet was completed with the start and stop times of the serum and antibody incubations; it did not indicate if it was for food or inhalants; the following items were not documented: positive and negative controls, reagent kit lot numbers, panel numbers, and patient identifications 06/12/2017 Moderate food and Southeastern Inhalants: one Planner Sheet was completed with the start and stop times of the serum and antibody incubations; it did not indicate if it was for food or inhalants; the following items were not documented: reagent kit lot numbers and panel numbers 08/02/2017 Moderate food and Southeastern Inhalants: Antibody incubation stop times and negative controls were not documented 10/04/2017 Moderate food and Southeastern Inhalants: positive and negative controls were not documented 10/09 /2017 Moderate food and Southeastern Inhalants: positive and negative controls, reagent kit lot numbers, and panel numbers were not documented 12/13/2017 Moderate food: serum incubation stop time and Antibody start and stop time were not documented 09/06/2018 Moderate food and Southeastern Inhalants: reagent kit lot number was not documented 10/22/2018 Moderate food and Southeastern Inhalants: positive and negative controls were not documented The laboratory did not document

	all required information on the "Standard Overnight Assay Planner Sheet" to ensure manufacturer's instructions were met. 3. During the exit interview on 12/19/2018 at 12: 32 pm, Testing Person-1 and Testing Person-2 confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of the Hitachi CLA-1 Negative Control Serum package insert, review of temperature logs, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for the storage of quality control material for 53 of 62 days in 2017 and 179 of 227 days in 2018. Findings: 1. Review of Hitachi CLA-1 Negative Control Serum stated: "4. Storage and Stability When stored at -20 +/- 10C, the CLA Negative Control Serum is stable until the expiration date indicated on the vial label." "Only one freeze-thaw cycle is recommended." 2. During a tour of the laboratory on 12/18/18 at 1:55 pm, the surveyor observed negative quality control material stored in the "Hot Point" frost-free refrigerator/freezer. CLA IgE Negative Allergy Control Serum Lot #48D09035, Expiration Date: 2020-03-31 The laboratory failed to ensure the proper storage of quality control material. The laboratory did not ensure storage of quality control material was in a non-frost free freezer. 3. The laboratory's defined temperature range was -25-0C; this was not consistent with the manufacturer's defined range of -20 +/- 10C. 4. Review of temperature logs revealed the temperature was not within range for 53 of 62 days in 2017 and 179 of 227 days in 2018. The following is a sampling: 10/02/2017 -5C 10/03/2017 -5C 10/04/2017 -5C 10 /05/2017 -5C 11/06/2017 -7C 11/07/2017 -6C 11/08/2017 -7C 11/09/2017 -6C 11/10 /2017 -7C 12/26/2017 -4C 03/05/2018 -7C 03/06/2018 -7C 03/07/2018 -7C 03/08 /2018 -8C 04/23/2018 -8C 04/24/2018 -8C 04/25/2018 -8C 04/26/2018 -7C 04/27 /2018 -8C 09/04/2018 -6C The frost-free freezer did not maintain storage requirements for CLA negative quality control material. 5. During an interview on 12 /18/19 at 1:55 pm, with TP-1 and TP-2 they confirmed that the laboratory failed to ensure the proper storage of CLA negative quality control material.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of the manufacturer's instructions, and staff

	interview, it was revealed that the laboratory failed to have documentation of the open date and/or the revised expiration date for the in-use Urine Toxicology quality control materials. Findings included: 1. Observed in the laboratory refrigerator on 12/18/2018 at 1540 hours were the following urine toxicology quality control materials in use with no documented open date: a. One vial of Low Level MGC Select XTC Control Lot number 730233349/Expiration Date 2020/01 No Open date b. One vial of High Level MGC Select XTC Control Lot number 730233350/Expiration Date 2020/01 No Open date The manufacturer's instructions for MGC Select XTC controls stated, "The MGC Select control set is stable until the expiration date indicated on the label." c. One vial of Creatinine Detect 1.3 Control Lot number 73079519/Expiration Date 2018 /12 No Open date d. One vial of Creatinine Detect 7.5 Control Lot number 73079520 /Expiration Date 2018/12 No Open date e. One vial of Creatinine Detect 23.0 Control Lot number 73079543/Expiration Date 2018/12 No Open date The manufacturer's instructions for DRI Creatinine-Detect test stated, "All assay components (reagents, calibrators, and controls), when stored properly, are stable until the expiration date indicated on the label." f. One vial of Low Level DRI General Oxidant-Detect Control Lot number 73181372/Expiration Date 2019/09 No Open date g. One vial of High Level DRI General Oxidant-Detect Control Lot number 73181373/Expiration Date 2019/09 No Open date The manufacturer's instructions for DRI General Oxidant-Detect Test stated, "All assay components (reagents, calibrators, controls), opened or unopened, are stable, until the expiration date indicated on their respective labels." 2. Observed in the laboratory refrigerator on 12/18/2018 at 1540 hours were the following urine toxicology quality control materials in use: a. One vial of Level 2 MAS DOA Total Control Lot number DAT18122A/Expiration Date 2018-12-31 No Open date; No revised expiration date b. One vial of Level 3 MAS DOA Total Control Lot number DAT18123A/Expiration Date 2018-12-31 No Open date; No revised expiration date c. One vial of Level 4 MAS DOA Total Control Lot number DAT18124A/Expiration Date 2018-12-31 No Open date; No revised expiration date d. One vial of Level 5 MAS DOA Total Control Lot number DAT18125A/Expiration Date 2018-12-31 No Open date; No revised expiration date 2. The Thermo Scientifc MAS DOA Total Control package insert (DOAT-INS-M Rev. 6) stated, "After opening, controls are stable for 30 days when stored at 2-8C" 3. Observed in the laboratory refrigerator on 12/18/2018 at 1540 hours were the following urine toxicology quality control materials in use: a. One vial of Low Level CEDIA Buprenorphine Control Lot number 73008237/Expiration Date 2019/08 No Open date; No revised expiration date b. One vial of High Level CEDIA Buprenorphine Control Lot number 73008238/Expiration Date 2019/08 No Open date; No revised expiration date 4. The Thermo Scientifc CEDIA Buprenorphine Assay Control package insert (10007591-7-EN; 2018 01)) stated, "For stability of the open calibrators or controls, 60 days or until the printed expiration date, whichever comes first. 5. Observed in the laboratory refrigerator on 12/18/2018 at 1540 hours were the following urine toxicology quality control materials in use: a. One vial of Low Level DRI Hydrocodone Assay Control Lot number 73122350/Expiration Date 2019/08 No Open date; No revised expiration date b. One vial of Low Level DRI Hydrocodone Assay Control Lot number 73122351/Expiration Date 2019/08 No Open date; No revised expiration date 6. The DRI Hydrocodone Assay Control package insert (10020120-1-EN; 2017 07)) stated, "Once opened the calibrators and controls are stable for 60 days when stored at 2 to 8C. Do not use calibrators and controls beyond the expiration date." 7. An interview with technical consultant in the laboratory on 12 /18/2018 at 1540 hours confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, verification studies, and confirmed in interview, the laboratory failed to demonstrate that the Hitachi analyzer can obtain performance specifications for all allergens comparable to those established by the manufacturer in accuracy, precision, and reference intervals. Findings: 1. Review of the "METHOD PERFORMANCE VERIFICATION/VALIDATION" policy stated: "PURPOSE B. The following will be considered when the evaluation is made. 1. Precision 2. Accuracy" "EVALUATION PROCEDURE: Unless otherwise specified by the manufacturer, the following procedures must be followed accordingly: A. Precision: 1. Run 20 replicates in one run. Calculate the CV. (Intra-assay). 2. Run 20 replicates over a period of 5 days (totaling 20) (Inter-assay) B. Accuracy. 1. Using the normal and abnormal assayed controls from the precision run, determine the accuracy of the method." The policy did not include verifying reportable range and reference intervals. 2. Review of verification studies performed on 02-24-2017 revealed that only three samples were tested for the South Eastern Inhalants panel. The panel included the allergens: Cat, Dog, Mite (D farinae), Housedust, Timothy Grass, Bermuda Grass, Bahia Grass, Cockroach Mix, Aspergillus, Penicillium, Alterneria, Cladosporium, Candida, White Oak, Maple Box Elder, Melaleuca, Cedar Mountain, Beech, Eastern Cottonwood, Acacia, Pine Mix, Mulberry Mix, Walnut/Hickory /Pecan, White Ash, Privet, Birch Alder Mix, American Sycamore, Lamb's Quarters, Short Ragweed, Marshelder Rough, English Plantain, Waterhemp, Sheep Sorrel, Cocklebur, Pigweed The verification studies did not include 20 replicates for accuracy and precision, as stated in their own policy. The studies did not include verification and evaluation of reference intervals. Moderate food allergen validation studies were not performed. The food panel included the allergens: Tomato, Wheat, Vegetable Mix, Tuna, Soybean, Shellfish Mix, Rice, Potato, Pork, Peanut, Orange, Onion Mix, Oat, Milk, Garlic, Whole Egg, Corn, Chocolate, Chicken, Beef, White Bean, Barely, Baker's Yeast, Apple, Almond The studies were incomplete. They did not include 20 replicates for accuracy and precision, verification and evaluation of reference intervals and reportable range. The verification studies were signed by the laboratory director on May 24, 2017, however, the box for verificaion approval was not checked. The laboratory failed to follow its own written policy for performing verification studies for the Hitachi analyzer. 3. According to records the laboratory had an annual test volume of 42,000 allergy tests on the Hitachi analyzer. 4. During an interview on 12 /17/18 at 2:38 pm, Testing Person-1 (TP-1) stated that the verification studies had been performed prior to his hiring. TP-1 confirmed that the laboratory failed to perform completed verification studies prior to patient testing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed

in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
I. Based on review of manufacturer's package inserts, review of the United Stated Food and Drug Administration (FDA) for Clinical Laboratory Improvement Amendments (CLIA) website, review of verification studies for the AU 480 analyzer, review of patient records from 03/03/2017 through 12/12/2018, and staff interview, it was revealed the laboratory failed to establish performance specifications for analytical sensitivity and analytical specificity to include interfering substances when the laboratory introduced assay reagents that were not subject to FDA clearance. Findings included: 1. Review of the laboratory's manufacturer's package inserts for urine toxicology testing on the Beckman Coulter AU 480 analyzer revealed the following assay reagents were utilized by the laboratory: a. Thermo Scientific DRI Amphetamine Assay b. Thermo Scientific DRI Barbiturate Assay c. Thermo Scientific DRI Benzodiazepine Assay d. Thermo Scientific DRI Cocaine Metabolite Assay e. Thermo Scientific DRI Esctasy Assay f. Thermo Scientific DRI Hydrocodone Assay g. Thermo Scientific DRI Phencyclidine Assay h. Thermo Scientific DRI Propoxyphene Assay 2. Review of the FDA CLIA website revealed the assays listed above were NOT approved by the FDA for testing on the Beckman Coulter AU 480 analyzer. Since the laboratory had modified the instrument system as approved by the Food and Drug Administration (FDA), the test system becomes high complexity and the test system performance specifications for sensitivity, specificity, accuracy, precision, and interfering substances could be affected. Performance specification studies must be performed by the laboratory. 3. Review of the laboratory records revealed the laboratory failed to conduct performance specification studies for the modified, non-FDA approved tests for interfering substances. The laboratory provided studies for sensitivity, specificity, accuracy, precision, reportable range, and reference range but NO studies were provided for interfering substances. 4. The laboratory has an annual volume of 90,000 urine toxicology tests. 5. The above findings were confirmed in an interview with laboratory staff on 12/17/2018 at 1515 hours in the conference room. The laboratory manager stated that he was not aware the assays were not approved by the FDA for testing on the AU 480 analyzer. II. Based on staff interview, review of manufacturer's package inserts, review of patient test records from 03/03/2017 through 12/12/2018 and review of verification studies for the AU 480 analyzer, it was revealed the laboratory failed to establish performance specifications for specimen collection and handling when the laboratory modified the manufacturer's stated specimen collection and handling requirements. Findings included: 1. During an interview on 12/19/2018 at 1140 hours in the laboratory, the laboratory manager was asked to explain the specimen collection and handling procedure. He stated that urine specimens from the adjoining clinic were walked to the laboratory and placed in the refrigerator. Other facilities collected the urine specimen, placed the specimen in a refrigerator until shipment and shipped the specimen to the laboratory at ambient temperature. When the specimen was received at the laboratory it was then placed in the refrigerator until tested. The laboratory manager further stated that the untested specimen was rejected or discarded after

being refrigerated for 30 days. 2. Review of the Thermo Scientific DRI assay manufacturer's instructions for urine toxicology analytes specified the following in the section titled "Specimen Collection and Handling": a. Amphetamines (0138-12-EN 2017 08) "Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for several weeks. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C indefinitely." b. Barbiturates (0353-12-EN 2017 11) "Collect urine specimens in plastic or glass containers. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 7 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20 C." c. Benzodiazepine (0372-11-EN 2015 07) "Collect urine specimens in plastic or glass containers. Testing of fresh urine specimens is suggested. Specimens that do not receive an initial test within 7 days of arrival in the laboratory should be placed into secure refrigeration units." d. Buprenorphine (10007988-13-EN 2018 01) "Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed. Specimens kept at room temperature that do not receive initial test within 8 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 30 days. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C. Studies have shown buprenorphine analytes in urine are stable at -20C up to 85 days." e. Cannabinoid (0142-10-EN 2017 12) "Collect urine specimens in plastic or glass containers. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to 4 weeks. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C." f. Cocaine Metabolite (0139-9-EN 2015 10) "Collect urine specimens in plastic or glass containers. Fresh urine should be used. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units at 2 to 8C." g. Ecstasy Assay (10006188-8-EN 2015-07) "Collect urine specimens in plastic or glass containers. Testing of fresh urine is suggested. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units." h. Ethyl Alcohol (0318-11-EN 2017 12) "Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C." i. Hydrocodone (10020160-1 2017 07) "Collect urine specimens in plastic or glass containers. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C" j. Methadone (0666-7-EN 2015-10) "Collect urine specimens in plastic or glass containers. Testing of fresh urine is suggested. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units." k. Opiate (0140-13-EN 2017 07) "Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is

assayed. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8C (Celsius) for up to two months. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C." l. Oxydodone (10008282-7-EN 2015 07) "Collect urine specimens in plastic or glass containers. Testing of fresh urine is suggested. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units." m. Phencyclidine (0141-12-EN 2018 01) "Collect urine specimens in plastic or glass containers. Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory may be placed in a secure refrigeration unit at 2 to 8? C (Celsius) for up to six months. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20C." n. Propoxyphene (0229-3-EN 201408) "Collect urine specimens in plastic or glass containers. Testing of fresh urine is suggested. Specimens that do not receive initial test within 7 days of arrival at the laboratory may be placed in secure refrigeration units." The laboratory failed to follow manufacturer's specified performance specifications for specimen collection and handling and did not conduct studies for specimen handling through their system when the laboratory modified manufacturer's instructions. 3. A review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03 /2017 through 12/12/2018 revealed the laboratory tested 67 patients. The following is a random sample of those patient specimens: Patient 170303001 Collection Date: 02 /20/2017 Receive Date: 03/03/2017 Test Date: 03/08/2017 Days Elapsed from collection to testing=16 days Specimen Tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 17071200 Collection Date: 04/25/2017 Receive Date: 04/25/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing =78 Days; Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Specimen tested for Buprenorphine beyond the manufacturer's specified 30 days. Specimen tested for Cannabinoid beyond the manufacturer's specified 28 days. Specimen tested for Ethyl Alcohol beyond the manufacturer's specified 2 months. Specimen tested for Hydrocodone beyond the manufacturer's specified 2 months. Specimen tested for Opiates beyond the manufacturer's specified 2 months. Patient 170712001 Collection Date: 05/25/2017 Receive Date: 07/12/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing = 48 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Specimen tested for Buprenorphine beyond the manufacturer's specified 30 days. Specimen tested for Cannabinoid beyond the manufacturer's specified 28 days. Patient 170711002 Collection Date: 06/20/2017 Receive Date: 06/20/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing= 22 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 170711003 Collection Date: 06/20/2017 Receive Date: 06/20/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing= 22 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 170711004 Collection Date: 06/19/2017 Receive Date: 06/19/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing= 23 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 170711001 Collection Date: 06/22/2017 Receive Date: 06/22/2017 Test Date: 07/12/2017 Days Elapsed from collection to testing= 20 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 171116001 Collection Date: 11/16/2017 Receive Date: 11/16/2017 Test Date: 11/28/2017 Days Elapsed from collection to testing= 12 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 1810118002 Collection Date: 01/01/2018 Receive Date: 01/18/2018 Test Date: 01/18/2018 Days Elapsed from collection to testing= 17 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 181009002 Collection Date: 09/24/2018 Receive Date: 10/09/2018 Test Date: 10/09/2018 Days

	Elapsed from collection to testing= 15 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 181009004 Collection Date: 09/24/2018 Receive Date: 10/09/2018 Test Date: 10/09/2018 Days Elapsed from collection to testing= 15 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 181009001 Collection Date: 09/25/2018 Receive Date: 10/09/2018 Test Date: 10/10/2018 Days Elapsed from collection to testing= 15 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. Patient 181009003 Collection Date: 09/25/2018 Receive Date: 10/09/2018 Test Date: 10/09/2018 Days Elapsed from collection to testing= 14 Days Specimen tested for Barbiturate beyond the manufacturer's specified 7 days. 4. Review of the laboratory's verification records revealed the laboratory failed to establish specimen collection and handling performance specification studies to ensure stability of urine toxicology specimens from time of collection to time of testing. In an interview on 12/19/2018 at 1140 hours, the laboratory manager was asked to provide document of urine toxicology stability studies for the laboratory's specimen handling policy. No documentation was provided. This confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, manufacturer's instructions, performance check records, an in staff interview, the laboratory failed to perform and document the calibrations at least once every 6 months in 2018 (10/2018) for the Hitachi analyzer. Findings: 1. Review of the laboratory's procedure manual for the Hitachi analyzer revealed it failed to have a procedure in place for the calibration of the analyzer every 6 months. 2. Review of the manufacturer's instructions for the Hitachi analyzer page 5-5 stated: "Performance Check For The CLA-1 Luminometer ...HCD recommends that a CLA-1 Control scan be 1) performed three times in succession at least once every six (6) months to monitor the ongoing performance and sensitivity of the CLA-1 Luminometer." 3. Review of the Performance Check records revealed the last documented performance check ran three times in succession was 04/23/2018. There were no records for the performance for 10/23/2018. The laboratory did not follow manufacturer's instructions for the frequency required for the performance check of the analyzer. 4. During the exit interview on 12/19/2018 at 12:32 pm, Testing Person-1 and Testing Person-2 confirmed they failed to follow manufacturer's instructions for the frequency in conducting performance checks.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of laboratory policies, review of the laboratory's calibration verification records for 2017 and 2018 and staff interview it was revealed the laboratory failed to have documentation of performing calibration verification every six months for analytes tested on the Beckman Coulter AU 480 urine toxicology analyzer. 1. Review of the laboratory test menu revealed the following urine toxicology tests were performed on the Beckman Coulter AU 480 urine toxicology analyzer (Serial Number 6040092): Amphetamines Barbiturate Benzodiazepine Buprenorphine Cannabinoid Cocaine Ethyl Alcohol Ecstasy Methadone Hydrocodone Opiates Oxycodone Phencyclidine Propoxyphene Oxidant-Detect Urine Creatinine 2. Review of the laboratory policy (approved by the laboratory director 02/05/2016) titled "Calibration Frequency and Verification" stated, "Perform calibration verification procedures in accordance with the manufacturer's calibration verification instructions when they meet or exceed the requirement specified below, or in accordance criteria established including the number, type and concentration of calibration materials, acceptable limits for calibration verification and frequency of calibration verification, and using calibration appropriate for the methodology and if possible, traceable to a reference method or reference material of known value, and verifying the established reportable range of patient test results, which must include at least a minimal (zero) value, a mid-point value, and a maximum upper limit of that range, at least once every six months." 3. Review of the laboratory calibration verification records from 2017 and 2018 revealed the last date calibration verification was performed was 02/16/2017. The laboratory failed to perform calibration verifications 02/2018 and 08/2018 for 16 of 16 urine toxicology analytes. 4. The above findings were confirmed by the laboratory manager on 12/17 /2018 at 1515 hours in the conference room.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The

laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy, manufacturer's instructions, Beckman Coulter AU 480 urine toxicology analyzer quality controls (QC) records from 06/2017 through 12/2018, AU 480 operator's User guide, and staff interview, the laboratory failed to have a system in place to monitor over time the accuracy and precision of AU 480 analyzer test performance with current and accurate statistical parameters. Findings included: 1. The laboratory policy titled "Quality Control Review" (Approved by the Laboratory Director on 12/1/2016) stated the following: " B. United BioScience Laboratory Supervisor ..... 5. Parallel Studies: Directs all parallel studies for new lot number of controls. Step 1 Action Controls are run multiple times (20 if possible) in parallel with existing control material. Step 2 Action Calculate the mean, standard deviation (SD) and coefficient of variation (CV). Step 3 Action Review the performance characteristics of the instrument or test system. Step 4 Action Assess the calculated 2SD range based on the clinical significance of the test results. (NOTE: There was not a step 5 in this policy) Step 6 Document the range determination. Step 7 Enter the range into the LIS and analyzer." 2. The manufacturer's instructions for urine toxicology stated the following: a. MAS DOA Total Liquid Assayed Drugs of Abuse Control (2018-12-31) in the section titled "Control Ranges" stated "Expected values may vary slightly with different reagent and/or methodologies used. Values provided are for this lot of control only and should be used to assist the laboratory in establishing its own target values." b. DRI Hydrocodone Assay Calibrators and Controls (100009065-1 2010 05) in the section titled "Results and Expected Values" stated, "The control should be used in parallel to verify the assay. The results of the controls should be within the range established by each laboratory." c. Cedia Buprenorphine (10007988-13-EN 2018 01) in the section titled "Quality Control" stated, "Reassess control targets and ranges following a change of reagent lot." d. Creatinine Detect (10009579-0 2005 07) in the section titled "Quality Control" stated, "Ensure the control results are within the established range." (The manufacture provided established ranges.) e. DRI General Oxidant Detect (100009957-4-EN 2014 12) in the section titled "Quality Control' stated, "Ensure the control results are within the established range." (The manufacturer provided established ranges.) 3. Review of laboratory quality control records revealed the following sets of urine toxicology control material that had been utilized or were currently in use: a. MAS DOA Total Liquid Assay Drugs of Abuse control material: Previous Lot Numbers: MAS DOA Total L2; Lot number DAT17072A; Expiration date 7-31-17 MAS DOA Total L3; Lot number DAT18023A; Expiration date 2-28-18 MAS DOA Total L4; Lot number DAT17074A; Expiration date 7-31-17 MAS DOA Total L5; Lot number DAT17075A; Expiration date 7-31-17 Lot Numbers currently in use: MAS DOA Total L2; Lot number DAT18122A; Expiration date 12-31-18 MAS DOA Total L3; Lot number DAT18123A; Expiration date 12-31-18 MAS DOA Total L4; Lot number DAT18124A; Expiration date 12-31-18 MAS DOA Total L5; Lot number DAT18125A; Expiration date 12-21-18 b. DRI Hydrocodone Assay control material: Previous Lot Numbers: DRI Hydrocodone Low Control; Lot number 72329751;

Expiration date 5-31-2017 DRI Hydrocodone High Control; Lot number 72329745; Expiration date 5-31-2017 Lot Numbers currently in use: DRI Hydrocodone Low Control; Lot number 73122350; Expiration date 08-2019 DRI Hydrocodone High Control; Lot number 73122351; Expiration date 08-2019 c. Cedia Buprenorphine control material: Previous Lot Numbers: Cedia Buprenorphine Low Control; Lot number 72428405; Expiration date 9-30-17 Cedia Buprenorphine High Control; Lot number 72428406; Expiration date 9-30-17 Lot Numbers currently in use: Cedia Buprenorphine Low Control; Lot number 73008237; Expiration date 08-2019 Cedia Buprenorphine High Control; Lot number 73008238; Expiration date 08-2019 d. Creatinine Detect control material: Previous Lot Numbers: Creatinine Detect 1.3 mg /dl Control; Lot number 72363194; Expiration date 1-31-17 Creatinine Detect 7.5 mg /dl Control; Lot number 72363192; Expiration date 1-31-17 Creatinine Detect 23.0 mg /dl Control; Lot number 72363190; Expiration date 1-31-17 Lot Numbers currently in use: Creatinine Detect 1.3 mg/dl Control; Lot number 73079519; Expiration date 12-2018 Creatinine Detect 7.5 mg/dl Control; Lot number 73079520 Expiration date 12-2018 Creatinine Detect 23.0 mg/dl Control; Lot number 73079543; Expiration date 12-2018 e. DRI General Oxidant Detect control material: Previous Lot Numbers: DRI General Oxidant Detect Negative Control; Lot number 72372818; Expiration date 5-31-2017 DRI General Oxidant Detect Positive Control; Lot number 72372822; Expiration 5-31-2017 Lot Numbers currently in use: DRI General Oxidant Detect Negative Control; Lot number 73181372; Expiration date 09-2019 DRI General Oxidant Detect Positive Control; Lot number 73181373; Expiration date 09-2019 3. The AU 480 operator's user guide (July 24, 2009) stated, "Check the performance of the AU 480 regularly by analyzing QC sample. Each laboratory should establish its own control frequency. A good laboratory practice is to test QC samples each time patient samples are tested and each time calibration is performed. If any trends or sudden shifts in values are detected, review all operating parameters." Further review of the AU 480 operator's guide revealed QC selection options are: 1. "Preset" Direct input of the reference values (Mean value, the standard deviation, and the range reference value) or 2. "Cumulative" The reference value is calculated from the past cumulative data. This feature allows the facility to enter a start date and end date for calculations of statistical parameters. 3. Review of the "QC-Monitor Day to Day Chart" generated from the AU 480 analyzer reveal the following for each analyte. This is an example of the QC data shown on this chart for Amphetamine: DOAT 2 (This is MS DOA Total Liquid Assayed Drugs of Abuse Control Level 2) N (NUMBER OF TESTS RUN) 39 Mean 833.7 This is the mean from the 39 runs of control material (820.1) This is the mean that was programmed into the analyzer SD (Standard Deviation) 48.35 This is the SD of the 39 runs of control material (57.20) This is SD that was programmed into the analyzer CV (Coefficient of Variation) 5.80 This is the CV of the 39 runs of control material (6.97) This is the CV programmed into the analyzer Range 219 This is the range from the 39 runs of control material (152) The is the number programmed into the analyzer. This number represents the number of SD's from the mean times 2. For example, a 4SD value would represent 2 SD on either side of the mean. The laboratory manager provided 2 QC-Monitor Day to Day Charts with amphetamine QC statistical data. One from 06/28/2017 through 12 /29/2017 and another from 01/20/2017 through 12/18/2018. Both charts had a mean of 820.1 programmed into the instrument. Review of the package insert for MAS DOA Total liquid assayed drugs of abuse control material for Level 2, Lot number DAT18122A revealed a mean value of 750 for the amphetamine analyte. 4. In an interview on 12/18/2018 at 1540 hours in the conference room, the laboratory manager was asked how quality control was monitored for accuracy and precision. He provided the QC-Monitor Day to Day Charts. He explained that he used the "cumulative" setting for the evaluation of QC data and would program in a Start date

	and an End date for the instrument to evaluate the statistical parameters for that time frame. The laboratory manager was asked to provide documentation of a mean of 820.1 for the amphetamine analyte, either statistical analysis or the package insert for the QC material that corresponded to the means programmed into the AU 480. No documentation was provided. The laboratory manager was asked what the "152" numerical value represented. He could not explain what this number represented or provide documentation of the origin of this value. He stated, "The current lot was in use when I started." The laboratory manager was asked if the current control material lot number's statistical parameters were entered into the instrument when the material was put into use. He stated the QC values were in place when he started working at the facility and did not know if the new lot of quality control material statistical parameters were entered into the analyzer. The laboratory manager did not know when the facility started using the current lot numbers of QC material. The laboratory failed to have an effective system in place to monitor over time the accuracy and precision of AU 480 analyzer test performance using current quality control material statistical parameters.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's policy, manufacturer's instructions, quality control (QC) logs, patient records, and confirmed in interview, the laboratory failed to perform two levels of control each day of patient testing for 6 of 9 days reviewed in a random sampling from August 2017 through October 2018. Findings: 1. Review of the CLA-1 laboratory procedures revealed the laboratory did not include a quality control policy for allergy testing on the Hitachi analyzer. 2. Review of CLA Allergen-Specific IgE Assay package insert page 3 stated: "10 Quality Control B. IgE Positive and Negative Control Sera Hitachi Chemical Diagnostics recommends testing with two levels of serum controls ...Frequency of testing with control should be decided by each laboratory according to regulatory agencies' requirements." 3. Southeastern Inhalants panel included the allergens: Cat, Dog, Mite (D farinae), Housedust, Timothy Grass, Bermuda Grass, Bahia Grass, Cockroach Mix, Aspergillus, Penicillium, Alterneria, Cladosporium, Candida, White Oak, Maple Box Elder, Melaleuca, Cedar Mountain, Beech, Eastern Cottonwood, Acacia, Pine Mix, Mulberry Mix, Walnut/Hickory/Pecan, White Ash, Privet, Birch Alder Mix, American Sycamore, Lamb's Quarters, Short Ragweed, Marshelder Rough, English Plantain, Waterhemp, Sheep Sorrel, Cocklebur, Pigweed. The moderate food panel included the allergens: Tomato, Wheat, Vegetable Mix, Tuna, Soybean, Shellfish Mix, Rice, Potato, Pork, Peanut, Orange, Onion Mix, Oat, Milk, Garlic, Whole Egg, Corn, Chocolate, Chicken, Beef, White Bean, Barely, Baker's Yeast, Apple, Almond. 4. Review of QC logs and patient records for analysis of allergy testing revealed two levels of external QC were not performed each day of patient testing: Test date: 08/17 /2017, no positive or negative controls were run for moderate food Patients 170816007, 170816006 were tested for moderate foods Test date: 09/15/2017, no positive or negative controls were run for southeastern inhalants and moderate food

	Patient 170914002 was tested for inhalants Patient 170914003 was tested for inhalants and food Patient 170914004 was tested for inhalants and food Patient 170824004 was tested for inhalants Patient 170914005 was tested for inhalants and food Test date: 09 /17/2018, no positive or negative controls were run for southeastern inhalants and moderate food Patient 180913007 was tested for inhalants and food Test date: 10/23 /18, no negative controls were run for south eastern inhalants, no positive controls were run for moderate food Patient 180917001 was tested for inhalants (note year of testing was illegible on instrument printout only month and day (Oct 23) Patient 181008007 was tested for inhalants and food (note day of testing was illegible on instrument print out only month and year (Oct 2018) for inhalants) Patient 181008006 was tested for inhalants and food Patient 181008005 was tested for inhalants and food (note day of testing was illegible on instrument print out only month and year (Oct 2018) for inhalants) Patient 181008001 was tested for inhalants and food (note day of testing was illegible on instrument print out only month and year (Oct 2018) for inhalants) Patient 181008002 was tested for inhalants and food (note day of testing was illegible on instrument print out only month and year (Oct 2018) for inhalants) Patient 181008003 was tested for inhalants and food Patient 181008004 was tested for inhalants and food Test date 09/07/2018 no positive or negative QC were run for southeastern inhalants and moderate food Patient 180904010 was tested for inhalants and food (note month and year illegible on instrument print out not visible for moderate food) Test date 10/25/2018 no negative QC was run for moderate food panel Patient 180917001 was tested for food Note: dates of patient testing that were illegible were obtained from the planner sheets. 5. During an interview on 12/18/2018 at 4: 25pm, Testing Person-1 stated that he only runs QC once for each new kit used and not every day of patient testing. This confirmed the above findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, manufacturer's instructions, Beckman Coulter AU 480 urine toxicology analyzer quality controls records from 07/2016 through 12 /2018 and staff interview, the laboratory failed to provide documentation of establishing quality control target ranges for 14 of 28 lot numbers of control material the Beckman Coulter AU 480 urine toxicology analyzer. Findings included: 1. The laboratory policy titled "Quality Control Review" (Approved by the Laboratory Director on 12/1/2016) stated the following: " B. United BioScience Laboratory Supervisor ..... 5. Parallel Studies: Directs all parallel studies for new lot number of controls. Step 1 Action Controls are run multiple times (20 if possible) in parallel with

existing control material. Step 2 Action Calculate the mean, standard deviation (SD) and coefficient of variation (CV). Step 3 Action Review the performance characteristics of the instrument or test system. Step 4 Action Assess the calculated 2SD range based on the clinical significance of the test results. (NOTE: There was not a step 5 in this policy) Step 6 Document the range determination. Step 7 Enter the range into the LIS and analyzer." 2. The manufacturer's instructions for urine toxicology stated the following: a. MAS DOA Total Liquid Assayed Drugs of Abuse Control (2018-12-31) in the section titled "Control Ranges" stated "Expected values may vary slightly with different reagent and/or methodologies used. Values provided are for this lot of control only and should be used to assist the laboratory in establishing its own target values." b. DRI Hydrocodone Assay Calibrators and Controls (100009065-1 2010 05) in the section titled "Results and Expected Values" stated, "The control should be used in parallel to verify the assay. The results of the controls should be within the range established by each laboratory." c. Cedia Buprenorphine (10007988-13-EN 2018 01) in the section titled "Quality Control" stated, "Reassess control targets and ranges following a change of reagent lot." d. Creatinine Detect (10009579-0 2005 07) in the section titled "Quality Control" stated, "Ensure the control results are within the established range." (The manufacturer provided established ranges.) e. DRI General Oxidant Detect (100009957-4-EN 2014 12) in the section titled "Quality Control' stated, "Ensure the control results are within the established range." (The manufacturer provided established ranges.) 3. Review of laboratory quality control records revealed the following sets of urine toxicology control material that had been utilized or were currently in use: a. MAS DOA Total Liquid Assay Drugs of Abuse control material: MAS DOA Total L2; Lot number DAT17072A; Expiration date 7-31-17 MAS DOA Total L3; Lot number DAT18023A; Expiration date 2-28-18 MAS DOA Total L4; Lot number DAT17074A; Expiration date 7-31-17 MAS DOA Total L5; Lot number DAT17075A; Expiration date 7-31-17 MAS DOA Total L2; Lot number DAT18122A; Expiration date 12-31-18 MAS DOA Total L3; Lot number DAT18123A; Expiration date 12-31-18 MAS DOA Total L4; Lot number DAT18124A; Expiration date 12-31-18 MAS DOA Total L5; Lot number DAT18125A; Expiration date 12-21-18 b. DRI Hydrocodone Assay control material: DRI Hydrocodone Low Control; Lot number 72329751; Expiration date 5-31-2017 DRI Hydrocodone High Control; Lot number 72329745; Expiration date 5-31-2017 DRI Hydrocodone Low Control; Lot number 73122350; Expiration date 08-2019 DRI Hydrocodone High Control; Lot number 73122351; Expiration date 08-2019 c. Cedia Buprenorphine control material: Cedia Buprenorphine Low Control; Lot number 72428405; Expiration date 9-30-17 Cedia Buprenorphine High Control; Lot number 72428406; Expiration date 9-30-17 Cedia Buprenorphine Low Control; Lot number 73008237; Expiration date 08-2019 Cedia Buprenorphine High Control; Lot number 73008238; Expiration date 08-2019 d. Creatinine Detect control material: Creatinine Detect 1.3 mg/dl Control; Lot number 72363194; Expiration date 1-31-17 Creatinine Detect 7.5 mg/dl Control; Lot number 72363192; Expiration date 1-31-17 Creatinine Detect 23.0 mg/dl Control; Lot number 72363190; Expiration date 1-31-17 Creatinine Detect 1.3 mg/dl Control; Lot number 73079519; Expiration date 12-2018 Creatinine Detect 7.5 mg/dl Control; Lot number 73079520 Expiration date 12-2018 Creatinine Detect 23.0 mg/dl Control; Lot number 73079543; Expiration date 12-2018 e. DRI General Oxidant Detect control material: DRI General Oxidant Detect Negative Control; Lot number 72372818; Expiration date 5-31-2017 DRI General Oxidant Detect Positive Control; Lot number 72372822; Expiration 5-31-2017 DRI General Oxidant Detect Negative Control; Lot number 73181372; Expiration date 09-2019 DRI General Oxidant Detect Positive Control; Lot number 73181373; Expiration date 09-2019 4. The laboratory was asked to provide documentation of parallel studies for

	new lot number of controls and the establishment of target values. No documentation was provided. 5. In an interview on 12/18/2018 at 1540 hours in the conference room, the laboratory manager was asked if parallel studies were performed for the new lot numbers of control material. He stated, "The current lot was in use when I started. No parallel studies were performed to his knowledge." The laboratory manager was asked if the current control material lot number's statistical parameters were entered into the instrument when the control material was put into use. He stated that all the statistical parameters were in place when he started working at the facility and did not know what parameters had been entered. This confirmed the above findings. 40420 II. Based on review of laboratory policies, manufacturer's instructions, Quality Control (QC) data, and in staff interview, the laboratory failed to establish the acceptability criteria for each lot number of CLA positive and negative control serum for allergens analyzed on the Hitachi analyzer since testing began in 05/2017. Findings: 1. The laboratory's written policy/procedures were written according to the manufacturer's package insert. The laboratory did not implement a policy for establishing acceptability criteria for each lot number of QC. 2. Review of the manufacturer's instructions for CLA control serum stated: "5 Expected Values ...Each laboratory should establish its own mean values and acceptable ranges and use those provided as guides." During an interview on 12/18/18 at 2:45 pm, Testing Person-1 (TP-1) was asked if the laboratory established their own QC range and he stated no and the ranges used were those provided in the package inserts. 3. Review of QC data for Hitachi CLA-1 Southeastern Inhalants and Moderate Food allergens revealed QC was analyzed from 05/2017-09/2018 with positive and negative controls. There was no documentation of established acceptable ranges. The laboratory did not retain the package inserts/expected value sheets for each lot number of QC used and did not always document the lot numbers on the "Planner Sheets," which included documentation that QC was tested followed by patients. QC instrument printouts did not include lot numbers of QC used. The manufacturer's expected values sheet used by the laboratory for acceptability did not include ranges for negative control for all southeastern inhalants and moderate food allergens. The expected value sheets for the positive control did not include ranges for the southeastern inhalant allergens: Acacia /Beech/Birch Alder Mix/Cottonwood, East/Elm, White/Melaleuca/Mulberry Mix/Pine Mix/Privet/Sycamore, Am/Bahia Grass/Bermuda Grass/Mrsheldr, Rgh/Pigweed /Waterhemp/Cockroach Mix/Candia/Clasporium and the moderate food allergens: Vegetable Mix/Tuna/Rice/Potato/Peanut/Onion Mix/Milk/Egg, Whole/Corn/Chocolate /Chicken/White, Bean/Barley/Apple/Almond. The laboratory did not establish the mean values and acceptable ranges for each allergen and for each lot number of control material used. (Note the laboratory did not ensure QC was within the ranges used for acceptability prior to patient testing. Refer to D5481.) The laboratory did not ensure their QC program provided accurate and reliable patient test results.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory's policy manual, manufacturer's instructions, Quality Control (QC) data, and in staff interview, the laboratory failed to ensure the results of QC for allergy testing were acceptable before reporting patient test results for 10 of 10

days in 2017 (06/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 1 of 1 day 2018 (10 /2018). Findings: 1. Review of the laboratory's policy "CLA Allergen-Specific IgE Assay" pages 4-5 stated: "Quality Control and Calibration A. Internal Control Threads Each Test Chamber contains a Positive Procedural Control and a Negative Blanking Control. These threads function as internal indicators for each Test Chamber. Positive Procedural Control: The Positive Procedural Control checks the performance of kit reagents. The Positive Procedural Control must generate a reading greater than or equal to 243 LUs in the CLA-1 Luminometer." "B. IgE Positive and Negative Control Sera Results Class values are assigned from 0 to 4 based on the amount of light emitted by the individual threads in the Test Chamber. Class 0 represents an absence of or non-detectable levels of allergen-specific antibodies." 2. Review of the manufacturer's instructions for CLA Positive Control Serum included expected values for the positive control, which was used by the laboratory for acceptability. The CLA Negative Control Serum did not include expected values for negative control. The laboratory did not establish their own ranges for allergens, as required by the manufacturer. Refer to D5469. 3. Review of the QC data for Southeastern Inhalant Panel, Moderate Food Panel, and Positive Internal Control revealed QC was not within range and there was no documented corrective action for the failed runs in 2017 and 2018: 06/07/2017 Positive or Negative QC lot numbers were not documented or available. Southeastern Inhalant Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalant Negative Control Cat: Class 1/0 (expected result: Class 0) Dog: Class 1/0 (expected result: Class 0) Mite, farina: Class 1/0 (expected result: Class 0) A total of 10 patients were tested and reported. Patient Specimen IDs: 170710008, 170608020, 170608019, 170608018, 170608017, 170608016, 17060815, 170608014, 17060813, 170608012 06/14/2017 Positive Serum Lot# 80621, Expiration date: 11/30/2018 Negative Serum Lot# J4K34895, no expiration date documented or available Southeastern Inhalant Positive Control Box Elder, Mpl: Class 1 (expected result: Class 2-4) Cedar, Mtn: Class 1/0 (expected result: Class 1-3) Oak, White: Class 1 (expected result: Class 2-4) Wlnt/Hck/Pcn: Class 0 (expected result: Class 1-3) Cocklebur: Class 1 (expected result: Class 2-4) Eng Plantain: Class 2 (expected result: Class 3-4) Lamb's Qtrs: Class 1 (expected result: Class 2-4) Ragwd, Short: Class 2 (expected result: Class 3-4) Sheep Sorrel: Class 2 (expected result: Class 3-4) Dog: Class 1 (expected result: Class 2-4) Housedust: Class 1 (expected result: Class 2-4) Mite, farinae: Class 1 (expected result: Class 2-4) Penicillium: Class 1 (expected result: Class 2-4) A total of 9 patients were tested and reported. Patient Specimen IDs: 170710007, 170608022, 170608021, 170608023, 170710011, 170710010, 170710009, 170710013, 170608024 Note: The Internal Procedural Control for Patient Specimen 17060804 failed in the first run with a value of 165 LU. The run was repeated and the Internal Procedural Control failed with a value of 191. The patient test results were still reported after the second failed run. No corrective action was documented. Moderate Food Positive Control Tomato: Class 1 (expected result: Class 3-4) Wheat: Class 1/0 (expected result: Class 2-4) Shellfish Mix: Class 1 (expected result: Class 2-4) Pork: Class 0 (expected result: Class 1-3) Orange: Class 1/0 (expected result: Class 2-4) Oat: Class 1 (expected result: Class 2-4) Garlic: Class 1/0 (expected result: Class 3-4) Beef: Class 0 (expected result: Class 1/0-2) Yeast, Bakers: Class 0 (expected result: Class 2-4) A total of 6 patients were tested and reported. Patient Specimen IDs: 170710007, 170608023, 170608023, 170710011, 170710010, 170608024 08/02/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/19 Negative Serum Lot # was not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Wlnt/Hck/Pcn: Class 1/0 (expected result: Class 0) Bahia Grass: Class 1/0 (expected result: Class 0) Bermuda Grass: Class 1/0 (expected

result: Class 0) Cat: Class 1/0 (expected result: Class 0) Dog: Class 1 (expected result: Class 0) Housedust: Class 1/0 (expected result: Class 0) Aspergillus: Class 1/0 (expected result: Class 0) Penicillium: Class 1/0 (expected result: Class 0) A total of 6 patients were tested and reported. Patient Specimen IDs: 170726007, 170726009, 170726008, 170726011, 170801008, 170728002 08/17/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/31/19 Negative Serum Lot# A1273-156K, Expiration Date: 2/28/19 Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Cat: Class 1/0 (expected result: Class 0) Dog: Class 1 (expected result: Class 0) Mite, farinae: Class 1/0 (expected result: Class 0) A total of 3 patients were tested and reported. Patient Specimen IDs: 170816007, 170816006 08 /31/2017 Positive and Negative Serum Control Lot #s were not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) A total of 6 patients were tested and reported. Patient Specimen IDs: 170824006, 170824005, 170831004, 170831003, 170831002, 170831001 09/12/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/19 Negative Serum Lot #A1273-156K, Expiration Date: 2/19 Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Cat: Class 1 (expected result: Class 0) Dog: Class 1 (expected result: Class 0) A total of 3 patients were tested and reported. Patient Specimen IDs: 170907001, 170907003, 170907002 09/26/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/19 Negative Serum Lot #A1273-156K, Expiration Date: 2/19 Southeastern Inhalants Positive Control Cedar, Mtn: Class 4 (expected result: Class 1-3) Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Lamb's Qtrs: Class 1/0 (expected result: 1/0) Cat: Class 1/0 (expected result: Class 0) Alternaria: Class 1/0 (expected result: Class 0) A total of 4 patients were tested and reported. Patient Specimen IDs: 170925004, 170925003, 170925002, 170925001 10 /04/2017 Positive and Negative Serum Control Lot #s were not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) Mite, farinae: Class 1/0 (expected result: Class 2-4) A total of 4 patients were tested and reported. Patient Specimen IDs: 170929004, 170929002, 170929003, 171004001 10/09/17 Positive and Negative Serum Control Lot #s were not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) A total of 5 patients were tested and reported. Patient Specimen IDs: 171005005, 171005006, 171005007, 171005008, 171005009 12/14 /2017 Positive Serum Lot# M4K34895, expiration date not documented or available Negative Serum Lot #A1273-156L, expiration date not documented or available The Internal Blanking Control failed five times for the positive control. Run #1: time illegible on instrument printout, Blanking value not visible only "FAIL" was visible Run #2: time 15:04, Blanking 50 LUs, Fail Run #3: time 15:26, Blanking 36 LUs, Fail Run #4: time 15:28, Blanking 35 LUs, Fail Run #5: time 15:33, Blanking 39 LUs, Fail A note was documented for the positive control stating: "Imperfection Noted in line 18 of Pette causing failur [sic] on Blank. Results consistant [sic] w/publish Ranges", signed by Testing Person-1 (TP-1) on 12/14/17. During an interview on 12/18/18 at 4: 25 pm, TP-1 stated that he called Hitachi about the internal QC blanking failure and they (Hitachi) instructed him to repeat the QC ten times and submit the results to them (Hitachi). There was no evidence or documentation indicating this was performed. There was no documentation of the phone call to Hitachi as well. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: 1-3) Southeastern

	Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) A total of 6 patients were tested and reported. Patient Specimen IDs: 171213004, 171213005, 171213006, 171213001, 171213002, 171213003 Moderate Food Positive Control Pork: Class 4 (expected result: Class 1-3) A total of 6 patients were tested and reported. Patient Specimen IDs: 171213004, 171213005, 171213006, 171213001, 171213002, 171213003 10/23/18 Positive Serum Control Lot # was not documented or available. Negative Serum Control was not analyzed. Refer to D5447. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) A total of 8 patients were tested and reported. Patient Specimen IDs: 180917001, 181008007, 181008006, 181008005, 181008001, 181008002, 181008003, 181008004 The expected value sheets for the positive control did not include ranges for the southeastern inhalants allergens: Acacia/Beech/Birch Alder Mix/Cottonwood, East /Elm, White/Melaleuca/Mulberry Mix/Pine Mix/Privet/Sycamore, Am/Bahia Grass /Bermuda Grass/Mrsheldr, Rgh/Pigweed/Waterhemp/Cockroach Mix/Candia /Clasporium. The expected value sheets for the positive control did not include ranges for the moderate food allergens: Vegetable Mix/Tuna/Rice/Potato/Peanut/Onion Mix /Milk/Egg, Whole/Corn/Chocolate/Chicken/White, Bean/Barley/Apple/Almond. The above mentioned allergens for southeastern inhalants and moderate food were included in every QC run and patient run. The laboratory did not establish ranges as required by the manufacturer, did not ensure their QC results were within the ranges they were using, and did not have any ranges for acceptability of Acacia/Beech/Birch Alder Mix/Cottonwood, East/Elm, White/Melaleuca/Mulberry Mix/Pine Mix/Privet /Sycamore, Am/Bahia Grass/Bermuda Grass/Mrsheldr, Rgh/Pigweed/Waterhemp /Cockroach Mix/Candia/Clasporium/Vegetable Mix/Tuna/Rice/Potato/Peanut/Onion Mix/Milk/Egg, Whole/Corn/Chocolate/Chicken/White, Bean/Barley/Apple/Almond allergens. 4. During the exit interview on 12/19/18 at 12:32 pm, TP-1 and TP-2 confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, manufacturer's instructions, Quality Control (QC) data, patient reports, and in staff interview, the laboratory failed to document corrective action for QC failures on the Hitachi analyzer for 10 of 10 days in 2017 (06/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 1 of 1 day 2018 (10 /2018). Findings: 1. Review of the laboratory's policy "Quality Assurance Plan" page 7-8 stated: "Quality Control ... 3. Corrective actions are taken and properly documented prior to the release of patient results." 2. Review of the Hitachi CLA-1 Luminometer Allergy System manual page 6-2 stated: "Unacceptable Results If the results of the Control Serum Test are considered unacceptable, the following actions should be taken: Document the fact that the test results were unacceptable. Positive

procedural control values are less than 243 LU's Check pette positioning and re-scan If the LU value is still less than 243 LU's, contact HCD Technical Service or your local distributor Negative blanking control values greater than 33 LU's Check pette positioning and re-scan If LU value is still greater than 33 LU's, contact HCD Technical Service or your local distributor" 3. Review of the QC data for Hitachi Southeastern Inhalant panel, Moderate Food Panel and Positive Internal Control revealed QC was not within range and there was no documented corrective action for the failed runs in 2017 and 2018: 06/07/2017 Positive or Negative QC lot numbers were not documented or available. Southeastern Inhalant Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalant Negative Control Cat: Class 1/0 (expected result: Class 0) Dog: Class 1/0 (expected result: Class 0) Mite, farina: Class 1/0 (expected result: Class 0) A total of 10 patients were tested and reported. Patient Specimen IDs: 170710008, 170608020, 170608019, 170608018, 170608017, 170608016, 17060815, 170608014, 17060813, 170608012 06/14/2017 Positive Serum Lot# 80621, Expiration date: 11/30/2018 Negative Serum Lot# J4K34895, no expiration date documented or available Southeastern Inhalant Positive Control Box Elder, Mpl: Class 1 (expected result: Class 2-4) Cedar, Mtn: Class 1/0 (expected result: Class 1-3) Oak, White: Class 1 (expected result: Class 2-4) Wlnt/Hck/Pcn: Class 0 (expected result: Class 1-3) Cocklebur: Class 1 (expected result: Class 2-4) Eng Plantain: Class 2 (expected result: Class 3-4) Lamb's Qtrs: Class 1 (expected result: Class 2-4) Ragwd, Short: Class 2 (expected result: Class 3-4) Sheep Sorrel: Class 2 (expected result: Class 3-4) Dog: Class 1 (expected result: Class 2-4) Housedust: Class 1 (expected result: Class 2-4) Mite, farinae: Class 1 (expected result: Class 2-4) Penicillium: Class 1 (expected result: Class 2-4) A total of 9 patients were tested and reported. Patient Specimen IDs: 170710007, 170608022, 170608021, 170608023, 170710011, 170710010, 170710009, 170710013, 170608024 Note: The Internal Procedural Control for Patient Specimen 17060804 failed in the first run with a value of 165 LU. The run was repeated and the Internal Procedural Control failed with a value of 191. The test results were still reported after the second failed run. No corrective action was documented. Moderate Food Positive Control Tomato: Class 1 (expected result: Class 3-4) Wheat: Class 1/0 (expected result: Class 2-4) Shellfish Mix: Class 1 (expected result: Class 2-4) Pork: Class 0 (expected result: Class 1-3) Orange: Class 1/0 (expected result: Class 2-4) Oat: Class 1 (expected result: Class 2-4) Garlic: Class 1/0 (expected result: Class 3-4) Beef: Class 0 (expected result: Class 1/0-2) Yeast, Bakers: Class 0 (expected result: Class 2-4) A total of 6 patients were tested and reported. Patient Specimen IDs: 170710007, 170608023, 170608023, 170710011, 170710010, 170608024 08/02/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/19 Negative Serum Lot # was not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Wlnt/Hck/Pcn: Class 1/0 (expected result: Class 0) Bahia Grass: Class 1/0 (expected result: Class 0) Bermuda Grass: Class 1/0 (expected result: Class 0) Cat: Class 1/0 (expected result: Class 0) Dog: Class 1 (expected result: Class 0) Housedust: Class 1/0 (expected result: Class 0) Aspergillus: Class 1/0 (expected result: Class 0) Penicillium: Class 1/0 (expected result: Class 0) A total of 6 patients were tested and reported. Patient Specimen IDs: 170726007, 170726009, 170726008, 170726011, 170801008, 170728002 08/17/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/31/19 Negative Serum Lot# A1273-156K, Expiration Date: 2/28/19 Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Cat: Class 1/0 (expected result: Class 0) Dog: Class 1 (expected result: Class 0) Mite, farinae: Class 1/0 (expected result: Class 0) A total of 3 patients were tested and reported. Patient Specimen IDs: 170816007, 170816006 08/31/2017 Positive and

Negative Serum Control Lot #s were not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) A total of 6 patients were tested and reported. Patient Specimen IDs: 170824006, 170824005, 170831004, 170831003, 170831002, 170831001 09/12/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/19 Negative Serum Lot #A1273-156K, Expiration Date: 2/19 Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Cat: Class 1 (expected result: Class 0) Dog: Class 1 (expected result: Class 0) A total of 3 patients were tested and reported. Patient Specimen IDs: 170907001, 170907003, 170907002 09/26/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/19 Negative Serum Lot #A1273-156K, Expiration Date: 2/19 Southeastern Inhalants Positive Control Cedar, Mtn: Class 4 (expected result: Class 1-3) Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Lamb's Qtrs: Class 1/0 (expected result: 1/0) Cat: Class 1/0 (expected result: Class 0) Alternaria: Class 1/0 (expected result: Class 0) A total of 4 patients were tested and reported. Patient Specimen IDs: 170925004, 170925003, 170925002, 170925001 10 /04/2017 Positive and Negative Serum Control Lot #s were not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) Mite, farinae: Class 1/0 (expected result: Class 2-4) A total of 4 patients were tested and reported. Patient Specimen IDs: 170929004, 170929002, 170929003, 171004001 10/09/17 Positive and Negative Serum Control Lot #s were not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) A total of 5 patients were tested and reported. Patient Specimen IDs: 171005005, 171005006, 171005007, 171005008, 171005009 12/14 /2017 Positive Serum Lot# M4K34895, expiration date not documented or available Negative Serum Lot #A1273-156L, expiration date not documented or available The Internal Blanking Control failed five times for the positive control. Run #1: time not visible on instrument printout, Blanking value not visible only "FAIL" was visible Run #2: time 15:04, Blanking 50 LUs, Fail Run #3: time 15:26, Blanking 36 LUs, Fail Run #4: time 15:28, Blanking 35 LUs, Fail Run #5: time 15:33, Blanking 39 LUs, Fail A note was documented for the positive control stating: "Imperfection Noted in line 18 of Pette causing failur [sic] on Blank. Results consistant [sic] w/publish Ranges", signed by Testing Person-1 (TP-1) on 12/14/17. During an interview on 12/18/18 at 4: 25 pm, TP-1 stated that he called Hitachi about the internal QC blanking failure and they (Hitachi) instructed him to repeat the QC ten times and submit the results to them (Hitachi). There was no evidence or documentation indicating this was performed. There was no documentation of the phone call to Hitachi as well. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) A total of 6 patients were tested and reported. Patient Specimen IDs: 171213004, 171213005, 171213006, 171213001, 171213002, 171213003 Moderate Food Positive Control Pork: Class 4 (expected result: Class 1-3) A total of 6 patients were tested and reported. Patient Specimen IDs: 171213004, 171213005, 171213006, 171213001, 171213002, 171213003 10/23/18 Positive Serum Control Lot # was not documented or available. Negative Serum Control was not analyzed. Refer to D5447. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) A total of 8 patients were tested and reported. Patient Specimen IDs: 180917001, 181008007, 181008006, 181008005, 181008001, 181008002, 181008003, 181008004 The expected value sheets for the positive control did not include ranges for the

	southeastern inhalants allergens: Acacia/Beech/Birch Alder Mix/Cottonwood, East /Elm, White/Melaleuca/Mulberry Mix/Pine Mix/Privet/Sycamore, Am/Bahia Grass /Bermuda Grass/Mrsheldr, Rgh/Pigweed/Waterhemp/Cockroach Mix/Candia /Clasporium. The expected value sheets for the positive control did not include ranges for the moderate food allergens: Vegetable Mix/Tuna/Rice/Potato/Peanut/Onion Mix /Milk/Egg, Whole/Corn/Chocolate/Chicken/White, Bean/Barley/Apple/Almond. The above mentioned allergens for southeastern inhalants and moderate food were included in every QC run and patient run. The laboratory did not establish ranges as required by the manufacturer, did not ensure their QC results were within the ranges they were using, and did not have any ranges for acceptability of Acacia/Beech/Birch Alder Mix/Cottonwood, East/Elm, White/Melaleuca/Mulberry Mix/Pine Mix/Privet /Sycamore, Am/Bahia Grass/Bermuda Grass/Mrsheldr, Rgh/Pigweed/Waterhemp /Cockroach Mix/Candia/Clasporium/Vegetable Mix/Tuna/Rice/Potato/Peanut/Onion Mix/Milk/Egg, Whole/Corn/Chocolate/Chicken/White, Bean/Barley/Apple/Almond allergens. 4. A random review of QC data from 06/2017-12/2017 revealed the following: 12/14/2017 Positive Serum Lot# M4K34895, expiration date not documented or available Negative Serum Lot #A1273-156L, expiration date not documented or available The Internal Blanking Control failed five times for the positive control. Run #1: time not visible on instrument printout, Blanking value not visible only "FAIL" was visible Run #2: time 15:04, Blanking 50 LUs, Fail Run #3: time 15:26, Blanking 36 LUs, Fail Run #4: time 15:28, Blanking 35 LUs, Fail Run #5: time 15:33, Blanking 39 LUs, Fail A note was documented for the positive control stating: "Imperfection Noted in line 18 of Pette causing failure [sic] on Blank. Results consistant [sic] w/publish Ranges", signed by Testing Person-1 (TP-1) on 12/14/17. During an interview on 12/18/18 at 4:25 pm, TP-1 stated that he called Hitachi about the internal QC blanking failure and they (Hitachi) instructed him to repeat the QC ten times and submit the results to them (Hitachi). There was no evidence or documentation indicating this was performed. There was no documentation of the phone call to Hitachi as well. No corrective action was documented. 5. A review of patient records on 06/14/17 revealed the following: Patient Specimen ID 17060804 Internal Procedural Control failed in the first run with a value of 165 LU. The run was repeated and the Internal Procedural Control failed with a value of 191. The patient test results were still reported after the second failed run. No corrective action was documented. Patient Specimen ID 170710010 Internal Procedural Control failed in the first run with a value of 157 LU. The run was repeated and the Internal Procedural Control passed with a value of 191. No corrective action was documented. 6. During the exit interview on 12/19/18 at 12:32 pm TP-1 and TP-2 confirmed corrective actions were not documented.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory's policy manual, manufacturer's instructions, Quality

Control (QC) data, and in staff interview, the laboratory failed to document evaluation of patient test results obtained in unacceptable test runs for 68 of 68 patients tested in 2017 and 2018 (06/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 8 of 8 patients in 2018 (10/2018). Findings: 1. Review of the laboratory's policy "CLA Allergen-Specific IgE Assay" pages 4-5 stated: "Quality Control and Calibration A. Internal Control Threads Each Test Chamber contains a Positive Procedural Control and a Negative Blanking Control. These threads function as internal indicators for each Test Chamber. Positive Procedural Control: The Positive Procedural Control checks the performance of kit reagents. The Positive Procedural Control must generate a reading greater than or equal to 243 LUs in the CLA-1 Luminometer." "B. IgE Positive and Negative Control Sera Results Class values are assigned from 0 to 4 based on the amount of light emitted by the individual threads in the Test Chamber. Class 0 represents an absence of or non-detectable levels of allergen-specific antibodies." Review of the laboratory's Quality Assurance Plan page 7 stated: "H. Quality Control 1. The laboratory establishes and maintains written procedures which direct the quality control program... f) Procedures for corrective action are defined, as applicable g) Quality control results are verified before patient values are reported. 3. Corrective actions are taken and properly documented prior to the release of patient results." 2. Review of the manufacturer's instructions for CLA Positive Control Serum included expected values for the positive control, which was used by the laboratory for acceptability. The laboratory did not establish their own ranges for allergens, as required by the manufacturer. Refer to D5469. 3. Review of the QC data for Southeastern Inhalant Panel, Moderate Food Panel, and Positive Internal Control revealed QC was not within range, there was no documented corrective action for the failed runs, and no documentation of evaluation of patients in unacceptable test runs in 2017 and 2018: 06/07/2017 Positive or Negative QC lot numbers were not documented or available. Southeastern Inhalant Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalant Negative Control Cat: Class 1/0 (expected result: Class 0) Dog: Class 1/0 (expected result: Class 0) Mite, farina: Class 1/0 (expected result: Class 0) A total of 10 patients were tested and reported. Patient Specimen IDs: 170710008, 170608020, 170608019, 170608018, 170608017, 170608016, 17060815, 170608014, 17060813, 170608012 06/14/2017 Positive Serum Lot# 80621, Expiration date: 11/30/2018 Negative Serum Lot# J4K34895, no expiration date documented or available Southeastern Inhalant Positive Control Box Elder, Mpl: Class 1 (expected result: Class 2-4) Cedar, Mtn: Class 1/0 (expected result: Class 1-3) Oak, White: Class 1 (expected result: Class 2-4) Wlnt/Hck/Pcn: Class 0 (expected result: Class 1-3) Cocklebur: Class 1 (expected result: Class 2-4) Eng Plantain: Class 2 (expected result: Class 3-4) Lamb's Qtrs: Class 1 (expected result: Class 2-4) Ragwd, Short: Class 2 (expected result: Class 3-4) Sheep Sorrel: Class 2 (expected result: Class 3-4) Dog: Class 1 (expected result: Class 2-4) Housedust: Class 1 (expected result: Class 2-4) Mite, farinae: Class 1 (expected result: Class 2-4) Penicillium: Class 1 (expected result: Class 2-4) A total of 9 patients were tested and reported. Patient Specimen IDs: 170710007, 170608022, 170608021, 170608023, 170710011, 170710010, 170710009, 170710013, 170608024 Note: The Internal Procedural Control for Patient Specimen 17060804 failed in the first run with a value of 165 LU. The run was repeated and the Internal Procedural Control failed with a value of 191. The test results were still reported after the second failed run. No corrective action was documented. Patient Specimen ID 170710010 Internal Procedural Control failed in the first run with a value of 157 LU. The run was repeated and the Internal Procedural Control passed with a value of 191. No corrective action was documented. Moderate Food Positive Control Tomato: Class 1 (expected result: Class 3-4) Wheat: Class 1/0 (expected result: Class 2-4) Shellfish Mix: Class 1 (expected result: Class 2-4) Pork: Class 0 (expected result: Class 1-3) Orange: Class 1

/0 (expected result: Class 2-4) Oat: Class 1 (expected result: Class 2-4) Garlic: Class 1 /0 (expected result: Class 3-4) Beef: Class 0 (expected result: Class 1/0-2) Yeast, Bakers: Class 0 (expected result: Class 2-4) A total of 6 patients were tested and reported. Patient Specimen IDs: 170710007, 170608023, 170608023, 170710011, 170710010, 170608024 08/02/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/19 Negative Serum Lot # was not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Wlnt/Hck /Pcn: Class 1/0 (expected result: Class 0) Bahia Grass: Class 1/0 (expected result: Class 0) Bermuda Grass: Class 1/0 (expected result: Class 0) Cat: Class 1/0 (expected result: Class 0) Dog: Class 1 (expected result: Class 0) Housedust: Class 1/0 (expected result: Class 0) Aspergillus: Class 1/0 (expected result: Class 0) Penicillium: Class 1/0 (expected result: Class 0) A total of 6 patients were tested and reported. Patient Specimen IDs: 170726007, 170726009, 170726008, 170726011, 170801008, 170728002 08/17/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/31/19 Negative Serum Lot# A1273-156K, Expiration Date: 2/28/19 Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Cat: Class 1/0 (expected result: Class 0) Dog: Class 1 (expected result: Class 0) Mite, farinae: Class 1/0 (expected result: Class 0) A total of 3 patients were tested and reported. Patient Specimen IDs: 170816007, 170816006 08/31/2017 Positive and Negative Serum Control Lot #s were not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) A total of 6 patients were tested and reported. Patient Specimen IDs: 170824006, 170824005, 170831004, 170831003, 170831002, 170831001 09/12/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/19 Negative Serum Lot #A1273-156K, Expiration Date: 2/19 Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Cat: Class 1 (expected result: Class 0) Dog: Class 1 (expected result: Class 0) A total of 3 patients were tested and reported. Patient Specimen IDs: 170907001, 170907003, 170907002 09/26/2017 Positive Serum Lot# K4K34895, Expiration Date: 1/19 Negative Serum Lot #A1273-156K, Expiration Date: 2/19 Southeastern Inhalants Positive Control Cedar, Mtn: Class 4 (expected result: Class 1-3) Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Oak, White: Class 1/0 (expected result: Class 0) Lamb's Qtrs: Class 1/0 (expected result: 1/0) Cat: Class 1/0 (expected result: Class 0) Alternaria: Class 1/0 (expected result: Class 0) A total of 4 patients were tested and reported. Patient Specimen IDs: 170925004, 170925003, 170925002, 170925001 10 /04/2017 Positive and Negative Serum Control Lot #s were not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) Mite, farinae: Class 1/0 (expected result: Class 2-4) A total of 4 patients were tested and reported. Patient Specimen IDs: 170929004, 170929002, 170929003, 171004001 10/09/17 Positive and Negative Serum Control Lot #s were not documented or available. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) A total of 5 patients were tested and reported. Patient Specimen IDs: 171005005, 171005006, 171005007, 171005008, 171005009 12/14 /2017 Positive Serum Lot# M4K34895, expiration date not documented or available Negative Serum Lot #A1273-156L, expiration date not documented or available The Internal Blanking Control failed five times for the positive control. Run #1: time not visible on instrument printout, Blanking value not visible only "FAIL" was visible

	Run #2: time 15:04, Blanking 50 LUs, Fail Run #3: time 15:26, Blanking 36 LUs, Fail Run #4: time 15:28, Blanking 35 LUs, Fail Run #5: time 15:33, Blanking 39 LUs, Fail A note was documented for the positive control stating: "Imperfection Noted in line 18 of Pette causing failur on Blank. Results consistant w/publish Ranges", signed by Testing Person-1 (TP-1) on 12/14/17. During an interview on 12/18/18 at 4:25 pm, TP-1 stated that he called Hitachi about the internal QC blanking failure and they (Hitachi) instructed him to repeat the QC ten times and submit the results to them (Hitachi). There was no evidence or documentation indicating this was performed. There was no documentation of the phone call to Hitachi as well. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: 1-3) Southeastern Inhalants Negative Control Dog: Class 1/0 (expected result: Class 0) A total of 6 patients were tested and reported. Patient Specimen IDs: 171213004, 171213005, 171213006, 171213001, 171213002, 171213003 Moderate Food Positive Control Pork: Class 4 (expected result: Class 1-3) A total of 6 patients were tested and reported. Patient Specimen IDs: 171213004, 171213005, 171213006, 171213001, 171213002, 171213003 10/23/18 Positive Serum Control Lot # was not documented or available. Negative Serum Control was not run. Refer to D5447. Southeastern Inhalants Positive Control Alternaria: Class 4 (expected result: Class 1-3) A total of 8 patients were tested and reported. Patient Specimen IDs: 180917001, 181008007, 181008006, 181008005, 181008001, 181008002, 181008003, 181008004 The expected value sheets for the positive control did not include ranges for the southeastern inhalants allergens: Acacia/Beech/Birch Alder Mix/Cottonwood, East /Elm, White/Melaleuca/Mulberry Mix/Pine Mix/Privet/Sycamore, Am/Bahia Grass /Bermuda Grass/Mrsheldr, Rgh/Pigweed/Waterhemp/Cockroach Mix/Candia /Clasporium. The expected value sheets for the positive control did not include ranges for the moderate food allergens: Vegetable Mix/Tuna/Rice/Potato/Peanut/Onion Mix /Milk/Egg, Whole/Corn/Chocolate/Chicken/White, Bean/Barley/Apple/Almond. The above mentioned allergens for southeastern inhalants and moderate food were included in every QC run and patient run. The laboratory did not establish ranges as required by the manufacturer, did not ensure their QC results were within the ranges they were using, and did not have any ranges for acceptability of: Acacia/Beech/Birch Alder Mix/Cottonwood, East/Elm, White/Melaleuca/Mulberry Mix/Pine Mix/Privet /Sycamore, Am/Bahia Grass/Bermuda Grass/Mrsheldr, Rgh/Pigweed/Waterhemp /Cockroach Mix/Candia/Clasporium/Vegetable Mix/Tuna/Rice/Potato/Peanut/Onion Mix/Milk/Egg, Whole/Corn/Chocolate/Chicken/White, Bean/Barley/Apple/Almond allergens. 4. During the exit interview on 12/19/18 at 12:32 pm, TP-1 and TP-2 confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance (QA) Plan, and staff interview, it was revealed the laboratory failed to follow its written policies to assess, monitor, and correct problems in analytic systems. Findings: 1. Review of QA policy revealed the "continuous quality improvement program will be evaluated annually." Review of laboratory records revealed that no QA was performed annually in 2017 and 2018. 2.

	The laboratory failed to have a mechanism in place to monitor, assess, and when indicated, correct problems identified in analytic systems, as follows: a) The laboratory failed to follow its own written policy to test the pH for 67 of 67 patients tested for urine toxicology. Refer to D5401, I. b) The laboratory failed to follow its own written policy to confirm a positive result by another method for 14 of 15 patients with a positive result. Rerfer to D5401, II. c) The laboratory failed to implement a written policy for split sample testing when not all analytes not included in subpart I of this part and not covered by the PT company for ensuring verification of accuracy at least twice annually for allergy and urine drug screen testing. Refer to D5403. d) The laboratory failed to follow manufacturer's instructions for documenting all required information on the "Standard Overnight Assay Planner Sheet" for 6 of 6 days in 2017 and 2 of 2 days in 2018 (random review). Refer to D5411. e) The laboratory failed to follow manufacturer's instructions for the storage of quality control material for 53 of 62 days in 2017 and 179 of 227 days in 2018. Refer to D5413. f) The laboratory failed to have documentation of the open date and/or the revised expiration date for the in-use Urine Toxicology quality control materials. Refer to D5415. g) The laboratory failed to demonstrate that the Hitachi analyzer can obtain performance specifications for all allergens comparable to those established by the manufacturer in accuracy, precision, and reference intervals. Refer to D5421. h) The laboratory failed to establish performance specifications for analytical sensitivity and analytical specificity to include interfering substances when the laboratory introduced assay reagents that were not subject to FDA clearance. Refer to D5423, I. i) The laboratory failed to establish performance specifications for specimen collection and handling when the laboratory modified the manufacturer's stated specimen collection and handling requirements. Refer to D5423, II. j) The laboratory failed to perform and document the calibrations at least once every 6 months in 2018 (10/2018) for the Hitachi analyzer. Refer to D5437. k) The laboratory failed to have documentation of performing calibration verification every six months for analytes tested on the Beckman Coulter AU 480 urine toxicology analyzer. Refer to D5439. l) The laboratory failed to have a system in place to monitor over time the accuracy and precision of AU 480 analyzer test performance with current and accurate statistical parameters. Refer to D5441. m) The laboratory failed to perform two levels of control each day of patient testing for 6 of 9 days reviewed in a random sampling from August 2017 through October 2018. Refer to D5447. n) The laboratory failed to provide documentation of establishing quality control target ranges for 14 of 28 lot numbers of control material the Beckman Coulter AU 480 urine toxicology analyzer. Refer to D5469, I. o) The laboratory failed to establish the acceptability criteria for each lot number of CLA positive and negative control serum for allergens analyzed on the Hitachi analyzer since testing began in 05/2017. Refer to D5469, II. p) The laboratory failed to ensure the results of QC for allergy testing were acceptable before reporting patient test results for 10 of 10 days in 2017 (06/2017, 08/2017, 09/2017, 10 /2017, 12/2017) and 1 of 1 day 2018 (10/2018). Refer to D5481. q) The laboratory failed to document corrective action for QC failures on the Hitachi analyzer for 10 of 10 days in 2017 (06/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 1 of 1 day 2018 (10/2018). Refer to D5781. r) The laboratory failed to document evaluation of patient test results obtained in unacceptable test runs for 68 of 68 patients tested in 2017 and 2018 (06/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 8 of 8 patients in 2018 (10 /2018). Refer to D5783.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification

	requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on review of CMS 209 form and personnel records, the laboratory failed to have a technical consultant who meets the qualification requirements. The laboratory failed to employ a technical consultant (TC) who meets qualifications to provide technical oversight of moderate complexity testing, as required. Refer to D6035.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on review of CMS 209 form and personnel records, the laboratory failed to employ a technical consultant (TC) who meets qualifications to provide technical oversight of moderate complexity testing, as required. Findings included: 1. Review of the CMS 209 form included one individual listed as the TC for providing oversight of moderate complexity testing (chemistry testing on AU480 analyzer). 2. Personnel records for individual listed as TC revealed educational documents did not meet the

	qualifications for serving as a TC. The listed TC education included a diploma for a bachelor of science in agriculture. The listed TC provided additional transcripts that included completed science classes but no completion of degrees. The individual did not meet the educational requirements for serving as a TC: have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based review of laboratory policy, manufacturer's instructions, laboratory records, patient test records, College of American Pathologists (CAP) proficiency testing (PT) records, Quality Control (QC) records, personnel records, the Laboratory Director failed to provide overall management and direction as evidenced by: 1. The Laboratory Director failed to ensure quality laboratory services, that included preanalytic and analytic phases of testing. Refer to D6082. 2. The Laboratory Director failed to ensure verification procedures were adequate to determine accuracy, precision, reference intervals, analytical sensitivity, and analytical specificity. Refer to D6086. 3. The Laboratory Director failed to ensure a quality control (QC) plan was established and followed. Refer to D6093. 4. The Laboratory Director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identifiy failures in quality. Refer to D6094. 5. The Laboraotry Director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characterisitcs are identified. Refer to D6096. 6. The Laboratory Director failed to ensure all personnel had appropriate education and experience prior to providing oversight of laboratory services. Refer to D6102. 7. The Laboratory Director failed to ensure policies were established and competency assessment was maintained for individuals who perform testing and provide technical oversight. Refer to D6103. 8. The Laboratory Director failed to specify, in writing, delegated duties and responsibilities for the technical supervisor providing technical oversight of laboratory services. Refer to D6107.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, a random review of Beckman Coulter AU 480 urine toxicology analyzer patient test records from 03/03 /2017 through 12/12/2018, review of laboratory records, laboratory's specimen processing policy, Thermo Scientific DRI urine assay manufacturer's instructions,

	laboratory's documents, client services manual, patient requisitions, and final patient test reports, College of American Pathologist (CAP) proficiency testing (PT) records, laboratory's allergy panels, quality control records (QC), performance check records, Hitachi CLA-1 Negative Control Serum package insert, temperature logs, and confirmed in interview, the Laboratory Director failed to ensure quality laboratory services, that included preanalytic and analytic phases of testing as evidenced by: Findings: 1. The laboratory failed to ensure the test requisitions solicited the tests to be performed for 8 of 29 requisitions. Refer to D5305. 2. The laboratory failed to follow its own written policy and manufacturer instructions for testing specimens for urine toxicology analytes within the specified stability requirements for 13 of 67 patients from 03/03/2017 through 12/12/2018. Refer to D5311, I. 3. The laboratory failed to ensure the correct specimen storage, preservation and conditions for transportation, according to manufacturer's instructions for 11 of 11 specimens in 2017 (random sampling). Refer to D5311, II. 4. The laboratory failed to establish a policy for the rejection of hemolyzed specimens used in allergy testing. Refer to D5311, III. 5. The laboratory failed to document the time 67 of 67 patient specimens were received into the laboratory for processing and testing. Refer to D5313, I. 6. The laboratory failed to document the received time of specimens that were received from outside clients for 60 of 60 patients in 2017 (06/2017, 07/2017, 08/2017, 09/2017, 10 /2017, 12/2017) and 10 of 10 patients 2018 (08/2018, 09/2018, 10/2018) for allergy testing. Refer to D5313, II. 7. The laboratory failed to ensure all components for proper handling of urine specimens were included in their client services document. Refer to D5317, I. 8. The laboratory failed to ensure the client services manual was consistent with manufacturer's instructions for specimen handling for allergy specimens that were received from clients. Refer to D5317, II. 9. The laboratory failed to follow its own written policy to test the pH for 67 of 67 patients tested for urine toxicology. Refer to D5401, I. 10. The laboratory failed to follow its own written policy to confirm a positive result by another method for 14 of 15 patients with a positive result. Rerfer to D5401, II. 11. The laboratory failed to implement a written policy for split sample testing when not all analytes not included in subpart I of this part and not covered by the PT company for ensuring verification of accuracy at least twice annually for allergy and urine drug screen testing. Refer to D5403, I. 12. The laboratory failed to implement a policy for verification studies when relocating an analyzer to ensure accurate and reliable test results. Refer to D5403, II. 13. The laboratory failed to include a quality control policy for allergy testing and failed to establish the acceptability criteria for each lot of CLA positive and negative control serum for allergens on the Hitachi analyzer. Refer to D5403, III. 14. The laboratory failed to establish a calibration procedure for the Hitachi CLA-1 analyzer. Refer to D5403, IV. 15. The laboratory failed to follow manufacturer's instructions for documenting all required information on the "Standard Overnight Assay Planner Sheet" for 6 of 6 days in 2017 and 2 of 2 days in 2018 (random review). Refer to D5411. 16. The laboratory failed to follow manufacturer's instructions for the storage of quality control material for 53 of 62 days in 2017 and 179 of 227 days in 2018. Refer to D5413. 17. The laboratory failed to have documentation of the open date and /or the revised expiration date for the in-use Urine Toxicology quality control materials. Refer to D5415.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, verification studies, laboratory records, and confirmed in interview, the Laboratory Director failed to ensure verification procedures were adequate to determine accuracy, precision, reference intervals, analytical sensitivity, and analytical specificity. Findings: 1. The laboratory failed to demonstrate that the Hitachi analyzer can obtain performance specifications for all allergens comparable to those established by the manufacturer in accuracy, precision, and reference intervals. Refer to D5421. 2. The laboratory failed to establish performance specifications for analytical sensitivity and analytical specificity to include interfering substances when the laboratory introduced assay reagents that were not subject to FDA clearance. Refer to D5423, I. 3. The laboratory failed to establish performance specifications for specimen collection and handling when the laboratory modified the manufacturer's stated specimen collection and handling requirements. Refer to D5423, II. 4. The laboratory failed to perform and document the calibrations at least once every 6 months in 2018 (10/2018) for the Hitachi analyzer. Refer to D5437. 5. The laboratory failed to have documentation of performing calibration verification every six months for analytes tested on the Beckman Coulter AU 480 urine toxicology analyzer. Refer to D5439. 6. The laboratory failed to have a system in place to monitor over time the accuracy and precision of AU 480 analyzer test performance with current and accurate statistical parameters. Refer to D5441.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, manufacturer's instructions, and staff interview, it was revealed the Laboratory Director failed to ensure a quality control (QC) plan was established and followed. Findings: 1. The laboratory failed to perform two levels of control each day of patient testing for 6 of 9 days reviewed in a random sampling from August 2017 through October 2018. Refer to D5447. 2. The laboratory failed to provide documentation of establishing quality control target ranges for 14 of 28 lot numbers of control material the Beckman Coulter AU 480 urine toxicology analyzer. Refer to D5469, I. 3. The laboratory failed to establish the acceptability criteria for each lot number of CLA positive and negative control serum for allergens analyzed on the Hitachi analyzer since testing began in 05 /2017. Refer to D5469, II. 4. The laboratory failed to ensure the results of QC for allergy testing were acceptable before reporting patient test results for 10 of 10 days in 2017 (06/2017, 08/2017, 09/2017, 10/2017, 12/2017) and 1 of 1 day 2018 (10/2018). Refer to D5481.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assurance Plan and staff interview, the Laboratory Director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identifiy failures in quality as evidenced by: 1. The laboratory failed to follow its written policies to assess, monitor and correct problems in preanalytic systems. Refer to D5391. 2. The laboratory failed to follow its written policies to assess, monitor, and correct problems in analytic systems. Refer to D5791.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, manufacturer's instructions, Quality Control (QC) data, patient reports, and in staff interview, the Laboraotry Director failed to ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characterisitcs are identified. Findings: 1. The laboratory failed to document corrective action for QC failures on the Hitachi analyzer for 10 of 10 days in 2017 (06 /2017, 08/2017, 09/2017, 10/2017, 12/2017) and 1 of 1 day 2018 (10/2018). Refer to D5781. 2. The laboratory failed to document evaluation of patient test results obtained in unacceptable test runs for 68 of 68 patients tested in 2017 and 2018 (06/2017, 08 /2017, 09/2017, 10/2017, 12/2017) and 8 of 8 patients in 2018 (10/2018). Refer to D5783.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of CMS 209 form and personnel records, the laboratory director failed to ensure all personnel had appropriate education and experience prior to providing oversight of laboratory services, as evidenced by: 1. The laboratory failed to employ a technical consultant (TC) who meets qualifications to provide technical oversight of moderate complexity testing, as required. Refer to D6035 2. The laboratory failed to employ a technical supervisor (TS) who meets qualifications to provide technical oversight of high complexity testing, as required. Refer to D6111.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)

	The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on review of laboratory policy, CMS 209 form, personnel records, and in interview with staff, the laboratory director failed to ensure policies were established and competency assessment was maintained for individuals who perform testing and provide technical oversight, as evidenced by: 1. The laboratory failed to establish and follow written policies to assess consultant competency for 1 of 1 technical consultant (TC), technical supervisor (TS), and general supervisor (GS) in 2018 (01/2018). Refer to D5209, I. 2. The laboratory failed to include allergy testing in their personnel competency assessment policy. Refer to D5209, II.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of CMS 209 form, personnel records, and in interview with staff, the laboratory director failed to specify, in writing, delegated duties and responsibilities for the technical supervisor providing technical oversight of laboratory services. Findings included: 1. Review of the CMS 209 form included one individual listed as the TS for providing oversight of high complexity testing: urine drug screen testing performed on AU480 analyzer and allergy testing performed on Hitachi CLA-1. 2. Personnel records for the individual listed as the TS did not include written delegated responsibilities and duties, as specified by the laboratory director. 3. During an interview on 12/17/2018 at 11:10 am, the TS was asked whether he could provide written delegated responsibilities and duties, as specified by the laboratory director. The TS was unable to provide the requested documentation.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by:

	Based on review of CMS 209 form and personnel records, the laboratory failed to have a technical supervisor who meets the qualifications to provide technical oversight of high complexity testing, as evidenced by: 1. The laboratory failed to employ a technical supervisor (TS) who meets qualifications to provide technical oversight of high complexity testing, as required. Refer to D6111. 2. The technical supervisor (TS) failed to evaluate and document competency assessment for 1 of 2 testing persons (TP-2), at least semiannually during the first year the individual was testing patient specimens in 2018 (02/2018). Refer to D6127.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the

American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in

clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in

clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the

specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or

paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of

	histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology. This STANDARD is not met as evidenced by: Based on review of CMS 209 form and personnel records, the laboratory failed to employ a technical supervisor (TS) who meets qualifications to provide technical oversight of high complexity testing, as required. Findings included: 1. Review of the CMS 209 form included one individual listed as the TS for providing oversight of high complexity testing: urine drug screen testing performed on AU480 analyzer and allergy testing performed on Hitachi CLA-1. 2. Personnel records for individual listed as TS revealed educational documents did not meet the qualifications for serving as a TS. The listed TS education included a diploma for a bachelor of science in agriculture. The listed TS provided additional transcripts that included completed science classes but no completion of degrees. The individual did not meet the educational requirements for a TS: have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, CMS 209 form, personnel records, and in interview with staff, the technical supervisor (TS) failed to evaluate and document competency assessment for 1 of 2 testing persons (TP-2), at least semiannually during the first year the individual was testing patient specimens in 2018 (02/2018). Findings included: 1. Review of the laboratory's policy "Personnel Competency Check" stated, "In order to assure Chemistry employee competence and to maintain accuracy and consistency in their reports, newly hired technologist must be verified, semiannually during the first year with their technical verified, semiannually during the first year, with their technical competencies specified in this protocol before they are assigned to duties in Chemistry." The policy did not include the specialty Immunology (Allergy Testing), only Chemistry. 2. Review of the CMS 209 revealed TP-2 listed as performing high complexity testing, that included urine drug screen testing on the AU480 analyzer and allergy testing on the Hitachi CLA-1 analyzer. Personnel record for TP-2 revealed hire date was 08/10/2017 and documented training for urine drug screen and allergy testing was in 08/2017. There was no documentation of competency assessment at least semiannually during the first year TP-2 was testing patient specimens (02/2018). 3. The TS did not assess competency for TP-2 at least semiannually during the first year TP-2 was testing patient specimens. The TS did not follow the laboratory's own written policy for ensuring competency was performed and documented, at least semiannually. 4. During an interview on 12/17/2018 at 11:10 am, the TS reviewed and confirmed the above findings.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manual, manufacturer's instructions, Quality Control (QC) data, patient reports, AU 480 operator's User guide, and staff interview the general supervisor failed to provide general supervision as evidenced by: 1. The general supervisor failed to monitor test analysis to ensure that acceptable levels of analytic performance were maintained. Refer to D6148. 2. The general supervisor failed to ensure patient test results were not reported until all corrective actions had been taken. Refer to D6150.
D6148	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(a)(4) The general supervisor is responsible for monitoring test analyses and specimen examinations to ensure that acceptable levels of analytic performance are maintained. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, manufacturer's instructions, quality controls (QC) records, AU 480 operator's User guide, patient records, and staff interview, the general supervisor failed to monitor test analysis to ensure that acceptable levels of analytic performance were maintained as evidenced by: 1. The laboratory failed to have a system in place to monitor over time the accuracy and

	precision of AU 480 analyzer test performance with current and accurate statistical parameters. Refer to D5441. 2. The laboratory failed to perform two levels of control each day of patient testing for 6 of 9 days reviewed in a random sampling from August 2017 through October 2018. Refer to D5447. 3. The laboratory failed to provide documentation of establishing quality control target ranges for 14 of 28 lot numbers of control material the Beckman Coulter AU 480 urine toxicology analyzer. Refer to D5469, I. 3. The laboratory failed to establish the acceptability criteria for each lot number of CLA positive and negative control serum for allergens analyzed on the Hitachi analyzer since testing began in 05/2017. Refer to D5469, II. 4. The laboratory failed to ensure the results of QC for allergy testing were acceptable before reporting patient test results for 10 of 10 days in 2017 (06/2017, 08/2017, 09/2017, 10 /2017, 12/2017) and 1 of 1 day 2018 (10/2018). Refer to D5481.
D6150	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(2) The director or technical supervisor may delegate to the general supervisor the responsibility for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, manufacturer's instructions, Quality Control (QC) data, patient reports, and in staff interview, the general supervisor failed to ensure patient test results were not reported until all corrective actions had been taken as evidenced by: 1. The laboratory failed to document corrective action for QC failures on the Hitachi analyzer for 10 of 10 days in 2017 (06 /2017, 08/2017, 09/2017, 10/2017, 12/2017) and 1 of 1 day 2018 (10/2018). Refer to D5781. 2. The laboratory failed to document evaluation of patient test results obtained in unacceptable test runs for 68 of 68 patients tested in 2017 and 2018 (06/2017, 08 /2017, 09/2017, 10/2017, 12/2017) and 8 of 8 patients in 2018 (10/2018). Refer to D5783.