Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	04D2126474	01/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Vitas Laboratory	1311 Fort Street, Barling, AR	

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	This is the initial survey of the laboratory conducted on 1/31/2018 through 2/1/2018. At the time of the initial survey the laboratory was not in compliance with the following conditions with immediate jeopardy: 493.801 Enrollment and Testing of Proficiency Samples 493.1230 General Laboratory Systems 493.1240 Preanalytic Systems (Immediate Jeopardy) 493.1250 Analytic Systems (Immediate Jeopardy) 493.1403 Laboratory Director Moderate Complexity (Immediate Jeopardy) 493.1409 Technical Consultant Moderate Complexity (Immediate Jeopardy) 493.1441 Laboratory Director High Complexity (Immediate Jeopardy)
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Through observation, lack of documentation, and interview it was determined that the laboratory failed to monitor room temperature in two of four rooms (identified as room numbers 1,2,3, and 4 on Vitas laboratory evacuation plan diagram) in which supplies with temperature requirements were stored. Not following manufacturer's storage instructions for test supplies and reagents has the potential of affecting all patients tested. Findings follows: A. During a tour of the laboratory on 1/31/18 at approximately 03:15 p.m., eleven ea. Clarity Drugs of Abuse screening kits lot # D1709160 with an expiration date of 2018-08 and a temperature requirement of 2 degrees C to 30 degrees C. were observed in a closed storage room identified as number 3 on a Vitas evacuation plan diagram. B. Upon request, the laboratory was unable to provide temperature records for the storage room numbers 3 as identified

	above. C. In an interview on 1/31/18 at approximately 03:30 p.m., the technical consultant identified as number 1 on the CMS 209 form confirmed that the room temperature had not been monitored on the storage room identified above
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: . Through a review of verification studies for the Sysmex Hematology analyzer, patient testing logs, lack of documentation, as well as interviews with staff, it was determined the Laboratory failed to enroll in proficiency testing for the Specialty of Hematology and Virology as evidenced by: A. A review of the verification studies for Sysmex Hematology analyzer revealed the Laboratory started patient testing for Complete Blood Counts (CBC) on September 18, 2017. B. A review of patient testing logs revealed the laboratory analyze the following viruses on the Verigene Respiratory PCR instrument: Adenovirus, Human Metapneumovirus, Influenza A-Subtype H1, Influenza A-Subtype H3, Influenza B (Parainfluenza type 1-4) Respiratory Syncytial Virus A&B and Rhinovirus. C. A review of patient testing logs for Virology revealed the Laboratory started patient testing on December 13, 2017. D. The surveyor requested Proficiency testing documentation for Hematology and Virology none was provided. There was no documentation that the laboratory had enrolled in proficiency testing program. E. In an interview on 01/31/2018 at 1:00 p.m., the technical consultant (as listed on CMS form 209) confirmed the Laboratory did not enrolled in proficiency testing until January 15, 2018.
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: . Through a review of Quality Control data, lack of documentation, as well as interview with laboratory staff, it was determined the laboratory failed to retain quality control records for at least two years. As evidenced by: A. A review of Hematology Quality Control (QC) daily printouts for the month of September 2017 revealed the Laboratory failed to retain the Sysmex e-check assay logs which contained the QC ranges for Lot # 72130804-Level I, Lot #72130805-Level II and Lot #72130806-Level III put in use on September 14, 2017. B. A review of Hematology QC daily printouts for the month of October 2017, revealed the Laboratory started a new lot of QC on 10/23/2017. The surveyor requested the Sysmex e-check assay logs

	for Lot #72690804-Level, Lot #72690805-Level II and Lot #72690806, none was provided. C. In an interview at 09:30 am on 02/01/2018, Laboratory employee #8 (as listed on form CMS-209) stated that the Sysmex e-check assay QC logs for September and October 2017 were not available. 35659 Through review of LC/MS quality control policy , quality control reports, lack of documentation, and interview it was determined that the laboratory failed to document corrective action taken when quality control results were outside of acceptable levels. Findings follow: A. Review of the policy and procedure for quality control of drug testing on the LC/MS quad instrument revealed that acceptable range for QC was defined as plus or minus 25% of the target value for each drug tested and results outside of the plus or minus 25% range required corrective action to be documented and patient results not to be reported until acceptable quality control results were obtained. B. Review of quality control reports from May 2017 through December 2017 revealed that there was no documentation of quality control results outside of acceptable limits. C. In an interview on 2/1/17 at approximately 01:00 p.m. the surveyor asked the general supervisor identified as number 2 on the CMS 209 form and the testing personnel identified as number 4 on the CMS 209 form if there were instances of quality control results being outside of acceptable limits and, if so, if there was documentation of corrective action. The testing personnel identified as number 4 on the CMS 209 form stated that there were instances of quality control results outside of acceptable limits and in those cases the quality control results and corrective actions were not documented. The general supervisor identified as number 2 on the CMS 209 form verified the statements of the testing personnel identified as number 4 on the CMS 209 form.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: . Through a review of the personnel records, patient testing logs, lack of documentation as well as interviews with staff, it was determined the laboratory failed to meet the general laboratory systems requirements and to monitor and evaluate the overall quality of the general laboratory systems as cited at: D5209: The laboratory failed to assess personnel competency. D5217: The laboratory failed to verify the accuracy of Toxicology confirmation testing at least twice annually.
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:

	Surveyor 35659 Through review of personnel records, lack of documentation, and interview it was determined that the laboratory failed to perform competency evaluations on the technical consultant and general supervisor identified on the CMS 209 form. Findings follow: A. Review of personnel records revealed that no competency evaluations were provided for the technical consultant / technical supervisor identified as number 1 on the CMS 209 form or the general supervisor identified as number 2 on the CMS 209 form. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 1/31/18 at approximately 01:30 p.m., the technical consultant identified as number 1 on the CMS 209 form confirmed that competency evaluations had not been performed on the personnel identified above.
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: . Through a review of patient testing logs, lack of documentation, as well as interviews with staff, it was determined the laboratory failed to verify the accuracy of Toxicology drug confirmation testing at least twice annually as evidenced by: A. A review of patient testing logs revealed the laboratory analyzed the following drug level confirmation testing on the Sciex Triple Quad LCMS Analyzer: Amphetamines, Buprenorphine, Benzoylecgonine (Cocaine Metabolite), Fentanyl, Norfentanyl, Gabapentin, Zolpidem, Zolpidem Phenytl-4-Cooh, Cotinine (Nicotine Metabolite), Opioids, Paroxetine, Citalopram, Tapentadol, Imipramine, Amitriptyline, Nortriptyline, Tramadol, Methyltramadol, Oxycodone, Benzodiazepine, 6-MAM (Heroin Metabolite) and Methadone. B. A review of Toxicology patient testing logs revealed the laboratory started patient testing on June 30, 2017. C. The surveyor requested documentation for verifying the accuracy of Toxicology confirmation testing none was provided. There was no documentation that the laboratory had enrolled in a CMS approved proficiency testing program. D. In an interview on 1/31 /2018 at 1:00 p.m., the technical consultant (as listed on form CMS 209) confirmed the Laboratory did not verify the accuracy of Toxicology confirmation testing. The Laboratory did not enroll in proficiency testing until January 15, 2018.
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: Through a review of the Toxicology Procedure Manual, the document titled "Vitas Laboratory Client Handbook", patient Toxicology reports, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to meet

	preanalytic system requirements for drug level confirmation testing on the Sciex Triple Quad LCMS Analyzer for Amphetamines, Buprenorphine, Benzoylecgonine (Cocaine Metabolite), Fentanyl, Norfentanyl, Gabapentin, Zolpidem, Zolpidem Phenytl-4-Cooh, Cotinine (Nicotine Metabolite), Opioids, Paroxetine, Citalopram, Tapentadol, Imipramine, Amitriptyline, Nortriptyline, Tramadol, Methyltramadol, Oxycodone, Benzodiazepine, 6-MAM (Heroin Metabolite) and Methadone. as evidenced by: D5311 - the laboratory failed to follow written policies for specimen storage D5317 - the laboratory failed to have a Client Handbook with written instructions for clients who referred specimens to the laboratory Failure to meet requirements for Preanalytic Systems is an immediate jeopardy to patient care.
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: Through a review of the Toxicology Procedure Manual, the document titled "Vitas Laboratory Client Handbook", and patient Toxicology reports, it was determined the laboratory failed to follow written policies for specimen storage. Findings follow: A. A review of the Toxicology Procedure Manual revealed the policy for acceptable specimen stated the specimen should be less than 7 days old. There was no establishment study or reference for the 7 day stability. B. The "Vitas Laboratory Client Handbook" dated 2/1/2018 states that urine samples for drug analysis are stable for three days at room temperature and refrigerated for 10 days which is inconsistent with the Toxicology Procedure Manual. C. Through a review of patient Toxicology reports for eight randomly selected patients it was determined one of eight patients specimens failed to meet requirements for an acceptable specimen but was tested and reported. Patient #124 (from the Patient Identification Worksheet) had a collection date documented as 6/16/2017, a specimen received date of 6/28/2017 (12 days after collection), and a report date of 8/1/2017.
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: Through lack of documentation, review of Vitas Laboratory Client Handbook, and interviews with staff, it was determined the laboratory failed to have a Client Handbook with written instructions for clients who referred specimens to the laboratory. Findings follow: A. On 1/31/2018 at 03:50 p.m. the surveyor requested client instructions for submitting specimens to the laboratory. The technical consultant stated that he was "working on a client services manual but not finished". B. On 2/1

	/2018 at approximately 10:38 am the technical consultant presented a document titled Vitas Laboratory Client Services Handbook. The implementation date was 2/1/2018. The Vitas Laboratory Client Services Handbook had no documentation that it had been approved or signed by the laboratory director. C. The laboratory had been accepting urine drug confirmation specimens from June 2017, hematology specimens since September 2017, and Molecular Virology specimens since December 2017 without an approved handbook of instructions for the clients submitting specimens. D. Without written instructions the laboratory could not ensure that specimens were collected, stored, and shipped properly for the testing performed. The CMS-116 form dated 2/20/2017 includes annual test volumes of 2000 Diagnostic Immunology, 20,000 Chemistry, and 10,000 Hematology.
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: Through a review of the General Laboratory Policy and Procedure Manual, Toxicology Procedure Manual, and the Molecular Procedure Manual, instrument manufacturer's manual, preventive maintenance records, package inserts, validation documentation for the Sysmex 1000 XS-1000i Hematology Analyzer and Verigene Respiratory Panel, FDA "Accessdata" web site, review of documentation presented, Verigene Respiratory Panel quality control documentation, patient test Summary Reports, Sysmex e-check control assay sheets quality control (QC) data, Sysmex Hematology patient data log, LC/MS quality control reports, observation, lack of documentation, and through interviews with laboratory staff it was determined the laboratory failed to meet analytic systems requirements as evidenced by: D5403 - the laboratory's procedure manual failed to include a procedure for imminently life-threatening test results, panic or alert values for Hematology tests D5407 - the laboratory procedures were not approved, signed and dated by the current laboratory director before use D5411 - the laboratory failed to perform required six-month maintenance on the Sciex Triple Quad LCMS serial number BM27091504H system D5413 - the laboratory failed to monitor room temperature in two of four rooms in which supplies with temperature requirements were stored D5415 - the laboratory did not change expiration dates on control materials after opening as required on the package insert D5417 - the laboratory had one of four bottles of Vitros Universal Wash available for use when it had exceeded its expiration date D5421 - the laboratory failed to demonstrate that the Sysmex XS-1000i Hematology Analyzer could obtain accuracy, precision, and reportable range established by the manufacturer and failed to have the director approve the validation of the Verigene Respiratory Panel D5423 - the laboratory failed to establish and verify performance specifications of the Sciex Triple Quad LCMS system used to perform drug level confirmations D5449 - the laboratory failed to perform quality control for qualitative procedures at least once each day patient specimens are assayed D5783 - the laboratory failed to

	document corrective action when QC was outside the laboratory's established criteria for acceptability Failure to meet requirements for Analytic Systems is an immediate jeopardy to patient care.
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: . Through a review of the laboratory policy and procedure manual, lack of documentation, as well as interview with staff, it was determined the laboratory's procedure manual failed to include a procedure for imminently life-threatening test results, panic or alert values for Hematology tests performed in the laboratory since September 18, 2017. As evidenced by: A. A review of the laboratory policy and procedure manual revealed the procedure manual did not include a procedure for imminently life-threatening test results, or panic or alert values for Hematology tests Complete Blood Counts (CBC). B. The surveyor requested the policy for panic or alert values none was provided. C. In an interview on 2/1/2018 at 10:30 am, the technical consultant, (as listed on form CMS-209), confirmed the Policy and Procedure Manual did not include a procedure for imminently life-threatening test results, or panic or alert values for Complete Blood Counts.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Through a review of the Laboratory Policy and Procedure Manual, Toxicology Procedure Manual, and the Molecular Procedure Manual and through interviews with laboratory staff, it was determined the laboratory procedures were not approved, signed and dated by the current laboratory director before use. Survey findings follow: A. Through a review of the Laboratory Policy and Procedure Manual, Toxicology

	Procedure Manual, and the Molecular Procedure Manual it was determined the laboratory director failed to approve and sign the procedure manuals or each policy. Each policy within the procedure manual had a space for an approval signature. At the time of the survey none of the policies had an approval signature of the laboratory director. B. In an interview at 01:31 p.m. on 1/31/2018 the technical consultant (as listed on the form CMS-209) confirmed the laboratory director has not approved or signed any of the laboratory's procedures. C. In an interview at 01:31 p.m. on 1/31 /2018 the laboratory owner stated that the laboratory director has not been in the laboratory at any time to approve and sign the laboratory's procedures.
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: Through review of the instrument manufacturer's manual, preventive maintenance records, and interview it was determined that the laboratory failed to perform required six-month maintenance on the Sciex Triple Quad LCMS serial number BM27091504H system. This had the potential of affecting all patients tested since December of 2017. Findings follow: A: Review of the manufacturer's maintenance requirements for the Sciex Triple Quad LCMS serial number BM27091504H system revealed that the air filter should be replaced at six-month intervals. B. Review of laboratory's maintenance records for the Sciex Triple Quad LCMS serial number BM27091504H for the period of May 2017 through January 2018 revealed that there was no documentation of the required change of the air filter. C. In an interview on 2/1 /18 at approximately 01:30 p.m., the general supervisor identified as number 2 on the CMS 209 form confirmed that the air filter had not been changed from May 2017 through January 2018.
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: Through observation, lack of documentation, and interview it was determined that the laboratory failed to monitor room temperature in two of four rooms (identified as room numbers 1,2,3, and 4 on Vitas laboratory evacuation plan diagram) in which supplies with temperature requirements were stored. Not following manufacturer's storage instructions for test supplies and reagents has the potential of affecting all patients tested. Findings follows: A. During a tour of the laboratory on 1/31/18 at

	approximately 03:15 p.m., three ea. Vitros Universal Wash lot # 8401 expiration date of 6/27/2018 and a temperature requirement of 15 degrees C. to 30 degrees C. were observed in a closed storage room identified as number 3 on a Vitas evacuation plan diagram. B. During a tour of the laboratory on 1/31/18 at approximately 03:30 p.m. , 2700 BD Vacutainer 8.5 ml SST blood collection tubes Lot # 7125693 and 1600 BD Vacutainer 5.0 EDTA blood collection tubes lot # 367844 with temperature requirement of 4 degrees C. to 25 degrees C. were observed in a closed storage room identified as number 4 on a Vitas evacuation plan diagram. C. Upon request, the laboratory was unable to provide temperature records for the storage rooms numbers 3 and 4 as identified above. D. In an interview on 1/31/18 at approximately 03:30 p.m., the technical consultant identified as number 1 on the CMS 209 form confirmed that the room temperature had not been monitored on the storage rooms identified above.
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: Surveyor 35659 Through review of package inserts, observation, and interview it was determined that the laboratory did not change expiration dates on control materials after opening as required on the package insert for three of three vials of control material. A. Package inserts for Sysmex E-Check XS controls state that product expires in fourteen days after vial is opened and punctured and the expiration dates should be changed as required after opening. B. During a tour of the laboratory on 1 /31/18 at approximately 03:00 p.m., the surveyor observed three of three Sysmex E-Check XS vials (lot #'s 341507, 341508, and 341509, expiration date 4/8/2018) which were punctured and in current use without a date of when the controls were opened written on the vials and the expiration date written on the vials was 4/8/2018 which is the same as the expiration date for the lot #'s provided by the manufacturer. C. In an interview on 1/31/18 at approximately 03:00 p.m., the technical consultant identified as number 1 on the CMS 209 form and the general supervisor identified as number 2 on the CMS 209 form verified that the controls were punctured and in use and date of opening was not written on the open vials and the written expiration was incorrect.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Surveyor 35659 . Through observations made during a tour of the laboratory it was determined the laboratory had one of four bottles of Vitros Universal Wash available for use when it had exceeded its expiration date. Findings follow: A. During a tour of the laboratory on 1/31/18 at 03:00 p.m., the surveyor observed one of four Vitros

	Universal Wash lot # 8255 with an expiration date of 1/16/18 which was partially used and available for use.
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: 35451 . 1. Through a review of CMS 116 report (page 3), new instrument validation documentation for the Sysmex 1000 XS-1000i Hematology Analyzer, lack of documentation,as well as interviews with laboratory staff, it was determined the laboratory failed to demonstrate that the Sysmex XS-1000i Hematology Analyzer could obtain accuracy, precision, and reportable range established by the manufacturer: As evidenced by: A. A review of the CMS 116 report (page 3) revealed the Laboratory tested 10,000 patients for Hematology. B. A review of the material provided to the surveyor as the verification data dated 09/14/2017 when the Sysmex 1000 XS-1000i Hematology Analyzer was installed in the laboratory failed to include the following: 1. patient normal range study 2. documentation that the analyzer could obtain accuracy and precision as established by the manufacturer. 3. package inserts for reagents, controls used for the study 4. verification of the quality control ranges 5. no overall assessment and review by the Laboratory Director. C. The following is a sample listing of patients (as listed on the patient identification worksheet) who had Complete Blood Counts performed on Sysmex Hematology Analyzer from September 2017-January 2018: patient #00001, patient #00002, patient #00003, patient #00004, patient #00005, patient #00006, patient #00007, patient #00008, patient #00009, patient #00010, patient #00011, patient #00012, patient #00013, patient #00014, patient #00015, patient #00016, patient #00017, patient #00018, patient #00019, patient #00020, patient #00021, patient #00022, patient #00023, patient #00024, patient #00025, patient #00026, patient #00027, patient #00028, patient #00029, patient #00030, patient #00031, patient #00032, patient #00033, patient #00034, patient #00035, patient #00036, patient #00037, patient #00038, patient #00039 and patient #00040. D. In an interview at 01:30 p.m. on 8/30/2016, the technical consultant (as listed on the form CMS-209) confirmed the laboratory did not verify the accuracy, precision, and reportable range of the Sysmex 1000 XS-1000i Hematology Analyzer at the time it was installed. 2. Through a review of new instrument validation documentation for the Verigene Respiratory Panel, a review of the summary reports and session reports for the Verigene Respiratory Panel, lack of documentation, and interviews with laboratory staff, it was determined the laboratory failed to have the director approve the validation of the Verigene Respiratory Panel. Two patients were tested before the Verigene Respiratory Panel validation was completed. And 80 patients were tested without an validation of the Verigene Respiratory Panel being approved by the laboratory director. Findings include: A. The signature page for the validation of the Verigene Respiratory Panel included a completion date of 12/13/2017. The signature page includes space for the Technical Consultant and the Laboratory Director to approve, sign, and date the form to indicate

	their approval of the validation. Neither the Technical Consultant nor the Laboratory Director had signed the form to document the approval of the validation of the Verigene Respiratory Panel. B. Through a review of the "Summary Report" for the Verigene Respiratory Panel, which lists patients tested, results, and date completed, it was found that two patients have documented results for the Verigene Respiratory Panel prior to the completion of the validation for this test. Patient #122 from the Patient Identification Worksheet had Respiratory Panel results reported on 11/15/2017 and Patient #123 from the Patient Identification Worksheet had Respiratory Panel results reported on 12/11/2017 prior to the validation completion on 12/13/2017. C. Review of session reports for the Verigene Respiratory Panel revealed 80 patients were tested on the Verigene Reader #17261008 without having laboratory director approval of the test system validation.
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: . Through observation, review of the FDA "Accessdata" website, review of documentation presented and interview it was determined that the laboratory failed to establish and verify performance specifications of the Sciex Triple Quad LCMS system used to perform drug level confirmations. This has the potential to affect all drug level confirmations performed. Review of the CMS 116 form revealed that the laboratory performs 20,000 urine toxicology tests annually. Findings follow: A. On a tour of the laboratory on 1/31/18 at approximately 11:15 am, a Sciex Triple Quad LCMS serial # BM27091504H was observed in the toxicology area of the laboratory. B. In an interview on 1/31/18 at approximately 11:15 am the technical supervisor identified as number 1 on the CMS 209 form stated that the laboratory utilized the Sciex Triple Quad LCMS serial # BM27091504H to perform drug level confirmation. C. Review of the FDA "Accessdata" website revealed that the Sciex Triple Quad LCMS BM27091504H had not been evaluated and approved for the performance of drug level confirmations and thus tests performed on the instrument become "high complexity" requiring test establishment studies in the laboratory performing the tests. D. Upon request to provide test establishment studies the laboratory provided data which did not have a date of performance and did not have documentation of the review and acceptance by the laboratory director. E. In an interview on 2/1/18 at approximately 02:00 p.m. the general supervisor identified as number 2 on the CMS 209 form stated that the data presented for test establishment had been performed in 2016 at another laboratory in a different location.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Through a review of the Molecular Policy and Procedure Manual, external quality control documentation, patient test Summary Reports, and interviews with laboratory staff, it was determined the laboratory failed to perform quality control for qualitative procedures at least once each day patient specimens are assayed. Survey findings follow: A. The procedure for the Verigene Respiratory Panel states that external quality control should be tested at least every 30 days. The procedure also states that external quality control should be evaluated when there is a change of reagent lot numbers. B. In an interview, at 9:40 am on 2/1/2018, laboratory employee #3 confirmed the laboratory tests external quality control for the Verigene Respiratory Panel every 30 days and at reagent lot change. At the time of the interview the surveyor requested documented IQCP (Individualized Quality Control Plan) and was told that there was not an IQCP for the Verigene Respiratory Panel. C. Through a review of the Verigene Quality Control Log for Reader 17261008 (external quality control) it was revealed that, after that validation was completed on 12/13/2017, external quality control for Verigene Respiratory Panel on Reader #17261008 is documented on 12/19/2017 (no lot number documented), 1/5/2018 (new lot number 121517024A), and 1/31/2018 (new lot number 012518024A). D. Through a review of the "Summary Report", which lists patients tested, results, and date completed, it was determined the laboratory performed quality control testing on six of twenty-two days of testing patient samples with the Verigene Respiratory Panel. The following are examples of patients tested on days when no quality control was run: 12/15/2017 four patients tested (#52, #53, #54, and #55 from the Patient Identification Worksheet); 12 /20/2017 six patients tested (#56, #57, #58, #59, #60, and #61); 12/21/2017 one patient tested (#62 from the Patient Identification Worksheet); 12/22/2017 two patients tested (#63 and #64 from the Patient Identification Worksheet) ; 12/28/2017 two patients tested #65 and #66 from the Patient Identification Worksheet) ; 12/29 /2017 two patients tested #67 and #68 from the Patient Identification Worksheet); 1/8 /18 one patient tested #69 from the Patient Identification Worksheet); 1/10/2018 one patient tested #70 from the Patient Identification Worksheet); 1/12/2018 one patient tested (patient #71 from the Patient Identification Worksheet); 1/15/2018 four patients tested (patients #72, #73, and #74 from the Patient Identification Worksheet); 1/16 /2018 seven patients tested (#75, #76, #77, #78, #79, #80, and #81 from the Patient Identification Worksheet); 1/17/2018 five patients tested (#82, #83, #84, #85, and #86 from the Patient Identification Worksheet); 1/18/2018 nine patients tested (#87, #88, #89, #90, #91, #92, #93, #94, and #95 from the Patient Identification Worksheet); 1/19 /2018 nine patients tested (#96, #97, #98, #99, #100, #101, #102, #103, and #104 from the Patient Identification Worksheet); 1/22/2018 four patients tested (#105, #106, #107, and #108 from the Patient Identification Worksheet); 1/23/2018 five patients tested (#109, #110, #111, #112, and #113 from the Patient Identification Worksheet); and 1/24/2018 four patients tested (#114, #115, #116, and #117 from the Patient Identification Worksheet)
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: . Through a review of Laboratory Policy and Procedure manual, Sysmex e-check quality control (QC) assay logs, (QC) data, patient testing logs, lack of documentation, as well as interview with staff, it was determined the laboratory failed to document corrective action when QC was outside the laboratory's established criteria for acceptability. As evidenced by: A. The policy and procedure manual section 3.0 System Components states: "Quality Control Programs are under surveillance by the laboratory supervisor designee. Corrective measures for quality control are documented." B. A review of the Sysmex e-check assay logs revealed the White Blood Count QC range as 14.78-17.34 for Lot #73250806-Level III. C. A review of QC data for January 2018 revealed on six of twenty-two days the White Blood Count (WBC) was out of range and no corrective action documented: on 1/5/18 WBC=17.42; 1/12/18 WBC=17.50; 1/22/18 WBC= 17.61; 1/23/18 WBC=17.59; 1/24 /18 WBC=17.56 and on 1/29/18 WBC=17.48. D. A review of the Sysmex e-check assay logs revealed the Platelet Count (PLT) QC range as 40-72 for Lot # 73250804-Level I and the PLT range for Lot #73250805-Level II as 206-262. E. A review of QC data for January 2018 revealed on thirteen of twenty-two days Level-I Platelet Count was out of range and no corrective action documented: on 1/3/18 PLT= 39; 1/8/18 PLT =38; 1/11/18 PLT=36; 1/12/18 PLT=37; 1/16/18 PLT=34; 1/17/18 PLT=36; 1/18 /18 PLT=37; 1/19/18 PLT=39; 1/22/18 PLT=32; 1/23/18 PLT=39; 1/24/18 PLT= 38; 1 /29/18 PLT=36 and on 1/30/18 PLT= 39. F. A review of QC data for January 2018 revealed on two of twenty-two days Level-II Platelet Count was out of range and no corrective action documented: on 01/8/2018 PLT Count = 200, and on 01/16/2018, PLT Count = 201. G. A review of Hematology patient data logs revealed on 1/8/2018, the Laboratory reported PLT Count on patient #6281952. According to QC data for January 2018, the Laboratory did not have an accept QC result for this day. H. In an interview on 2/1/18 at 10:30 am, the technical consultant confirmed the laboratory did not document corrective actions on the days QC were documented outside of the laboratory acceptable criteria and a patient was reported when QC results were outside of the Laboratory criteria for acceptability.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

	This STANDARD is not met as evidenced by: Surveyor 35659 Through review of the laboratory's "Intake Send Out Report", patient final results, and interview it was determined that the laboratory referred 542 drug confirmation tests to two outside laboratories (identified as laboratory A and laboratory B on a laboratory identification list) from August 8, 2017 to September 11, 2017 inclusive, and final results did not include the name and address of the laboratory that performed the tests. Findings follow: A: Review of the "Intake Send Out Report" revealed that from August 8, 2017 to September 11, 2017, 542 drug confirmation tests were referred to two outside laboratories identified as laboratory A and laboratory B in a separate laboratory identification sheet. B. Review of final reports from five patients (identified as patients numbers 1, 2, 3, 4 and 5 on a separate patient identification list) randomly selected from tests referred to each laboratory revealed that the name and address of the laboratory performing the tests were not on the final result report. C. In an interview on 2/1/18 at approximately 01:00 p.m., the general supervisor identified as number 2 on the CMS 209 report confirmed that the names and addresses of the laboratories performing the tests were not included on the final reports of all the tests referred during the dates of August 8, 2017 to September 11, 2017.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: . Through a review of new instrument validation documentation for the Sysmex 1000 XS-1000i Hematology Analyzer and Verigene Respiratory Panel, patient testing logs, Molecular Policy and Procedure Manual, quality control documentation, patient test Summary Reports, General Laboratory Policy and Procedure Manual, Sysmex e-check control assay sheets quality control (QC) data, Sysmex Hematology patient data log, the lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to provide overall management and direction as evidenced by: D6013 - the laboratory director failed to review and approve verification procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics D6015 - the Laboratory Director failed to ensure the laboratory is enrolled in an approved proficiency testing program D6020 - the laboratory director failed to ensure the quality control program is established and maintained Failure to meet requirements for Laboratory Director is an immediate jeopardy to patient care.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) 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: . Through a review of new instrument validation documentation for the Sysmex 1000 XS-1000i Hematology Analyzer and Verigene Respiratory Panel, and the lack of documentation, and interviews with laboratory staff, it was determined the laboratory director failed to review and approve verification procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method as cited at: D5421 - the laboratory failed to demonstrate that the Sysmex XS-1000i Hematology Analyzer could obtain accuracy, precision, and reportable range established by the manufacturer and failed to have the director approve the validation of the Verigene Respiratory Panel
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: . Through a review of verification studies for the Sysmex Hematology analyzer, patient testing logs, lack of documentation, as well as interviews with staff, it was determined the Laboratory Director failed to ensure the laboratory is enrolled in an approved proficiency testing program as cited at: D2000 - the Laboratory failed to enroll in proficiency testing for the Specialties of Hematology and Virology
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: . Through a review of the Molecular Policy and Procedure Manual, molecular and hematology quality control documentation, patient test Summary Reports, General Laboratory Policy and Procedure Manual, Sysmex e-check control assay sheets quality control (QC) data, Sysmex Hematology patient data log, lack of documentation, and interviews with laboratory staff it was determined the laboratory director failed to ensure the quality control program is established and maintained as evidenced by: D5449 - the laboratory failed to perform quality control for qualitative

	procedures at least once each day patient specimens are assayed D5783 - the laboratory failed to document corrective action when QC was outside the laboratory's established criteria for acceptability
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: . Through a review of new instrument validation documentation for the Verigene Respiratory Panel, Molecular Policy and Procedure Manual, quality control documentation, patient test Summary Reports, Laboratory policy and procedure manual, Sysmex e-check control assay sheets, quality control (QC) data, Sysmex Hematology patient data log, LC/MS quality control reports, personnel records, lack of documentation, and interviews with laboratory staff it was determined the technical consultant failed to provide technical oversight as evidenced by: D6040 - the technical consultant failed to review and approve verification procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics D6042 - the technical consultant failed to establish a quality control program appropriate for testing performed D6044 - the technical consultant failed to ensure patient tests are not reported until all corrective actions have been taken D6046 - the technical consultant failed to evaluate competency on seven of seven personnel Failure to meet requirements for Technical Consultant is an immediate jeopardy to patient care.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: . Through a review of new instrument validation documentation for the Verigene Respiratory Panel, lack of documentation, and interviews with laboratory staff, it was determined the technical consultant failed to review and approve verification procedures to ensure they are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method as cited at: D5421 - the laboratory failed to demonstrate that the Sysmex XS-1000i Hematology Analyzer could obtain accuracy, precision, and reportable range established by the manufacturer and failed to have the technical consultant approve the validation of the Verigene Respiratory Panel
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for

	acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: . Through a review of the Molecular Policy and Procedure Manual, quality control documentation, patient test Summary Reports, Laboratory policy and procedure manual, Sysmex e-check control assay sheets, quality control (QC) data, Sysmex Hematology patient data log, lack of documentation, and interviews with laboratory staff, it was determined the technical consultant failed to establish a quality control program appropriate for testing performed as evidenced by: D5449 - the laboratory failed to perform quality control for qualitative procedures at least once each day patient specimens are assayed
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: . Through review of LC/MS quality control reports, Laboratory policy and procedure manual, Sysmex e-check quality control (QC) assay logs, (QC) data, patient testing logs, lack of documentation, and interview it was determined the technical consultant failed to ensure patient tests are not reported until all corrective actions have been taken as evidenced by: D5783 - the laboratory failed to document corrective action when QC was outside the laboratory's established criteria for acceptability
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: . Through review of personnel records, lack of documentation, and interview it was determined that the laboratory failed to perform competency evaluations on five of five moderate complexity testing personnel identified on the CMS 209 form. Findings follow: A. Review of personnel records revealed that no competency evaluations were provided for moderate complexity testing personnel identified as numbers 3 through 7 on the CMS 209 form. B. Upon request, the laboratory could not provide competency evaluations for the personnel identified above. C. In an interview on 1/31/18 at approximately 01:30 p.m., the technical consultant identified as number 1 on the CMS 209 form confirmed that competency evaluations had not been performed on the personnel identified above.
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: . Through observation, review of the FDA "Accessdata" website, quality control reports, personnel records, establishment studies documentation presented and interview was determined the laboratory director failed to provide overall management and direction as evidenced by: D6086 - the laboratory director failed to ensure the laboratory established and verified performance specifications of the Sciex Triple Quad LCMS D6103 - the laboratory director identified as number 8 on the CMS 209 form failed to ensure competency evaluations were performed on seven of seven personnel D6107 - the laboratory director did not specify in writing the examinations and procedures that six of six testing personnel are authorized to perform Failure to meet requirements for Laboratory Director is an immediate jeopardy to patient care.
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: Surveyor 35659 . Through observation, review of the FDA "Accessdata" website, review of documentation presented and interview it was determined that the laboratory director failed to ensure the laboratory established and verified performance specifications of the Sciex Triple Quad LCMS system used to perform drug level confirmations as cited at: D5423 - the laboratory failed to establish and verify performance specifications of the Sciex Triple Quad LCMS system
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: Surveyor 35659 . Through review of personnel records, lack of documentation, and interview it was determined that the laboratory director identified as number 8 on the CMS 209 form failed to ensure competency evaluations were performed on seven of seven personnel identified on the CMS 209 form as cited at: D5209 - the laboratory failed to perform competency evaluations on seven of seven personnel

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: Surveyor 35659 . Through review of personnel records, lack of documentation, and interview it was determined that the laboratory director did not specify in writing the examinations and procedures that six of six testing personnel are authorized to perform. Findings follow: A. Review of personnel records provided by the laboratory revealed that there was no written authorization to perform testing included for testing personnel identified as numbers two through seven on the CMS 209 form. B. Upon request, the laboratory could not provide written authorization to test for the personnel identified above. C. In an interview on 1/31/18 at approximately 01:30 p.m., the technical supervisor identified as number 1 on the CMS 209 confirmed that written authorizations to test were not available for the testing personnel identified above and that he was unaware of the requirement of a written authorization to test.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Surveyor 35659 . Through review of personnel records, lack of documentation, and interview it was determined that the laboratory failed to perform competency evaluations on one of one high complexity testing personnel identified on the CMS 209 form. Findings follow: A. Review of personnel records revealed that no competency evaluations were provided for the general supervisor who performs high complexity testing and is identified as number 2 on the CMS 209 form B. Upon request, the laboratory could not provide competency evaluations for the high complexity testing personnel. C. In an interview on 1/31/18 at approximately 01:30 pm, laboratorry employee #1 (as listed on the CMS 209 form) confirmed that competency evaluations had not been performed on the high complexity testing personnel.