Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2143868	02/14/2020
Name of Provider or Supplier	**Street Address, City, State**	
Praxeo Health, Llc	7920 Belt Line Road Suite 215, Dallas, 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 laboratory representatives 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 02/13/2020 - 02/14/2020, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1240 Pre-Analytic Systems 493.1250 Analytic Systems 493.1441 Laboratory Director, (high complexity) 493.1447 Technical Supervisor 493.1487 Testing Personnel (high complexity) The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. NOTE: The laboratory was asked to cease urine screen and confirmation toxicology testing. The laboratory voluntarily ceased urine toxicology screen and confirmation testing on patients. See letter dated 02/17/2020 and signed by the laboratory director. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider /supplier, the State Survey Agency (SA) should be notified immediately.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by:

	Based on review of laboratory College of American Pathologists (CAP) laboratory proficiency testing (PT) records and confirmed in interview, the laboratory failed to verify the accuracy of the analytes not graded by the proficiency testing program. Findings were: 1. Review of the CAP Actions Laboratories Should Take When PT Result is not Graded (Rev 8/2019) revealed "your laboratory must identify all analytes with an exception reason code, review and document the acceptability of performance as outlined below and retain documentation of review for at least 2 years. [27] - Lack of participant or referee consensus: Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If comparison is not available, perform and document alternative assessment (i.e. split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested. " 2. Review of the 2019 CAP laboratory records revealed 2 of 4 events with no documentation of the self evaluation for the [27] exception codes per the manufacturer's instructions: UDC-B 2019 Forensic Urine Drug Test Confirmatory Benzoylecgonine UDC-16: lab result - present [27] Hydromorphone UDC-11: lab result - present [27] UDC-D 2019 Forensic Urine Drug Test Confirmatory Benzoylecgonine UDC-37: lab result - present [27] 3. An interview with the technical supervisor on 2/14/20 at 1005 hours in the conference room confirmed the above results.
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: Based on review of laboratory policy, laboratory proficiency testing (PT) records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated urine toxicology analytes at least twice annually for 3 of 4 testing events in 2018 and 2019. Findings included: 1. The laboratory policy titled "Proficiency Testing" (Number QA-004, Effective 05/22/2018) stated the following: "A2. Any tests performed that are not part of this program [Proficiency testing program] must have their accuracy and precision verified at least twice a year by an alternate method ...C1. Alternative Proficiency Testing Assessment. 1. The PT sample will either be shipped to another laboratory or an internal analysis will be performed. The samples are prepared and coded by one blind member of the Pre-Analytic Department. Testing is then performed by one blind member of the Technical Department. Data analysis will finally be performed by someone other than the preparer of specimens within the Technical Department." 2. Review of laboratory proficiency testing records (2018 and 2019) revealed the laboratory failed to verify the accuracy of non-regulated the urine toxicology analytes Mitragynine, Naloxone, and Naltrexone at least twice annually in 2018 and 2019. No documentation was provided for 2018 (2nd Event) and 2019 (1st and 2nd Event). 3. In an interview on 02/13/2020 at 0938 hours, the laboratory administrator confirmed the above findings.
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 review of the laboratory policies, laboratory records, patient test records, and confirmed in interview, it was revealed that the laboratory did not meet the applicable preanalytic system(s) requirements and failed to monitor and evaluate the quality of all preanalytic systems as evidenced by: 1. Tthe laboratory failed to document complete preanalytical studies for the confirmatory drug testing on the Agilent 6460 LCMS. Refer to D5311-I 2. The laboratory failed to document complete preanalytical studies for the toxicology screening testing on the non-FDA approved tests on the Olympus AU680. Refer to D5311-II
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 policies, laboratory records, patient test records, and confirmed in interview, the laboratory failed to document preanalytical studies to substantiate the specimen stability for the confirmatory drug testing on the Agilent 6460 LCMS. Findings were: 1. Review of the laboratory policy for Specimen Processing under Storage of Urine Toxicology Specimens revealed "if samples are not tested immediately, they may be stored in the refrigerator for up to 3 days (72 hours) at 2-8C prior to testing. Urine toxicology specimens pending testing may be refrigerated for up to 3 days (72 hours) before they must be frozen, if there is a significant delay in testing. If a testing delay of greater than 3 days (72 hours) is anticipated, shipment of such urine toxicology specimens to the reference laboratory should be performed...following testing of urine toxicology specimens they are to be retained in frozen storage for a minimum of 30 days and then safely discarded." 2. Review of the laboratory policy Specimen Stability and transport study revealed "[the laboratory] will determine stability at the following temperatures: Room Temp 15-25 C; Refrigerated 2- 8C, Freezer 0 - -20C; Incubator 26-50 C...if the results were within +/- 20% the drug was considered stable for that transportation temperature." 3. Review of the laboratory records revealed the laboratory performed the following 63 analytes for confirmatory toxicology testing on the Agilent 6460 LCMS (SN: SG133572223): 2-hydroxyalprazolam 6-acetylmorphine 7-aminoclonazepam 7-aminoflunitrazepam acetaminophen alprazolam amitriptyline amphetamine benzoylecgonine buprenorphine butalbital carisoprodol citalopram codeine cotinine cyclobenzaprine desipramine diazepam dihydrocodeine diphenhydramine duloxetine EDDP ethyl-glucuronide ethyl-sulfate fentanyl flunitrazepam fluoxetine flurazepam gabapentin hydrocodone hydromorphone imipramine ketamine lorazepam MDA MDEA MDMA meperidine meprobamate methadone methamphetamine methylphenidate mitragynine morphine naloxone naltrexone nor-buprenorphine

nordiazepam norfentany normeperidine nortriptyline oxazepam oxycodone oxymorphone phencyclidine phenobarbital phentermine pregabalin secobarbital tapentadol temazepam THC-COOH tramadol trazodone zolpidem 3. Review of the stability studies for 'transported at room temperature' revealed failures for 2 of 63 analytes for the following days: Flurazepam SRTLVL3 at day 6 - 103% difference diphenydramine LRTLVL5 at day 6 - -36% difference 4. Review of the stability studies for 'transported in a kangaroo pack' revealed failures for 1 of 63 analytes for the following days: Flurazepam SKLVL3 at day 6 - 85% difference 5. Review of the stability studies for 'transported in fridge revealed failures for 1 of 63 analytes for the following days: Flurazepam SRFLVL3 at day 6 - 84% difference 6. Review of the stability studies for 'transported in freezer' revealed failures for 6 of 63 analytes for the following days: Flurazepam SF2LVL3 at day 6 - 83% difference Midazolam SF2LVL3 at day 7 - 51% difference 7-Aminoclonazepam SF2LVL3 at day 14 - 62% difference 7-Aminoflunitrazepam SF2LVL3 at day 14 - 27% difference Hydroxyalprazolam SF2LVL3 at day 14 - 48% difference Alprazolam SF2LVL3 at day 14 - 75% difference 7. Review of the stability studies for 'transported in incubator' revealed failures for 1 of 63 analytes for the following days: THC-COOH SINLVL3 at day 6 - 29% difference 8. Review of the frozen stabilities studies revealed no documentation of stability for 30 days. Furthermore, the stability records revealed the laboratory stored stability specimens in the freezer with temperature that ranged -10.1 C to 19.4 C. No documentation of freezer temperature that was maintained from 0 - -20C, per the stability validation plan. 9. Random review of patient final reports from November 2019 to January 2020 revealed 5 of 8 specimens that the laboratory received, froze them on the day of receipt, and performed the testing on the following days despite stability failures for 6 of 63 analytes at frozen temperature for the following analytes at the following days: Flurazepam at day 6; Midazolam at day 7; 7-Aminoclonazepam at day 14; 7-Aminoflunitrazepam at day 14; Hydroxyalprazolam at day 14; Alprazolam SF2LVL3 at day 14. sample ID 1912310003 collected 12/30/19, received 12/30/19 , analyzed 1/13/20, elapsed time 14 days sample ID 1912310002, collected 12/30/19, received 12/30/19, analyzed 1/13/20, elapsed time 14 days sample ID 1911140002, collected 11/11/19, received 11/11/29, analyzed 11/22/19, elapsed time 11 days sample ID 1912160002, collected 12/16//19, received 12/16/19, analyzed 12/27/19, elapsed time 11 days sample ID 1912160001, collected 12/16/19, received 12/16/19, analyzed 12/27/19, elapsed time 11 days 10. An interview with the laboratory consultant on 2/14/20 at 1110 hours in the conference room confirmed the above findings. He acknowledged that the laboratory should only accept specimens up to the days with stability with acceptable results. II. Based on review of the FDA website, laboratory establishment studies, patient test results and confirmed in interview, the laboratory failed to document complete preanalytical studies for 7 of 11 non FDA approved analytes for the toxicology screening for the AU680 chemistry analyzer. Findings were: 1. Review of the FDA website revealed 7 of 11 analytes the laboratory performed on the AU680 chemistry analyzer were not FDA approved. pH Creatinine (CREA) Cotinine Aphetamines Cocaine Barbiturates Cannabinoids 2. Review of the laboratory policy Specimen Stability and transport study revealed "[the laboratory] will determine stability at the following temperatures: Room Temp 15-25 C; Refrigerated 2- 8C, Freezer 0 - -20C; Incubator 26-50 C...if the results were within +/- 20% the drug was considered stable for that transportation temperature." 3. Review of the establishment studies for the above analytes for room temperature (15-25 C, refrigerated 2-8 C, freezer 0 - -20C, and incubator 26-50) revealed stability studies for the AU680 with stability failures for 3 of 7 analytes for the following temperatures: Cotinine day 1 Refrigerated - 22.06% Cocaine day 1 Incubator - 37.62% Cannabinoids day 4 all temperatures 4. Review of the stability studies for the AU680 revealed stability failures for 7 of 7 analytes on day 3 for all temperatures. 5.

	Review of the frozen stability studies revealed no documentation of studies after day 5. 6. Random review of patient final reports from November 2019 to January 2020 revealed 5 of 8 specimens that the laboratory received, froze them on the day of receipt, and performed the testing on the following days despite no documentation of stability studies after day 5. sample ID 1912310003 collected 12/30/19, received 12/30 /19 , analyzed 1/13/20, elapsed time 14 days sample ID 1912310002, collected 12/30 /19, received 12/30/19, analyzed 1/13/20, elapsed time 14 days sample ID 1911140002, collected 11/11/19, received 11/11/29, analyzed 11/22/19, elapsed time 11 days sample ID 1912160002, collected 12/16//19, received 12/16/19, analyzed 12 /27/19, elapsed time 11 days sample ID 1912160001, collected 12/16/19, received 12 /16/19, analyzed 12/27/19, elapsed time 11 days 7. An interview with the laboratory consultant on 2/14/20 at 1110 hours in the conference room confirmed the above findings. He acknowledged that the laboratory had failures for the above dates and temperatures.
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 review of laboratory policies, laboratory establishment records, quality control records, patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of its analytic systems. Refer to D5429, D5439, D5445, D5781
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on manufacturer's instructions, review of maintenance logs, and confirmed in interview the laboratory failed to perform weekly maintenance for 2 of 52 weeks in 2019 (07/2019, 10/2019) and monthly maintenance for 3 of 12 month in 2019 (07 /2019, 09/2019, 11/2019) as required by the manufacturer on the AU680 chemistry analyzer. Findings: 1. Review of AU680 User Guide revealed the following: "8.2 Weekly Maintenance To obtain the highest level of performance from the system perform the following maintenance tasks on a weekly basis. 8.2.1 Perform a W2 ... 8.2.2 Perform a Photocal ... 8.2.3 Cleaning the Sample Pre-dilution Bottle ... 8.3 Monthly Maintenance To obtain the highest level of performance from the system perform the following maintenance tasks on a monthly basis. Maintenance Routines Perform the following tasks monthly: 8.3.1 Clean the Sample Probe, Reagent Probe, and HbA1c Wash Wells ... 8.3.2 Clean the Mix Bar Wash Wells ... 8.3.3 Clean the

	Wash Nozzle Unit and Check the Tube Mounting Joints ... 8.3.4 Clean the Deionized Water Filter, Sample Probe Filter, and Cleaning the Tank" Review of the maintenance log also included wiping down the "Sample Probe and Mix Bars" as part of the weekly maintenance tasks. 2. Review of the AU680 maintenance log revealed the laboratory failed to perform weekly maintenance in 2019, as required by the manufacturer: July week 5 October week 1 Review of the AU680 maintenance log revealed the laboratory failed to perform monthly maintenance in 2019, as required by the manufacturer: July, September, November 3. During the exit interview on 02/14 /2020 12:30 pm, the laboratory director confirmed the above findings. II. Based on review of maintenance logs (with manufacturer requirements), and confirmed in interview the laboratory failed to perform weekly maintenance for 2 of 4 weeks in 2018 (08/2018), 11 of 31 weeks in 2019 (05/2019, 06/2019, 07/2019, 08/2019, 09 /20219, 10/2019, 12/2019), 1 of 4 weeks in 2020 (01/2020), and monthly maintenance for 1 of 1 month in 2020 (01/2020) as required by the manufacturer on the Agilent LC /MS/MS 6460 chemistry analyzer. Findings: 1. Review of Agilent LC/MS/MS 6460 Maintenance Log revealed the following tasks that were required to be completed: Weekly: Reboot PC, Perform Checktune, Sonicate nebulizer needle and spray shield, Sonicate capillary cap Monthly: Perform Autotune, Check pump oil level The laboratory failed to perform weekly maintenance as required by the manufacturer on the following weeks: 2018: August- week 2, 4 2019: May- week 2 June- week 3 July- week 4, 5 August- week 2, 4 September- week 3, 4 October- week 1 December- week 4, 5 2020: January- week 2 The laboratory failed to perform monthly maintenance as required by the manufacturer on the following months: 2020: January 2. During the exit interview on 02/14/2020 at 12:30 pm, the laboratory director confirmed the above findings.
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 records and confirmed in interview, the laboratory failed to document the semi annual calibration verification for the all analytes

	performed on the AU680 chemistry analyzer. Findings were: 1. Random review of the calibration records from 2018- 2019 revealed 2 of 11 analytes on the AU680 used 2 levels of calibration. pH Creatinine (CREA) 2. Random review of the calibration records from 2018-2019 revealed 9 of 11 analytes on the AU680 used 1 level for calibration. Oxycodone Cotinine Methadone Opiates Aphetamines Cocaine Barbiturates Benzodiazepines Cannabinoids 3. Review of the laboratory records from 2018 - 2019 revealed no documentation of the calibration verification for the above analytes on the AU680 chemistry analyzer. 4. An interview with the technical supervisor on 2/14/20 at 1005 hours in the conference room confirmed the above findings. She was unaware the laboratory was required to perform calibration verification for qualitative testing.
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 laboratory policy, quality controls (QC) records (06/2019 and 07 /2019), direct observation and staff interview, the laboratory failed to have a system in place to monitor errors over time and the accuracy and precision of Beckman Coulter AU680 test performance with current and accurate statistical parameters for all lot numbers of control material. 1. Review of the laboratory policy titled, "Internal Quality Control" stated, "6. This procedure describes the practice used for ordering and using quality control in the LIS (laboratory information system) as well as the methodology, analytes within controls, and acceptance criteria per instrumentation used. Quality Control is performed daily before patient can be tested. The LIS automates the quality control orders, denies accepting results past pre-built acceptable reference ranges, and creates Levy-Jennings for week to monthly review." 2. Review of laboratory QC records (06/2019 and 07/2019) revealed the following control material and the analytes tested using the material on the Beckman Coulter AU680: a. For Amphetamine, Cocaine, Cotinine, Methadone, Opiates, and Oxycodone A-MAS DOAT-2; Lot number DAT19122A and DAT20092A A-MAS DOAT-3; Lot number DAT19053A b. For Barbiturates, Benzodiazepines, and THC (Tetrahydrocannabinol) A-MAS DOAT-4; Lot number DAT19124A A-MAS DOAT-5; Lot number DAT19125A 3. Review of laboratory QC records (06/2019 and 07/2019) submitted for laboratory director review to monitor errors over time and for accuracy and precision revealed the following: a. Only 1 Level (A-MAS DOAT-3; Lot number DAT19053A) was used for Amphetamine, Cocaine, Cotinine, Methadone, Opiates, and Oxycodone QC testing on 06/03/2019; 06/05/2019; 06/10/2019; 06/20/2019; 06 /21/2019; 06/25/2019; 06/26/2019; 06/27/2019; and 06/28/2019. No QC failures were included for review. No documentation of A-MAS DOAT-2 result values were submitted for laboratory director review. b. Only 1 Level (A-MAS DOAT-4; Lot

	number DAT19124A) was used for Barbiturates, Benzodiazepines, and THC on 6/03 /2019; 06/05/2019; 06/10/2019; 06/20/2019; 06/21/2019; 06/25/2019; 06/26/2019; 06 /27/2019; and 06/28/2019. No QC failures were included for review. No documentation of A-MAS DOAT-5 control values were submitted for laboratory director review. The laboratory failed to submit documentation for laboratory director review of testing 2 levels of quality control material for 06/2019. Only QC values within acceptable limits were submitted for review. 4. Further review of laboratory QC records (06/2019 and 07/2019) submitted for laboratory director review to monitor errors over time and the accuracy and precision revealed the following: a. A-MAS DOAT-2; Lot number DAT20092A was used for Amphetamine, Cocaine, Cotinine, Methadone, Opiates, and Oxycodone QC testing on 07/30/2019 and 07/31 /2019. No QC failures were included for review. No QC was included for review for 07/03/2019; 07/05/2019; 07/12/2019; 07/18/2019; 07/19/2019; 07/22/2019; 07/23 /2019; 07/26/2019; and 07/29/2019. b. A-MAS DOAT-3; Lot number DAT19053A was used for Amphetamine, Cocaine, Cotinine, Methadone, Opiates, and Oxycodone QC testing on 07/03/2019; 07/05/2019; 07/12/2019; 07/18/2019; 07/19/2019; 07/22 /2019; 07/23/2019; 07/26/2019; 07/29/2019; 07/30/2019 and 07/31/2019. No QC failures were included for review. The laboratory failed to submit documentation for laboratory director review of testing 2 levels of quality control material for 07/03 /2019; 07/05/2019; 07/12/2019; 07/18/2019; 07/19/2019; 07/22/2019; 07/23/2019; 07 /26/2019; and 07/29/2019. Only QC values within acceptable limits were submitted for review. 5. In an interview on 02/14/2020 at 0915 hours, the General Supervisor was asked if only 1 level of quality control was tested. She stated that the QC printed incorrectly and that the previous lot of QC material data does not show up on the printout once the new lot QC material information has been entered into the laboratory information system (LIS). She stated that 2 levels of each control material were performed on each day of testing in 06/2019 and 07/2019. She confirmed that the QC documents submitted for laboratory director review did not include both levels of QC data. The General Supervisor was asked why QC failures were not documented on the records submitted for review. She stated that only those QC results that are within acceptable range are documented on the records and submitted for laboratory director review. The laboratory failed to have a system in place to monitor errors over time and the accuracy and precision of Beckman Coulter AU680 test performance with current and accurate statistical parameters for all lot numbers of control material.
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 policy, Beckman Coulter AU680 chemistry analyzer data, and in interview with staff, the laboratory failed to document corrective action taken when quality control (QC) did not meet the laboratory's criteria for

	acceptability for 02/12/2020. Findings included: 1. Review of the laboratory policy titled, "Internal Quality Control" stated, "6. If a control is unacceptable, then perform corrective action to resolve before patient specimens are analyzed ....h. If control values were found to be unacceptable and corrective action was taken to resolve the unacceptable control value, then acceptable control values must be obtained before samples can be ran." The policy does NOT included instructions to document all corrective actions taken when QC did not meet the laboratory's criteria for acceptability. 2. Review of Beckman Coulter AU680 QC data from 02/12/2020 revealed the following analytes QC results, and acceptable range: a. Cotinine; Initial Result 415; Repeat Result 394; Acceptable range 334.95 - 407.38 b. Oxycodone; Initial Result 83; Repeat Result 76; Acceptable range 71.25 - 82.08 The laboratory was asked to provide documentation of corrective action take for unacceptable QC results. No documentation was provided. 3. In an interview on 02/14/2020 at 1000 hours, the General Supervisor was asked what actions were taken for unacceptable QC results. She stated that steps were taken to repeat QC but were not documented. This confirmed the above findings.
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: Based on review of the laboratory verification records, patient final reports, and confirmed in interview, the laboratory failed to ensure the accuracy and reliability of data for Creatinine on the AU680 chemistry analyzer. Findings were: 1. Review of the verification studies for Creatinine on the AU680 chemistry analyzer revealed the highest reportable range as 20 mg/dL. 2. Random review of patient final reports from November 2019 to January 2020 revealed 6 of 8 reports with Creatinine above the reportable range of 20 mg/dL sample ID 1912310003, CREA 72.5 mg/dL sample ID 1912310002, CREA 84.8 mg/dL sample ID 1911220001, CREA 24.2 mg/dL sample ID 1911220002, CREA 151.5 mg/dL sample ID 1911220003, CREA 40.2 mg/dL sample ID 1911140002, CREA 55.6 mg/dL 3. An interview with the laboratory consultant on 2/14/20 at 1005 hours in the conference room confirmed the above findings. He acknowledged that they should only report greater than 20 mg/dL.
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 on review of laboratory's records and staff interview, it was revealed the laboratory director failed to provide overall management and direction for high complexity testing. The findings were: 1. The laboratory director failed to ensure establishment studies were complete (refer to D6082). 2. The laboratory director failed to ensure a quality control program was established and followed (refer to D6093).
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 the laboratory's establishment studies for its confirmatory and nonFDA approved testing for toxicology, and staff interview, it was revealed the laboratory director failed to ensure the laboratory provided quality laboratory services for all aspects of test performances in preanalytical phases of testing. Refer to D5311-I, II
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 and staff interview, it was revealed the laboratory director failed to ensure a quality control plan was established and followed for high complexity testing. Refer to D5445, D5781
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 (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to employ a technical supervisor (TS-2) who meets qualifications to provide technical oversight of high complexity testing, as required. Refer to D6111.
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 (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to employ a technical supervisor (TS-2) who meets qualifications to provide technical oversight of high complexity testing, as required. Findings: 1. Review of the CMS-209 form listed TS-2 as a technical supervisor for providing oversight of high complexity testing. 2. Review of personnel records for TP-S included a "Bachelor of Science" transcript major "Forensic Chemistry." The educational documents did not meet the qualifications for serving as a TS. 3. During an interview on 02/13/2020 at 10:15 am, the lab administrator confirmed the above findings.
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 CMS (Centers for Medicare and Medicaid Services) 209 form, laboratory policy, personnel records, and interview with staff, the Technical Supervisor (TS) failed to evaluate and document performance of 1 of 2 Testing Persons (TP-2) responsible for high complexity testing at least semiannually during the first year that testing persons analyzed patient specimens. Findings included: 1. Review of the submitted CMS 209 form revealed Testing Person 2 listed to perform high complexity testing. 2. Review of laboratory's personnel competency policy revealed: "II. PROCEDURE ... B. The performance assessment of new employees is evaluated and documented at least-semiannually during the first year and annually thereafter. Annual assessments are performed for daily routine tests that are expected to be performed by the employee. Evaluation will be performed in the interim if a new test methodology or instrumentation is added." 3. Review of personnel records for TP-

	2 revealed semiannual competency was not performed in 2019 (due 10/2019). 4. During an interview on 02/13/2020 at 1:00 pm, the lab administrator confirmed the above findings.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure 1 of 3 testing persons (TP-3) met the requirements to perform high complexity testing. Refer to D6171.
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) 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 or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling,

	handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure 1 of 3 testing persons (TP-3) met the requirements to perform high complexity testing. Findings: 1. Review of the CMS-209 form listed TP-3 as performing high complexity testing. 2. Review of personnel records for TP-3 included a "Bachelor of Science" transcript major "Forensic Chemistry." The degree was not in a chemical, physical, biological or clinical laboratory science. 3. During an interview on 02/13/2020 at 10:15 am, the lab administrator confirmed the above findings.