| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D1020197 | 01/24/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Frisco Urgent Care & Clinic | 3220 Parkwood Blvd, Frisco, 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 |
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| **D0000** | An unannounced onsite complaint survey was performed on January 23rd, 2024, and the laboratory was found to NOT be in compliance with the CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1240 Pre-Analytic Systems 493.1250 Analytic Systems 493.1290 Post-Analytic Systems 493.1403 Laboratory Director, (moderate complexity). 493.1409 Technical Consultant 493.1441 Laboratory Director, (high complexity) 493.1447 Technical Supervisor 493.1463 General Supervisor 493.1487 Testing Personnel (high complexity) The laboratory's failure to be in compliance with the CLIA regulations was found to pose immediate jeopardy to the patients served by the laboratory. The laboratory abated the immediate jeopardy by letter signed by the laboratory director dated, 01/25/2024. The complaint was found to be substantiated. |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) 2023 Chemistry Core events and confirmed in interview, the Laboratory Director (or designee) failed to attest to the routine integration of proficiency samples into the patient workload for one of three Chemistry Core events in 2023. Findings Included: 1. Review of laboratory policy, "Proficiency Testing Protocol" (Approved by the Laboratory Director on 10/19/2023) revealed the following: " ...Reporting PT Results ...Ensure a copy of the signed attestation statement is filed in the manual. ...Retention of PT Records The Laboratory must retain an easily accessible record of proficiency testing processing as follows: ...Copy of signed attestation station [sic]" 2. Review of API instructions provided to the |

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| | laboratory by the PT agency for Chemistry Core 2nd Event in 2023, revealed the following: "ATTESTATION STATEMENT SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 3. Review of laboratory API PT Chemistry events in 2023 (1st, 2nd, and 3rd events) revealed the Laboratory Director or designee failed to sign the attestation statement for the 2nd Chemistry Core event in 2023. 4. During an interview on 01/23/2024 at 12:45 PM in the laboratory, Testing Person-1 confirmed the Laboratory Director (or designee) failed to attest to the routine integration of proficiency samples into the patient workload for one of three Chemistry Core events in 2023. |
| **D2089** | ROUTINE CHEMISTRY<br>CFR(s): 493.841(c)<br><br>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) Chemistry Core events for 2023, API Corrective Action Checklist, and confirmed in interview, the laboratory failed to participate in one of three Chemistry Core events in 2023. Findings Included: 1. Review of laboratory policy, "Proficiency Testing Protocol" (Approved by the Laboratory Director on 10/19 /2023) revealed the following: "Processing PT Event PT Results will be analyzed and results mailed back within the timeframe requested for each testing event. ...3. Missed cut-off dates, or failure to submit the results ...upon receipt of the summary report, the laboratory director or designee must determine a self-grade based on the analyte and method results reported. Document on Proficiency Testing Corrective Action Form." 2. Review of laboratory API PT Chemistry Core results in 2023 (1st, 2nd and 3rd events) revealed the following analytes scored as not graded by the PT program in the 1st event of 2023, due to the laboratory failing to submit Chemistry PT results to the PT program by the provided deadline: Chemistry Core 1st Event 2023 Beckman AU Chemistry System Analytes Sample; PT Performance a. Albumin CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded b. ALT (Alanine Aminotransferase) CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded c. Amylase CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded d. AST (Aspartate Aminotransferase) CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded e. Direct Bilirubin CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded f. Total Bilirubin CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded g. Total Calcium CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded h. Chloride |

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| | CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded i. Cholesterol, HDL CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded j. Cholesterol, Total CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded k. CO2 (Carbon Dioxide) CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded l. Creatine Kinase CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded m. Creatinine CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded n. GGT (Gamma Glutamyl Transferase) CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded o. Glucose CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded p. Lactate Dehydrogenase (LDH) CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded q. Lipase CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded r. Magnesium CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded s. Phosphorus CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded t. Potassium CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded u. Sodium CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded v. Total Protein CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded w. Triglycerides CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded x. Urea Nitrogen (BUN) CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded y. Uric Acid CH-01; Not Graded CH-02; Not Graded CH-03; Not Graded CH-04; Not Graded CH-05; Not Graded 3. Review of API PT Corrective Action Checklist for the 1st Chemistry Core event in 2023, revealed the following: " ... Notes: Event not assayed until after submission dated. Not submitted. Results were self-graded." (Note: The Corrective Action Checklist was not signed or approved by the Laboratory Director.) The surveyor requested documentation of self-grading for the above analytes not graded by the proficiency testing program in 2023, and no documentation was provided. 4. During an interview on 01/23/2024 at 12:58 PM in the laboratory, Testing Person-1 confirmed the laboratory failed to participate in one of three Chemistry Core events in 2023. |
| **D5203** | SPECIMEN IDENTIFICATION AND INTEGRITY<br>CFR(s): 493.1232<br><br>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policies and procedure manuals, and confirmed in interview, the laboratory failed to follow its own policy for patient specimen labeling for five of five specimens observed in January 2024. Findings Included: 1. During a tour of the laboratory on 01/23/2024 at 10:50 AM, the surveyor observed the following 5 patient specimens on the laboratory counter: 1. Patient 1 (See attached Patient Identification List): 1 urine collection cup and 1 EDTA (Ethylenediamine tetraacetic acid) tube 2. Patient 2: 1 urine collection cup 3. Patient 3: 1 urine collection cup 4. Patient 4: 1 urine collection cup Review of the patient |

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| | specimens revealed the only patient identifier listed was the patient's name written in black marker on the specimen containers. 2. Review of laboratory policy, "Specimen Collection, Labeling, & Handling" (Approved by the Laboratory Director on 10/19 /2023) revealed the following: "Policy ...Specimens will be collected and labeled immediately with patient name, date of birth, date of collection and collector's initials or with an approved and suitable barcode containing the correct patient's information. Confirm with the patient or patient's representative that the information on the label is the patient's correct information. The specimen must be labeled legibly to ensure accurate and reliable patient identification with patient test results." 3. During an interview on 01/23/2024 at 10:52 AM in the laboratory, Testing Person-4 (TP-4) was asked to describe the laboratory specimen labeling procedure. TP-4 stated the labeling of specimens varied depending on the collector. TP-4 further stated that usually specimens were labeled with the patient's name, and then after testing was completed on the specimen, a label was placed on the specimen containing unique patient identifiers. This confirmed the laboratory failed to follow its own policy for patient specimen labeling for five of five specimens observed in January 2024. |
| **D5211** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(a)<br><br>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) 2023 Hematology/Coagulation events and confirmed in interview, the Laboratory Director (or designee) failed to document evaluation of PT performance for one of three Hematology/Coagulation events in 2023. Findings Included: 1. Review of laboratory policy, "Proficiency Testing Protocol" (Approved by the Laboratory Director on 10/19/2023) revealed the following: " ...Retention of PT Records The Laboratory must retain an easily accessible record of proficiency testing processing as follows: ...Record of review by Laboratory Director/Technical Consultant" 2. Review of API instructions provided to the laboratory by the PT agency in 2023 revealed the following: "PERFORMANCE REVIEW AND CORRECTIVE ACTION After reviewing the evaluation reports, complete the information below and retain this form along with the enclosed reports for your records." 3. Review of laboratory API PT Hematology/Coagulation events in 2023 (1st, 2nd and 3rd), revealed the Laboratory Director or designee failed to document evaluation of PT performance for the 1st Hematology/Coagulation Event of 2023. The surveyor requested the above documentation, and none was provided. 4. During an interview on 01/23/2024 at 12:45 PM in the laboratory, Testing Person-1 confirmed the Laboratory Director (or designee) failed to document evaluation of PT performance for one of three Hematology/Coagulation events in 2023. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by: |

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| | Based on surveyor observation, review of laboratory policy and procedure manual, API (American Proficiency Institute) proficiency testing (PT) results, laboratory documentation, and confirmed in interview, the laboratory failed to perform twice annual accuracy verification for 40 of 40 non-regulated analytes from 2019-2023. Findings Included: 1. During a tour of the facility on 01/23/2024 at 02:17 PM, the inspector observed an operating LCMS (Liquid Chromatography Mass Spectrometry) (Serial Numbers: ABDG55671320; ABDXR5671010; ABDXR5671009; ABCXR5670469) toxicology laboratory in a side room of the facility, used for performing urine drug screen confirmation testing on patient specimens. Further observation revealed the following analytes performed on the LCMS analyzer: a. Amphetamines b. Benxoylecgonine c. Codeine/ Morphine / Oxymorphone d. Meperidine/ Normeperidine e. Methamphetamines f. Methylenedioxymethamphetamine (MDMA) g. Morphine h. Phencyclidine (PCP) i. Hydrocodone j. Hydromorphone k. Methadone l. Oxycodone m. Tramadol n. Tapentadol o. Propoxyphene p. 11-Carboxy-Tetrahydrocannabinol (THC) q. Fentanyl r. Carisoprodol s. 3,4-Methylenedioxy-N-ethylamphetamine (MDEA) t. Norbuprenorphine u. Cotinine v. Gabapentin w. Pregabalin x. Cyclobenzaprine y. Norfentanyl z. Amitriptyline aa. 7-aminoclonazepam bb. Alprazolam cc. Clonazepam dd. Nordiazepam ee. Nortriptyline ff. Oxazepam gg. Temazepam hh. Lorazepam ii. Butalbital jj. EDDP (Methadone metabolite) kk. Phenobarbital, urine ll. Buprenorphine mm. Methylphenidate/Ritalinic Acid nn. 6-acetylmorphine (Heroin) 2. Review of laboratory policies and procedures revealed the laboratory failed to have any policies in place regarding LCMS toxicology testing. 3. Review of API PT results and laboratory documentation, revealed the laboratory failed to document twice annual accuracy verification in 2019, 2020, 2021, 2022 and 2023. 4. During an interview on 01/23/2024 at 2:35 PM at the facility nursing station, the Laboratory Director stated he was not knowledgeable about the LCMS toxicology testing and was not aware if any twice annual verification was performed from 2019-2023. This confirmed the laboratory failed to perform twice annual accuracy verification for 40 of 40 non-regulated analytes from 2019-2023. |
| **D5300** | PREANALYTIC SYSTEMS<br>CFR(s): 493.1240<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of manufacturer's instructions, laboratory policy, staff interview, environmental logs, patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of the preanalytic systems and correct identified problems for 7 of 15 patient specimens reviewed in January 2024, as evidenced by: 1. The laboratory failed to follow manufacturer's instructions for specimen storage prior to analysis for 7 of 15 serum CO2 patient specimens reviewed in January 2024. (Refer to D5311) 2. The laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the pre-analytic phase of testing for 1 of 3 specialties (Chemistry) reviewed in January 2024. (Refer to D5393) |

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| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of manufacturer's instructions, laboratory policy, staff interview, environmental logs, patient final reports, annual patient testing volumes, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for specimen storage prior to analysis for 7 of 15 serum CO2 patient specimens reviewed in January 2024. Findings Included: 1. During a tour of the laboratory on 01/23/2024 at 10:55 AM, the surveyor observed one Beckman Coulter AU480 chemistry analyzer (Serial Number: 3102758) in the patient testing area. Further observation of the analyzer revealed the laboratory performed CO2 analysis on serum patient samples. 2. Review of manufacturer's instructions for the Beckman Coulter AU480 CO2 reagent, "CO2 Bicarbonate" (Version: BAOSR6X37) revealed the following: "Specimen Specimen Storage and Stability Once separated from cells, Bicarbonate in serum and plasma is stable for 24 hours when stored at 20-25 C and protected from exposure to air." (NOTE: The manufacturer did NOT provide acceptable specimen stability for refrigerated (2-8 C) samples.) 3. Review of laboratory policy, "Specimen Collection, Labeling, & Handling" (Approved by the Laboratory Director on 10/19/2023) revealed the following: " ...Serum Samples ... Store at 2-8 C for up to 24 hours otherwise. [sic] Protect from light at all times. Some methods require varying handling protocols - refer to each IFU for specific requirements." 4. During an interview on 01/23/2024 at 03:14 PM in the laboratory, Testing Person-1 (TP-1) stated ALL chemistry samples are placed in the refrigerator by facility staff, if TP-1 is not working on that date, and processed when TP-1 returns to work. TP-1 further stated they only worked on Tuesday's and Thursday's every week, and chemistry samples would remain in the refrigerator over the weekend or overnight on his off days. 5. Review of laboratory environmental logs in January 2024, revealed the laboratory refrigerator functioned at a temperature range of 2-8 Celsius. The laboratory failed to follow manufacturer's instructions for specimen storage prior to analysis. 6. Review of patient final reports revealed the following 7 of 15 serum CO2 patients stored at 2-8 Celsius prior to analysis: CO2 Reference Range: 22.0-31.0 mmol/L Collection Date 01/15/2024 (Monday) a. Patient Identification: Patient 5 Date of Analysis: 01/16/2024 (Tuesday) CO2 Result: 25.0 mmol/L b. Patient Identification: Patient 6 Date of Analysis: 01/18/2024 (Thursday) CO2 Result: 21.0 mmol/L (An alert of "Low" was noted by this result) c. Patient Identification: Patient 7 Date of Analysis: 01/18/2024 CO2 Result: 28.0 mmol/L 01/17/2024 (Wednesday) d. Patient Identification: Patient 8 Date of Analysis: 01/18/2024 CO2 Result: 28.0 mmol /L e. Patient Identification: Patient 9 Date of Analysis: 01/18/2024 CO2 Result: 28.0 mmol/L f. Patient Identification: Patient 10 Date of Analysis: 01/18/2024 CO2 Result: 19.0 mmol/L (An alert of "Low" was noted by this result) g. Patient Identification: Patient 11 Date of Analysis: 01/18/2024 CO2 Result: 22.0 mmol/L The surveyor also requested final CO2 patient reports from January 19th, 20th and 22nd in 2024. The facility medical assistant stated the final reports were not yet released by the physician, and they would be unable to provide the requested documentation. (Refer |

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| | to: D5803, II) 7. Review of laboratory annual testing volumes revealed the laboratory performed 19,456 CO2 tests annually. 8. During a phone interview on 01/24/2024 at 3: 08 PM, the Laboratory Director confirmed the laboratory failed to follow manufacturer's instructions for specimen storage prior to analysis for 7 of 15 serum CO2 patient specimens reviewed in January 2024. Word Key IFU- Instructions For Use mmol/L- millimoles per litre C- Celsius CO2- Bicarbonate/Carbon Dioxide |
| **D5393** | PREANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1249(b)(c)<br><br>The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, surveyor observation, manufacturer's instructions, and confirmed in interview, the laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the pre-analytic phase of testing for one of three specialties (Chemistry) reviewed in January 2024. Findings Included: 1. Review of laboratory policy, "Quality Assessment Program" (Approved by the Laboratory Director on 10/19/2023) revealed the following: "Purpose This QA Program will detect problems in the laboratory's system and identify opportunities for improvement. This laboratory will develop plans of corrective/preventive action based on the issue. The QA Program is to improve the reliability, efficiency, and quality of laboratory services to our patients. Pre-analytical (before testing) phase The phase that comes before actually performing the testing. Because pre-analytic activities are the input to testing, problems in this phase have a significant effect on our output- the test results. Many laboratory problems and errors occur in this phase, so we will pay special attention to pre-analytic activities: ... Specimen handling, collection, and labeling Ensure the following: The unique patient identifier used when labeling the specimen remains with the sample throughout the testing process. Specimens are collected, handled, and stored as appropriate." 2. The laboratory failed to follow manufacturer's instructions for specimen storage prior to analysis for 7 of 15 serum CO2 patient specimens reviewed in January 2024. (Refer to 5311) 3. During an interview on 01/23/2024 at 4:15 PM, at the facility nursing station, the Laboratory Director was asked to provide documentation of quality assessment reports. The Laboratory Director stated the previous Technical Consultant performed quality assessment reviews and he could not provide documentation of the reviews. This confirmed the above findings. Word Key CO2- Bicarbonate/Carbon Dioxide |
| **D5400** | ANALYTIC SYSTEMS<br>CFR(s): 493.1250<br><br>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. |

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| | This CONDITION is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policy, staff interview, environmental logs, patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems for three of three specialties (Chemistry, Hematology and Toxicology) performed from February 2019 to January 2024, as evidenced by: 1. The laboratory failed to have a policy in place for performing LCMS (Liquid Chromatography Mass Spectrometry) Toxicology analysis for 40 of 40 analytes from 2019-2023. (Refer to D5403, I) 2. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Beckman Coulter AU480 chemistry analyzer for 28 of 28 analytes performed in 2023. (Refer to D5403, II) 3. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Sysmex XN-330 hematology analyzer for five of five analytes performed in 2023. (Refer to D5403, III) 4. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage for four of four QC vials observed in January 2024. (Refer to D5413, I) 5. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage for 18 of 18 QC vials observed in January 2024. (Refer to D5413, II) 6. The laboratory failed to follow manufacturer's instructions for operating temperature of the AU480 chemistry analyzer for six of six months in 2023 (July-December). (Refer to D5413, III) 7. The laboratory failed to label XN-L Check Hematology QC (Quality Control) material with revised expiration date for three of three control vials reviewed in January 2024. (Refer to D5415) 8. The laboratory failed to ensure expired QC material was not available for use for 24 of 24 days performed in 2023 and 2024 (12/20/2023-01/23 /2024). (Refer to D5417, I) 9. The laboratory failed to ensure expired Beckman Coulter Chemistry Cleaning Solution was not available for use for one of one box observed in January 2024. (Refer to D5417, II) 10. The laboratory failed to ensure expired Total Bilirubin reagent was not available for use for one of one box observed in January 2024. (Refer to D5417, III) 11. The laboratory failed to ensure expired Hemolyzing Reagent was not available for use for one of one box observed in January 2024. (Refer to D5417, IV) 12. The laboratory failed to ensure the normal range for 5 of 5 CBC analytes (WBC, RBC, HGB, HCT, PLT) were verified by the laboratory's studies in 2022 (April). (Refer to D5421) 13. The laboratory failed to document a complete and approved establishment study for LCMS toxicology testing for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). (Refer to D5423) 14. The laboratory failed to document weekly maintenance for 10 of 24 weeks reviewed in 2023 (July-December). (Refer to D5431) 15. The laboratory failed to have documentation of performing calibration verification every 6 months for 40 of 40 analytes tested on the LCMS analyzer from 2019-2023. (Refer to D5439) 16. The laboratory failed to document review of chemistry QC records for errors over time for 28 of 28 analytes performed on the Beckman Coulter AU480 chemistry analyzer in 2022 and 2023. (Refer to D5441) 17. The laboratory failed to document corrective actions when freezer temperatures failed to fall in the acceptable range for 22 of 40 days reviewed in 2023 (October-December). (Refer to D5781) |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for |

specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:
I. Based on surveyor observation, review of laboratory policy and procedure manual, patient annual test volume, and confirmed in interview, the laboratory failed to have a policy in place for performing LCMS Toxicology analysis for 40 of 40 analytes from 2019-2023. Findings Included: 1. During a tour of the facility on 01/23/2024 at 02:17 PM, the inspector observed an operating LCMS (Liquid Chromatography Mass Spectrometry) (Serial Numbers: ABDG55671320; ABDXR5671010; ABDXR5671009; ABCXR5670469) toxicology laboratory in a side room of the facility, used for performing urine drug screen confirmation testing on patient specimens. Further observation revealed the laboratory began testing the following analytes by LCMS in February 2019: a. Amphetamines b. Benxoylecgonine c. Codeine/ Morphine / Oxymorphone d. Meperidine/ Normeperidine e. Methamphetamines f. Methylenedioxymethamphetamine (MDMA) g. Morphine h. Phencyclidine (PCP) i. Hydrocodone j. Hydromorphone k. Methadone l. Oxycodone m. Tramadol n. Tapentadol o. Propoxyphene p. 11-Carboxy-Tetrahydrocannabinol (THC) q. Fentanyl r. Carisoprodol s. 3,4-Methylenedioxy-N-ethylamphetamine (MDEA) t. Norbuprenorphine u. Cotinine v. Gabapentin w. Pregabalin x. Cyclobenzaprine y. Norfentanyl z. Amitriptyline aa. 7-aminoclonazepam bb. Alprazolam cc. Clonazepam dd. Nordiazepam ee. Nortriptyline ff. Oxazepam gg. Temazepam hh. Lorazepam ii. Butalbital jj. EDDP (Methadone metabolite) kk. Phenobarbital, urine ll. Buprenorphine mm. Methylphenidate/Ritalinic Acid nn. 6-acetylmorphine (Heroin) 2. Review of laboratory policy and procedure manual revealed the laboratory failed to have a policy in place for performing LCMS Toxicology analysis to include requirements for: a. Patient preparation, specimen collection, labeling, storage and preservation, transportation, processing, acceptability /rejection, and referral b. Step by Step procedure to include test calculations and interpretation. c. Preparation of calibrators, reagents, controls, and other materials for testing d. Calibration and calibration verification e. Control procedures f. Corrective action to take when calibration or control results fail to meet lab's acceptability criteria. g. Test limitations to include interfering substances. h. Critical alert values i. Literature references j. Description of action to take when test system becomes inoperable. 3. Review of patient annual test volumes revealed the laboratory performed 1,107 LCMS Toxicology tests annually. 4. During an interview on 01/23 /2024 at 2:35 PM at the facility nursing station, the Laboratory Director stated he was not knowledgeable about the LCMS toxicology testing. This confirmed the laboratory failed to have a policy in place for performing LCMS Toxicology analysis for 40 of 40 analytes performed from 2019-2023. II. Based on surveyor observation, review of

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| | laboratory policy and procedure manual, patient test volume, and confirmed in interview, the laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Beckman Coulter AU480 chemistry analyzer for 28 of 28 analytes performed in 2023. Findings Included: 1. During a tour of the laboratory on 01/23/2024 at 10:55 AM, the surveyor observed 1 Beckman Coulter AU480 chemistry analyzer (Serial Number: 3102758) in the patient testing area. Further review revealed the following analytes currently on the AU480 for patient testing: 1. ALT (Alanine Aminotransferase) 2. Albumin 3. AST (Aspartate Aminotransferase) 4. Creatine Kinase 5. Creatinine 6. Calcium 7. Magnesium 8. Potassium 9. Sodium 10. Triglycerides 11. Uric Acid 12. Total Bilirubin 13. Amylase 14. GGT (Gamma Glutamyl Transferase) 15. Chloride 16. Cholesterol 17. Urea (BUN) 18. CO2 (Carbon dioxide) 19. Glucose 20. Direct Bilirubin 21. Lactate Dehydrogenase (LDH) 22. Phosphorus 23. Total Protein 24. Lipase 25. Benzodiazepines 26. Opiates 27. Cannabinoids 28. Phencyclidine 2. Review of laboratory policy, "Quality Control Program" (Approved by the Laboratory Director on 10/19/2023) revealed the following: "Procedure: ...9. Have procedure manuals for all instruments. 10. Ensure SOPs used for test procedures include laboratory specific quality control and patient test resulting processes." The surveyor requested the Beckman Coulter AU480 test procedure to include quality control procedures, and none were provided. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Beckman Coulter AU480 chemistry analyzer. 3. Review of patient annual volumes for chemistry, revealed the laboratory performed 30,000 chemistry tests annually on the Beckman Coulter AU480 chemistry analyzer. 4. During an interview on 01/23/2024 at 02:32 PM, the Laboratory Director confirmed the laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Beckman Coulter AU480 chemistry analyzer for 28 of 28 analytes performed in 2023. III. Based on surveyor observation, review of laboratory policy and procedure manual, patient test volume, and confirmed in interview, the laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Sysmex XN-330 hematology analyzer for 5 of 5 analytes performed in 2023. Findings Included: 1. During a tour of the facility on 01 /23/2024 at 10:54 AM, the surveyor observed the following Sysmex XN-330 hematology analyzer (Serial Number: 15004) stored on the laboratory counter. Further observation revealed the following analytes reported on the hematology analyzer: a. White Blood Cells b. Red blood cells c. Hemoglobin d. Hematocrit e. Platelets 2. Review of laboratory policy, "Quality Control Program" (Approved by the Laboratory Director on 10/19/2023) revealed the following: "Procedure: ...9. Have procedure manuals for all instruments. 10. Ensure SOPs used for test procedures include laboratory specific quality control and patient test resulting processes." The surveyor requested the Sysmex XN-330 hematology test procedure to include quality control procedures, and none were provided. 3. Review of patient annual volumes, revealed the laboratory performed 4,107 hematology tests in 2023. 4. During an interview on 01 /23/2024 at 02:32 PM, the Laboratory Director confirmed the laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Sysmex hematology analyzer for 5 of 5 analytes performed in 2023. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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:
I. Based on surveyor observation, review of manufacturer's instructions, laboratory policy, environmental records, laboratory documentation, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for quality control (QC) storage for four of four Drugs of Abuse (DOA) QC vials observed in January 2024. Findings Included: 1. During a tour of the facility on 01/23/2024 at 10:50 AM, the surveyor observed the following Drugs of Abuse QC, stored in the laboratory freezer on the bottom shelf: UTAK Drugs of Abuse Quality Control Levels: Low (2 bottles), High (2 bottles) Lot Number: D1953; D1954 Expiration Date: 08/2024 Printed on the QC vials was a thermometer indicating the acceptable storage stability of 2-8 degrees Celsius. The surveyor observed a current temperature in the freezer of -17.38 Celsius. 2. Review of manufacturer's instructions, "UTAK: Drugs of Abuse Quality Control (Reference: 338171) " revealed the following: " ...IV. Storage and Stability: 1. Store the dried control material at 2-8 C. ...Limitations: 1. Results are dependent upon proper storage and adequate mixing." 3. Review of laboratory policy, "Test Instruments, Reagents & Supplies" (Approved by the Laboratory Director on 10/19 /2023) revealed the following: "Reagent Storage: All reagents and media are stored as recommended by the manufacturer." 4. Review of laboratory environmental records, revealed an acceptable freezer temperature of -10 to -20 Celsius. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage for 4 of 4 QC vials observed in January 2024. 5. Review of laboratory documentation submitted at time of survey, revealed the laboratory performed 10,000 drugs of abuse tests annually. 6. During an interview on 01/23/2024 at 12:40 PM in the laboratory, Testing Person-1 confirmed the above findings. II. Based on surveyor observation, review of laboratory policy, environmental records, laboratory documentation, and confirmed in interview, the laboratory failed to follow manufacturer's instructions for quality control (QC) storage for 18 of 18 BioRad Chemistry QC vials observed in January 2024. Findings Included: 1. During a tour of the facility on 01/23/2024 at 10:50 AM, the surveyor observed the following BioRad QC (Assayed Controls), stored in the laboratory freezer on the bottom shelf: BioRad Chemistry Assayed QC Level 1 Lot Number: 45931 Expiration Date: 07/31/2024 Level 3 Lot Number: 45933 Expiration Date: 07/31/2024 Printed on the QC vials was a thermometer indicating the acceptable storage stability of -20 to -70 degrees Celsius. The surveyor observed a current temperature in the freezer of -17.7 Celcius. (Refer to: D5781) 2. Review of manufacturer's instructions, "BioRad: Liquid Assayed Multiqual" (Reference: 5351-00) revealed the following: "Storage and Stability This product will be stable until the expiration date when stored unopened at -20 to -70 C." 3. Review of laboratory policy, "Test Instruments, Reagents & Supplies" (Approved by the Laboratory Director on 10/19/2023) revealed the following: "Reagent Storage: All reagents and media are stored as recommended by the manufacturer." 4. Review of laboratory environmental records, revealed an acceptable freezer temperature of -10 to -20 Celsius. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage for 18 of 18 QC vials observed in January 2024. 5. Review of laboratory documentation submitted at time of survey, revealed the laboratory performed 30,000 chemistry tests annually. 6. During an interview on 01/23/2024 at 12:40 PM in the laboratory, Testing Person-1 confirmed the above findings. III. Based on review of manufacturer's instructions, laboratory policy, environmental records and confirmed in interview, the laboratory failed to ensure an acceptable room temperature range was

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| | within manufacturer's specifications for six of six months reviewed in 2023 (July-December). Findings Included: 1. Review of manufacturer's instructions, "Beckman Coulter User's Guide" (Revision: B28624AA, 12/13) revealed the following: "Temperature and Humidity Conditions When in Use ...When the specified room temperature and humidity ranges fluctuate, the system data may not be reliable. When the system is in operation, make sure the following requirements are met: The temperature of the installation room is between 18 C and 32 C." 2. Review of laboratory policy, "Acceptable Temperature Ranges" (Approved by the Laboratory Director on 10/19/2023) revealed the following: "Room Temperature: 15-30 C +/- 2 C 3. Review of laboratory environmental logs for 2023 (July-December) revealed the acceptable room temperature range listed as 15-25 C. The laboratory failed to ensure room temperature ranges were within manufacturer's acceptable range for 6 of 6 months reviewed in 2023 (July-December). 4. During an interview on 01/23/2024 at 01:30 PM in the laboratory, Testing Person-1 confirmed the laboratory failed to ensure an acceptable room temperature range was within manufacturer's specifications for six of six months reviewed in 2023 (July-December). |
| **D5415** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of manufacturer's instructions, laboratory policy, final patient reports, and confirmed in interview, the laboratory failed to label XN-L Check Hematology QC (Quality Control) material with revised expiration dates for 3 of 3 control vials reviewed in January 2024. Findings Included: 1. During a tour of the facility on 01/23/2024 at 10:48 AM, the surveyor observed the following XN-L Check Hematology control for Sysmex XL-N analyzers, stored in the laboratory refrigerator door: XN-L Check Hematology control Levels 1, 2 and 3 Lot Number: 32941401; 32941402; 32941403 Expiration Date: 01/30/2024 PIU (Put in Use) Date: 12/04/2023 The surveyor inquired if the above QC vials were currently being used prior to patient testing. Testing Person-1 (TP-1) confirmed the QC vials were currently in use. 2. Review of manufacturer's instructions, "XN-L Check: Hematology control for Sysmex XL-N analyzers" (Revision: 350658-3), stated the following: " ... Storage and shelf life after first opening Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 C after being re-capped." (Note: The revised expiration date for the laboratory's QC would be 12/19 /2023.) 3. Review of laboratory policy, "Quality Control Program" (Approved by the Laboratory Director on 10/19/2023) revealed the following: "Purpose The purpose of the Quality Control Program is to ensure that the total testing process is maintained at a level significant enough to provide accurate and reliable testing processes and patient test results. ...Procedure ...6. Ensure that all opened reagent vials are marked with the date of receipt, open date, expiration date and initials. 7. The expiration date on the manufacturer's box is the shelf life of unopened products. It is customary the shelf life of an opened product is shorter than an unopened product. Laboratory personnel MUST know this new expiration date and mark all opened containers, their initials and date opened." 4. Review of final patient reports revealed the laboratory |

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| | performed hematology testing on 184 patients from the date QC was expired, 12/20 /2023, through the survey date, 01/23/2024. 5. During an interview on 01/23/2024 at 12:41 PM in the laboratory, TP-1 confirmed the laboratory failed to label XN-L Check Hematology QC (Quality Control) material with revised expiration dates for 3 of 3 control vials reviewed in January 2024. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on surveyor observation, review of manufacturer's instructions, laboratory policy, final patient reports, and confirmed in interview, the laboratory failed to ensure expired QC material was not available for use for 24 of 24 days performed in 2023 and 2024 (12/20/2023-01/23/2024). Findings Included: 1. During a tour of the facility on 01/23/2024 at 10:48 AM, the surveyor observed the following XN-L Check Hematology control for Sysmex XL-N analyzers, stored in the laboratory refrigerator door: XN-L Check Hematology control Levels 1, 2 and 3 Lot Number: 32941401; 32941402; 32941403 Expiration Date: 01/30/2024 PIU (Put in Use) Date: 12/04/2023 The surveyor inquired if the above QC vials were currently being used prior to patient testing. Testing Person-1 (TP-1) confirmed the QC vials were currently in use. 2. Review of manufacturer's instructions, "XN-L Check: Hematology control for Sysmex XL-N analyzers" (Revision: 350658-3), revealed the following: " ...Storage and shelf life after first opening Open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored at 2-8 C after being re-capped." 3. Review of laboratory policy, "Quality Control Program" (Approved by the Laboratory Director on 10/19/2023) revealed the following: "Purpose The purpose of the Quality Control Program is to ensure that the total testing process is maintained at a level significant enough to provide accurate and reliable testing processes and patient test results. ...Procedure ...6. Ensure that all opened reagent vials are marked with the date of receipt, open date, expiration date and initials. 7. The expiration date on the manufacturer's box is the shelf life of unopened products. It is customary the shelf life of an opened product is shorter than an unopened product. Laboratory personnel MUST know this new expiration date and mark all opened containers, their initials and date opened." 4. Review of final patient reports revealed the laboratory performed hematology testing on 184 patients from the date QC was expired, 12/20/2023, through the survey date, 01/23/2024. 5. During an interview on 01/23/2024 at 12:41 PM in the laboratory, Testing Person-1 confirmed the laboratory failed to ensure expired QC material was not available for use for 24 of 24 days performed in 2023 and 2024. II. Based on surveyor observation, review of manufacturer's instructions, laboratory policy, laboratory documentation, and confirmed in interview, the laboratory failed to ensure expired Beckman Coulter Chemistry Cleaning Solution was not available for use for one of one box observed in January 2024. Findings Included: 1. During a tour of the facility on 01/23/2024 at 10:50 AM, the surveyor observed the following Beckman Coulter Cleaning Solution stored on the 3rd shelf in the laboratory refrigerator: Lot Number: 2734 Expiration Date: 10/13/2023 1 box containing 6 bottles of Cleaning Solution The surveyor observed a line drawn through the above expiration date in black marker, with an updated expiration date of 08/18 /2024 written on the reagent box. The surveyor inquired as to why the reagent |

expiration date was updated, no documentation supporting this change was provided. 2. Review of manufacturer's instructions, "Beckman Coulter: AU480" (Revision: B28624AA, 12/13) revealed the following: "REAGENT PREPARATION: The AU480 reagents are ready to use. No preparation is required. STORAGE AND STABILITY 1. The unopened reagent is stable until the expiration date printed on the label when stored at 2 to 8 C." 3. Review of laboratory policy, "Test Instruments, Reagents & Supplies" (Approved by the Laboratory Director on 10/19/2023) revealed the following: " ...Laboratory Storage: ...Look for any expired or soon to be expired stock and make note. Properly discard any expired stock. ...Reagent Expiration Date: All reagents are monitored for expiration dates by testing personnel daily before patient testing begins." 4. Review of laboratory documentation submitted at time of survey, revealed the laboratory performed 30,000 chemistry tests annually. 5. During an interview on 01/23/2024 at 12:45 PM in the laboratory, Testing Person-1 confirmed the laboratory failed to ensure expired Beckman Coulter Chemistry Cleaning Solution was not available for use for one of one box observed in January 2024. III. Based on surveyor observation, review of manufacturer's instructions, laboratory policy, laboratory documentation, and confirmed in interview, the laboratory failed to ensure expired Total Bilirubin reagent was not available for use for one of one box observed in January 2024. Findings Included: 1. During a tour of the facility on 01/23/2024 at 10:50 AM, the surveyor observed the following Beckman Coulter Total Bilirubin reagent stored on the 2nd shelf in the laboratory refrigerator: Lot Number: 2625 Expiration Date: 08/01/2023 2. Review of manufacturer's instructions, "Beckman Coulter: AU480" (Revision: B28624AA, 12 /13) revealed the following: "REAGENT PREPARATION: The AU480 reagents are ready to use. No preparation is required. STORAGE AND STABILITY 1. The unopened reagent is stable until the expiration date printed on the label when stored at 2 to 8 C." 3. Review of laboratory policy, "Test Instruments, Reagents & Supplies" (Approved by the Laboratory Director on 10/19/2023) revealed the following: " ... Laboratory Storage: ...Look for any expired or soon to be expired stock and make note. Properly discard any expired stock. ...Reagent Expiration Date: All reagents are monitored for expiration dates by testing personnel daily before patient testing begins." 4. Review of laboratory documentation submitted at time of survey, revealed the laboratory performed 30,000 chemistry tests annually. 5. During an interview on 01/23/2024 at 12:45 PM in the laboratory, Testing Person-1 confirmed the laboratory failed to ensure expired Total Bilirubin reagent was not available for use for one of one box observed in January 2024. IV. Based on surveyor observation, review of manufacturer's instructions, laboratory policy, laboratory documentation, and confirmed in interview, the laboratory failed to ensure expired Hemolyzing Reagent was not available for use for one of one box observed in January 2024. Findings Included: 1. During a tour of the facility on 01/23/2024 at 10:50 AM, the surveyor observed the following Beckman Coulter Chemistry Hemolyzing Reagent bottle stored on the top shelf in the laboratory refrigerator: Lot Number: M208564 Expiration Date: 07/31/2023 2. Review of manufacturer's instructions, "Beckman Coulter: AU480" (Revision: B28624AA, 12/13) revealed the following: "REAGENT PREPARATION: The AU480 reagents are ready to use. No preparation is required. STORAGE AND STABILITY 1. The unopened reagent is stable until the expiration date printed on the label when stored at 2 to 8 C." 3. Review of laboratory policy, "Test Instruments, Reagents & Supplies" (Approved by the Laboratory Director on 10 /19/2023) revealed the following: " ...Laboratory Storage: ...Look for any expired or soon to be expired stock and make note. Properly discard any expired stock. ... Reagent Expiration Date: All reagents are monitored for expiration dates by testing personnel daily before patient testing begins." 4. Review of laboratory documentation submitted at time of survey, revealed the laboratory performed 30,000 chemistry tests

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| | annually. 5. During an interview on 01/23/2024 at 12:45 PM in the laboratory, Testing Person-1 confirmed the laboratory failed to ensure expired Hemolyzing Reagent was not available for use for one of one box observed in January 2024. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of verification studies for the Sysmex XN-330 hematology analyzer, manufacturer instructions, laboratory policies, laboratory records, and confirmed in interview, the laboratory failed to ensure the normal range for 5 of 5 CBC analytes (WBC, RBC, HGB, HCT, PLT) were verified by the laboratory's studies in 2022 (April). Findings included: 1. According to verification studies, the laboratory added the Sysmex N-330 hematology analyzer to their test menu on 04/2022. Further review of the verification studies revealed no normal range studies were performed for the WBC, RBC, HGB, HCT, PLT analytes. 2. Review of the Sysmex XN-330 Application Manual revealed: "Section 5 Additional Studies for Reference ... It is the customer's responsibility to perform any additional studies required by accrediting agencies." 3. Review of laboratory policy titled "Verification of Performance Specifications" revealed: "Policy For unmodified FDA-cleared or approved tests (EIA methods), the laboratory may use data from the manufacturers' information or published reports, BUT the laboratory must verify outside data on Accuracy Precision Reportable Range" The policy failed to include normal range (reference range). Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Procedural Duties ... 3. Ensure verification procedures used are adequate to determine accuracy, precision, and other pertinent performance characteristics of the method." Review of laboratory policy titled "Laboratory Test Menu - Normal Reference Ranges - Cut-Off Values" revealed a list of normal reference ranges for all tests performed by the laboratory. Under Sysmex XN-330 the reference ranges for WBC, RBC, HGB, HCT, PLT analytes were blank. 4. Review of laboratory records revealed the laboratory performed 4,017 CBCs in 2023. 5. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director stated he did not know where the reference ranges for CBC testing were obtained from. He further stated that he thought the previous testing person had performed all verification studies. These statements confirmed the above findings. Word Key: CBC- complete blood count WBC- white blood cell RBC- red blood cell HGB- hemoglobin HCT- hematocrit PLT- platelet EUA- Emergency Use Authorization FDA- Food and Drug Administration |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policy, LCMS establishment study, patient final reports, and confirmed in interview, the laboratory failed to perform analytic sensitivity to include interfering substances for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). Findings Included: 1. During a tour of the facility on 01/23/2024 at 02:17 PM, the inspector observed an operating LCMS (Liquid Chromatography Mass Spectrometry) (Serial Numbers: ABDG55671320; ABDXR5671010; ABDXR5671009; ABCXR5670469) toxicology laboratory in a side room of the facility, used for performing urine drug screen confirmation testing on patient specimens. Further observation revealed the following analytes performed on the LCMS analyzer: a. Amphetamines b. Benxoylecgonine c. Codeine/ Morphine / Oxymorphone d. Meperidine/ Normeperidine e. Methamphetamines f. Methylenedioxymethamphetamine (MDMA) g. Morphine h. Phencyclidine (PCP) i. Hydrocodone j. Hydromorphone k. Methadone l. Oxycodone m. Tramadol n. Tapentadol o. Propoxyphene p. 11-Carboxy-Tetrahydrocannabinol (THC) q. Fentanyl r. Carisoprodol s. 3,4-Methylenedioxy-N-ethylamphetamine (MDEA) t. Norbuprenorphine u. Cotinine v. Gabapentin w. Pregabalin x. Cyclobenzaprine y. Norfentanyl z. Amitriptyline aa. 7-aminoclonazepam bb. Alprazolam cc. Clonazepam dd. Nordiazepam ee. Nortriptyline ff. Oxazepam gg. Temazepam hh. Lorazepam ii. Butalbital jj. EDDP (Methadone metabolite) kk. Phenobarbital, urine ll. Buprenorphine mm. Methylphenidate/Ritalinic Acid nn. 6-acetylmorphine (Heroin) 2. Review of laboratory policy, "Verification of Performance Specifications" revealed the following: "Procedure ...For tests that are not FDA-cleared or approved (including tests developed in house), or for FDA-cleared/approved tests modified by the laboratory, the laboratory must establish: Accuracy; Precision; Analytic sensitivity & specificity; Interferences; Reportable range (as applicable) ...The director must provide a summary statement with each test documenting review of validation studies and approval of each test for clinical use. Attach this summary to the validation studies." 3. Review of laboratory establishment study, "Verification of the Bioanalytical Method for the Determination of a Positive Mode Panel in Human Urine on the Sciex TQ 3500" (Dated: 02/19/2019) revealed the Laboratory Director failed to sign/approve the establishment study prior to patient analysis. Further review of the establishment study revealed the laboratory failed to include performance of analytical specificity to include interfering substances. 4. Review of patient reports revealed the laboratory performed 1,107 LCMS toxicology tests annually. 5. During an interview on 01/23/2024 at 2:35 PM at the facility nursing station, the Laboratory Director stated he was not knowledgeable about the LCMS toxicology testing. This confirmed the laboratory failed to perform analytic sensitivity to include interfering substances for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS |

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| | CFR(s): 493.1254(a)(2)<br><br>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of manufacturer's instructions, laboratory policy, Beckman Coulter AU480 maintenance documentation, and confirmed in interview, the laboratory failed to document weekly maintenance for 10 of 24 weeks reviewed in 2023 (July-December). Findings Included: 1. During a tour of the laboratory on 01/23/2024 at 10:55 AM, the surveyor observed one Beckman Coulter AU480 chemistry analyzer (Serial Number: 3102758) in the patient testing area. 2. Review of manufacturer's instructions, "Beckman Coulter User's Guide" (Revision: B28624AA, 12/13) revealed the following: "8.4 Weekly Maintenance To obtain the highest level of performance from the system, perform these tasks on a weekly basis. 8.4.1 Clean the Sample Probe and Mix Bars 8.4.2 Perform a W2 8.4.3 Perform a Photocal 8.4.4 Clean the Pre-dilution Bottle 8.4.1 Clean the Sample Probe and Mix Bars CAUTION ...To prevent contamination and ensure proper analysis and results, clean the sample probe and mix bars on a weekly basis. ...8.4.2 Perform a W2 To obtain appropriate analysis results, clean the cuvettes once a week. ...8.4.3 Perform a Photocal ...8.4.4 Clean the Pre-dilution Bottle To maintain the reliability of the instrument and prevent contamination, clean the pre-dilution bottle once each week." 3. Review of laboratory policy, "Quality Assessment Program" (Effective Date: 07/03 /2023) revealed the following: " ...Analytical (during testing) phase Instruments Perform maintenance daily, weekly, and monthly maintenance, and documented as indicated by manufacturer instructions." 4. Review of Beckman Coulter AU480 maintenance in 2023, revealed the following weeks weekly maintenance was not documented: a. July Week 2: 10-15th, 2023 b. September Week 1: 4-9th, 2023 c. September Week 4: 25-30th, 2023 d. October Week 1, 2, 3, and 4 e. November Week 2: 6-11th, 2023 f. November Week 3: 13-18th, 2023 g. November Week 4: 20-25th, 2023 The surveyor requested the above undocumented maintenance, and none was provided. 5. During an interview on 01/23/2024 at 04:25 PM in the laboratory, Testing Person-1 confirmed the laboratory failed to document weekly maintenance for 10 of 24 weeks reviewed in 2023 (July-December). |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policies, laboratory LCMS toxicology documentation, patient reports, and confirmed in interview, the laboratory failed to have documentation of performing calibration verification every 6 months for 40 of 40 analytes tested on the LCMS analyzer from 2019-2023. Findings Included: 1. During a tour of the facility on 01/23/2024 at 02:17 PM, the inspector observed an operating LCMS (Liquid Chromatography Mass Spectrophotometry) (Serial Numbers: ABDG55671320; ABDXR5671010; ABDXR5671009; ABCXR5670469) toxicology laboratory in a side room of the facility, used for performing urine drug screen confirmation testing on patient specimens. Further observation revealed the following analytes performed on the LCMS analyzer: a. Amphetamines b. Benxoylecgonine c. Codeine/ Morphine / Oxymorphone d. Meperidine/ Normeperidine e. Methamphetamines f. Methylenedioxymethamphetamine (MDMA) g. Morphine h. Phencyclidine (PCP) i. Hydrocodone j. Hydromorphone k. Methadone l. Oxycodone m. Tramadol n. Tapentadol o. Propoxyphene p. 11-Carboxy-Tetrahydrocannabinol (THC) q. Fentanyl r. Carisoprodol s. 3,4-Methylenedioxy-N-ethylamphetamine (MDEA) t. Norbuprenorphine u. Cotinine v. Gabapentin w. Pregabalin x. Cyclobenzaprine y. Norfentanyl z. Amitriptyline aa. 7-aminoclonazepam bb. Alprazolam cc. Clonazepam dd. Nordiazepam ee. Nortriptyline ff. Oxazepam gg. Temazepam hh. Lorazepam ii. Butalbital jj. EDDP (Methadone metabolite) kk. Phenobarbital, urine ll. Buprenorphine mm. Methylphenidate/Ritalinic Acid nn. 6-acetylmorphine (Heroin) 2. Review of laboratory policy, "Calibration Protocol & Calibration Verification" revealed the following: "Policy This facility shall calibrate at a minimum of every six (6) months as required by COLA, or as required by the manufacturer." 3. Review of laboratory LCMS toxicology documentation revealed the laboratory failed to have documentation of performing 6-month calibration verification on the above analytes performed on the LCMS analyzer from 2019-2023. The surveyor requested the above documentation, and none was provided. 4. Review of patient reports revealed the laboratory performed 1,107 LCMS toxicology tests annually. 5. During an interview on 01/23/2024 at 2:35 PM at the facility nursing station, the Laboratory Director stated he was not knowledgeable about the LCMS toxicology testing. This confirmed the laboratory failed to have documentation of performing calibration verification every 6 months for 40 of 40 analytes tested on the LCMS analyzer from 2019-2023. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policy, laboratory QC documentation, and confirmed in interview, the laboratory failed to document review of chemistry QC records for errors over time for 28 of 28 analytes performed on the Beckman Coulter AU480 chemistry analyzer in 2022 and 2023. Findings Included: 1. During a tour of the laboratory on 01/23/2024 at 10:55 AM, the surveyor observed one Beckman Coulter AU480 chemistry analyzer (Serial Number: 3102758) in the patient testing area. Further review revealed the following analytes currently on the AU480 for patient testing: 1. ALT (Alanine Aminotransferase) 2. Albumin 3. AST (Aspartate Aminotransferase) 4. Creatine Kinase 5. Creatinine 6. Calcium 7. Magnesium 8. Potassium 9. Sodium 10. Triglycerides 11. Uric Acid 12. Total Bilirubin 13. Amylase 14. GGT (Gamma Glutamyl Transferase) 15. Chloride 16. Cholesterol 17. Urea (BUN) 18. CO2 (Carbon dioxide) 19. Glucose 20. Direct Bilirubin 21. Lactate Dehydrogenase (LDH) 22. Phosphorus 23. Total Protein 24. Lipase 25. Benzodiazepines 26. Opiates 27. Cannabinoids 28. Phencyclidine 2. Review of laboratory policy, "Quality Control Program" revealed the following: " ... Quantitative QC and Levy Jennings Graphs ...Each month, management reviews the end of month QC data Summary Report and Levy Jennings graphs for each test. These reviews determine if the QC material is shifting or trending too far away from the manufacturer mean." 3. Review of laboratory chemistry QC documentation, revealed the laboratory failed to have documentation of QC review for immediate errors or errors over time for 28 of 28 analytes in 2022 and 2023. 4. During an interview on 01/23/2024 at 02:15 PM, the Laboratory Director stated monthly QC documentation was reviewed by the Technical Consultant. The Laboratory Director was asked to provide the documentation of QC review by the Technical Consultant, and none was provided. This confirmed the laboratory failed to document review of chemistry QC records for errors over time for 28 of 28 analytes performed on the Beckman Coulter AU480 chemistry analyzer in 2022 and 2023. |
| **D5785** | CORRECTIVE ACTIONS<br>CFR(s): 493.1282(b)(3)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policy, environmental records, and confirmed in interview, the laboratory failed to document corrective actions when freezer temperatures failed to fall in the acceptable range for 22 of 40 days reviewed in 2023 (October-December). Findings Included: 1. During a tour of the facility on 01/23/2024 at 11:00 AM, the surveyor observed one small freezer on the laboratory floor (Serial Number: K00000001444). 2. Review of laboratory policy, "Acceptable Temperature Ranges" revealed the following: "Freezer: -20 C or colder ...Corrective action When temperatures are outside of the range on the Temperature Log, perform the following troubleshooting steps in this order: 1. Adjust the temperature apparatus |

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| | (room, refrigerator, freezer, etc.) 2. Turn the temperature log over and provide documentation as the example here: a. Date xx/xx/xxxx temperature read xxxx. Adjusted thermometer, Will wait and recheck within 30 minutes to one hour. b. After 30 minutes to one hour re-check the thermometer. If the reading is acceptable, document that temperature on the front side of the log in the appropriate date. ...e. Follow up with writing the entire incident on the Corrective Action Log and finalize the outcome after the issue was corrected. ...4. Document any remedial action on the temperature log. Use the back side of the log if needed or use the Corrective Action Form." 3. Review of laboratory environmental logs in 2023, revealed the following days freezer temperatures failed to fall within the acceptable range: October 2023 Date; Temperature recorded a. 10/02/2023; -16 C b. 10/03/2023; -17 C c. 10/08/2023; -17.2 C d. 10/19/2023; -19.6 C e. 10/29/2023; -19 C November 2023 f. 11/07/2023; -18 C g. 11/08/2023; -17 C h. 11/09/2023; -17 C i. 11/10/2023; -19 C j. 11/16/2023; -19.6 C k. 11/21/2023; -19.3 C l. 11/27/2023; -14.9 C m. 11/28/2023; -19.1 C December 2023 n. 12/06/2023; -15.4 C o. 12/07/2023; -18 C p. 12/13/2023; -19 C q. 12/14/2023; -18 C r. 12/15/2023; -18 C s. 12/18/2023; -17 C t. 12/19/2023; -19 C u. 12 /27/2023; -18.2 C v. 12/28/2023; -18 C The surveyor requested corrective action documentation for the above days, and none was provided. 4. Review of the laboratory corrective action log, and the back side of the temperature logs, revealed the laboratory failed to document corrective actions for the above days in 2023 when temperatures exceeded allowable limits. 5. During an interview on 01/23/2024 at 12: 45 PM in the laboratory, Testing Person-1 confirmed the laboratory failed to document corrective actions when freezer temperatures failed to fall in the acceptable range for 22 of 40 days reviewed in 2023 (October-December). |
| **D5793** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(b)(c)<br><br>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, surveyor observation, manufacturer's instructions, LCMS establishment study, environmental logs, maintenance records, patient records, and confirmed in interview, the laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the analytical phase of testing for three of three specialties (Chemistry, Hematology and Toxicology) performed from February 2019 to January 2024. Findings Included: 1. Review of laboratory policy, "Quality Assessment Program" revealed the following: "Purpose This QA Program will detect problems in the laboratory's system and identify opportunities for improvement. This laboratory will develop plans of corrective/preventive action based on the issue. The QA Program is to improve the reliability, efficiency, and quality of laboratory services to our patients. ...Analytical (during testing) phase Instruments Perform calibrations at the frequency indicated by the manufacturer or every six months ... Perform maintenance daily, weekly, and monthly maintenance, and documented [sic] as indicated by manufacturer instructions. Check quality control (QC) results, graphs, and corrective actions by ensuring that: Perform QC according to written policies and procedures. ...QC graphs are reviewed at least weekly. ...Verify Laboratory Director has signed QC charts |

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| | monthly. ...Check Reference ranges are appropriate for patient population: Verify patient normal reference ranges during performance specifications, or over-time with ample sample collection data. Compile data, using patient populous, by gender, age and when applicable ethnicity." 2. The laboratory failed to have a policy in place for performing LCMS Toxicology analysis for 40 of 40 analytes from 2019-2023. (Refer to D5403, I) 3. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Beckman Coulter AU480 chemistry analyzer for 28 of 28 analytes performed in 2023. (Refer to D5403, II) 4. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Sysmex XN-330 hematology analyzer for five of five analytes performed in 2023. (Refer to D5403, III) 5. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage for 4 of 4 QC vials observed in January 2024. (Refer to D5413, I) 6. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage for 18 of 18 QC vials observed in January 2024. (Refer to D5413, II) 7. The laboratory failed to follow manufacturer's instructions for operating temperature of the AU480 chemistry analyzer for six of six months in 2023 (July-December). (Refer to D5413, III) 8. The laboratory failed to label XN-L Check Hematology QC (Quality Control) material with revised expiration date for three of three control vials reviewed in January 2024. (Refer to D5415) 9. The laboratory failed to ensure expired QC material was not available for use for 24 of 24 days performed in 2023 and 2024 (12/20/2023-01/23/2024). (Refer to D5417, I) 10. The laboratory failed to ensure expired Beckman Coulter Chemistry Cleaning Solution was not available for use for one of one box observed in January 2024. (Refer to D5417, II) 11. The laboratory failed to ensure expired Total Bilirubin reagent was not available for use for one of one box observed in January 2024. (Refer to D5417, III) 12. The laboratory failed to ensure expired Hemolyzing Reagent was not available for use for one of one box observed in January 2024. (Refer to D5417, IV) 13. The laboratory failed to ensure the normal range for five of five CBC analytes (WBC, RBC, HGB, HCT, PLT) were verified by the laboratory's studies in 2022 (April). (Refer to D5421) 14. The laboratory failed to document a complete and approved establishment study for LCMS toxicology testing for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). (Refer to D5423) 15. The laboratory failed to document weekly maintenance for 10 of 24 weeks reviewed in 2023 (July-December). (Refer to D5431) 16. The laboratory failed to have documentation of performing calibration verification every 6 months for 40 of 40 analytes tested on the LCMS analyzer from 2019-2023. (Refer to D5439) 17. The laboratory failed to document review of chemistry QC records for errors over time for 28 of 28 analytes performed on the Beckman Coulter AU480 chemistry analyzer in 2022 and 2023. (Refer to D5441) 18. The laboratory failed to document corrective actions when freezer temperatures failed to fall in the acceptable range for 22 of 40 days reviewed in 2023 (October-December). (Refer to D5781) 19. During an interview on 01/23/2024 at 4:15 PM, at the facility nursing station, the Laboratory Director was asked to provide documentation of quality assessment reports. No documentation was provided. This confirmed the above findings. |
| **D5800** | POSTANALYTIC SYSTEMS<br>CFR(s): 493.1290<br><br>Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. |

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| | 1299 for each specialty and subspecialty of testing performed.<br><br>This CONDITION is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policy, staff interview, environmental logs, patient final reports, and confirmed in interview, the laboratory failed to monitor and evaluate the overall quality of the postanalytic systems and correct identified problems for 47 of 47 patient specimens in January 2024, as evidenced by: 1. The laboratory failed to have a system in place for ensuring patient test records were readily available for 47 of 47 LCMS (Liquid Chromatography Mass Spectrometry) urine confirmation patient specimens observed in January 2024. (Refer to D5803, I) 2. The laboratory failed to have a system in place for ensuring patient test records were readily available for three of five days patient specimens were tested in January 2024. (Refer to D5803, II) 3. The laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the postanalytical phase of testing for two of three specialties (Chemistry and Toxicology) performed from February 2019 to January 2024. (Refer to D5893) |
| **D5803** | TEST REPORT<br>CFR(s): 493.1291(b)<br><br>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on surveyor observation, review of laboratory policy, and confirmed in interview, the laboratory failed to have a system in place for ensuring patient test records were readily available for 47 of 47 LCMS urine confirmation patient specimens observed in January 2024. Findings Included: 1. During a tour of the laboratory on 01/23/2024 at 10:58 AM, the surveyor observed 1 yellow urine toxicology patient specimen rack, on the second shelf of the laboratory refrigerator, labeled with the information, "Confirmation Completed 11/27/2023". Further observation revealed the following random sampling of the above patients located in the yellow rack: a. Sample Identification: 0166884U b. Sample Identification: 0165710U c. Sample Identification: 0166991U d. Sample Identification: 0166873U The surveyor requested the final patient reports for these specimens, as well as the others contained in the rack, and none were provided. 2. Review of laboratory policy, "Records" revealed the following: "Policy The laboratory retains all records of patient testing, including worksheets, logs, and instrument printouts. Patient test results are stored electronically in the LIS." 3. During an interview on 01/30/2024 at 4:34 PM, the Laboratory Director stated the LIS was unable to provide the LCMS final patient reports for the urine toxicology patient specimens located in the laboratory refrigerator. This confirmed the laboratory failed to have a system in place for ensuring patient test records were readily available for 47 of 47 patient specimens observed in January 2024. Word Key LIS- Laboratory Information System II. Based on surveyor observation, review of laboratory policy, and confirmed in interview, the laboratory failed to have a system in place for ensuring patient test records were readily available for three of five days patient specimens were tested in January 2024. Findings Included: 1. During a tour of the laboratory on 01/23/2024 at 10:55 AM, the surveyor observed one Beckman Coulter AU480 chemistry analyzer (Serial Number: 3102758) in the patient testing area. The surveyor requested final chemistry patient reports from 01/15/2024, 01/17/2024, 01/19/2024, 01/20/2024, and 01/22/2024. The |

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| | laboratory medical assistant stated the reports for 01/19/2024, 01/20/2024, and 01/22 /2024, were not available in the patient chart for review, as the LIS was delayed in releasing patient information. 2. Review of laboratory policy, "Records" revealed the following: "Policy The laboratory retains all records of patient testing, including worksheets, logs, and instrument printouts. Patient test results are stored electronically in the LIS." 3. During an interview on 01/23/2024 at 3:18 PM in the laboratory, Testing Person-1 confirmed the laboratory failed to have a system in place for ensuring patient test records were readily available for three of five days patient specimens were tested in January 2024. |
| **D5893** | POSTANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1299(b)(c)<br><br>(b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, surveyor observation, manufacturer's instructions, LCMS establishment study, environmental logs, maintenance records, patient records, and confirmed in interview, the laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the postanalytical phase of testing for two of three specialties (Chemistry and Toxicology (high complexity)) performed from February 2019 to January 2024. Findings Included: 1. Review of laboratory policy, "Quality Assessment Program" revealed the following: "Purpose This QA Program will detect problems in the laboratory's system and identify opportunities for improvement. This laboratory will develop plans of corrective/preventive action based on the issue. The QA Program is to improve the reliability, efficiency, and quality of laboratory services to our patients. ...Post-analytical (after testing) phase ...Records Verify lab records and results on patient chart are the same Maintain records for at least two years." 2. The laboratory failed to have a system in place for ensuring patient test records were readily available for 47 of 47 LCMS urine confirmation patient specimens observed in January 2024. (Refer to D5803, I) 3. The laboratory failed to have a system in place for ensuring patient test records were readily available for three of five days patient specimens were tested in January 2024. (Refer to D5803, II) 4. During an interview on 01/23/2024 at 4:15 PM, at the facility nursing station, the Laboratory Director was asked to provide documentation of quality assessment reports. No documentation was provided. This confirmed the above findings. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory's policy, manufacturer's instructions, patient test |

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| | records, and quality control records, the Laboratory Director failed provide overall management and direction of the laboratory for three of three specialties reviewed (Chemistry, Hematology and Toxicology) in January 2024, as evidenced by: 1. The Laboratory Director failed to ensure quality laboratory services for moderate complexity preanalytic systems, for three of three specialties reviewed (Chemistry, Hematology and Toxicology) in January 2024. (Refer to D6007) 2. The Laboratory Director failed to ensure normal range verification was performed and documented for five of five CBC analytes in 2022. (Refer to D6013) 3. The Laboratory Director failed to ensure proficiency testing evaluations were documented for two of six events in 2023. (Refer to D6018) 4. The Laboratory Director failed to ensure effective quality assessment programs were established and maintained for pre-analytic and analytic phases of testing, for three of three specialties reviewed (Chemistry, Hematology and Toxicology) in January 2024. (Refer to D6021) 5. The Laboratory Director failed to ensure that four of four Testing Persons (TP-1, TP-2, TP-3, TP-4) received the appropriate training in moderate complexity testing prior to patient testing. (Refer to D6029) 6. The Laboratory Director failed to ensure policies were established and followed for three of three specialties reviewed (Chemistry, Hematology and Toxicology (moderate complexity)) in January 2024. (Refer to D6031) 7. The Laboratory Director failed to specify in writing the responsibilities and duties four of four Testing Persons (TP-1, TP-2, TP-3, TP-4) performing moderate complexity testing and one of two Technical Consultants (TC-2). (Refer to D6032) |
| **D6007** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(1)<br><br>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)(1) 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;<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, review of laboratory policy, laboratory records, manufacturer's instructions, laboratory's verification studies, patient final reports, and confirmed in staff interview, the Laboratory Director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provided quality laboratory services for preanalytic and analytic phase of testing for three of three specialties reviewed (Chemistry, Hematology and Toxicology (moderate complexity)) in January 2024, as evidenced by: 1. The laboratory failed to follow manufacturer's instructions for specimen storage prior to analysis for 7 of 15 serum CO2 patient specimens reviewed in January 2024. (Refer to 5311) 2. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Beckman Coulter AU480 chemistry analyzer for 28 of 28 analytes performed in 2023. (Refer to D5403, II) 3. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Sysmex XN-330 hematology analyzer for five of five analytes performed in 2023. (Refer to D5403, III) 4. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage for four of four QC vials observed in January 2024. (Refer to D5413, I) 5. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage |

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| | for 18 of 18 QC vials observed in January 2024. (Refer to D5413, II) 6. The laboratory failed to follow manufacturer's instructions for operating temperature of the AU480 chemistry analyzer for six of six months in 2023 (July-December). (Refer to D5413, III) 7. The laboratory failed to label XN-L Check Hematology QC (Quality Control) material with revised expiration date for three of three control vials reviewed in January 2024. (Refer to D5415) 8. The laboratory failed to ensure expired QC material was not available for use for 24 of 24 days performed in 2023 and 2024 (12 /20/2023-01/23/2024). (Refer to D5417, I) 9. The laboratory failed to ensure expired Beckman Coulter Chemistry Cleaning Solution was not available for use for one of one box observed in January 2024. (Refer to D5417, II) 10. The laboratory failed to ensure expired Total Bilirubin reagent was not available for use for one of one box observed in January 2024. (Refer to D5417, III) 11. The laboratory failed to ensure expired Hemolyzing Reagent was not available for use for one of one box observed in January 2024. (Refer to D5417, IV) 12. The laboratory failed to ensure the normal range for five of five CBC analytes (WBC, RBC, HGB, HCT, PLT) were verified by the laboratory's studies in 2022 (April). (Refer to D5421) 13. The laboratory failed to document weekly maintenance for 10 of 24 weeks reviewed in 2023 (July-December). (Refer to D5431) 14. The laboratory failed to document review of chemistry QC records for errors over time for 28 of 28 analytes performed on the Beckman Coulter AU480 chemistry analyzer in 2022 and 2023. (Refer to D5441) 15. The laboratory failed to document corrective actions when freezer temperatures failed to fall in the acceptable range for 22 of 40 days reviewed in 2023 (October-December). (Refer to D5781) 16. The laboratory failed to have a system in place for ensuring patient test records were readily available for 47 of 47 LCMS (Liquid Chromatography Mass Spectrometry) urine confirmation patient specimens observed in January 2024. (Refer to D5803, I) 17. The laboratory failed to have a system in place for ensuring patient test records were readily available for three of five days patient specimens were tested in January 2024. (Refer to D5803, II) 18. The laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the postanalytical phase of testing for two of three specialties (Chemistry and Toxicology) performed from February 2019 to January 2024. (Refer to D5893) |
| **D6013** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(ii)<br><br>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;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of verification studies for the Sysmex XN-330 hematology analyzer, manufacturer instructions, laboratory policies, laboratory records, and confirmed in interview, the Laboratory Director failed to ensure normal range verification was performed and documented for five of five CBC analytes in 2022, as evidenced by: The laboratory failed to ensure the normal range for five of five CBC analytes (WBC, RBC, HGB, HCT, PLT) were verified by the laboratory's studies in 2022 (April). (Refer to D5421) |
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| **D6018** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(4)(iii)<br><br>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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) 2023 results, and confirmed in interview, the Laboratory Director failed to ensure proficiency testing evaluations were documented for two of six events in 2023, evidenced by: 1. The Laboratory Director (or designee) failed to document evaluation of PT performance for one of three Hematology/Coagulation events in 2023. (Refer to D5211) 2. The laboratory failed to document verification of the accuracy of analytes that were not graded by the proficiency testing program for one of three Chemistry Core events in 2023. (Refer to D5213) |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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 quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's policies and staff interview, it was revealed the Laboratory Director failed to ensure effective quality assessment programs were established and maintained for pre-analytic and analytic phases of testing, for three of three specialties reviewed (Chemistry, Hematology and Toxicology (moderate complexity)) in January 2024, as evidenced by: 1. The laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the pre-analytic phase of testing for one of three specialties (Chemistry) performed in January 2024. (Refer to D5393) 2. The laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the analytical phase of testing for three of three specialties (Chemistry, Hematology and Toxicology ( moderate complexity)) performed from February 2019 to January 2024. (Refer to D5793) 3. The laboratory failed to monitor and evaluate the overall quality of the postanalytic systems and correct identified problems for 47 of 47 patient specimens in January 2024. (Refer to D5893) |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<br><br>The laboratory director is responsible for the overall operation and administration of |

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| | 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, personnel files and confirmed in interview the Laboratory Director failed to ensure that four of four Testing Persons (TP-1, TP-2, TP-3, TP-4) received the appropriate training in moderate complexity testing prior to patient testing. Findings included: 1. Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ... Personnel Duties ... 2. Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered and have demonstrated that they can perform all testing operations reliably to provide and report accurate results." Review of laboratory policy titled "Personnel Manual Protocol" revealed: "Procedure ... Personnel records ... The personnel manual shall include the following documents on all personnel ... Initial training documentation" 2. Review of personnel files for TP-1 revealed a hire date of 11/2023. There were no documented training records for the Sysmex XN-330 hematology analyzer or the AU-480 chemistry analyzer. Review of personnel files for TP-2 revealed a hire date of 06/01/2021. There were no documented training records for the ACT DIFF 2 hematology analyzer. Semiannual competency records revealed competency was evaluated on 01/2022. Review of personnel files for TP-3 revealed a hire date of 01/13/2023. There were no documented training records for the Sysmex XN-330 hematology analyzer. Review of personnel files for TP-4 revealed a hire date of 11/11/2021. There were no documented training records for the ACT DIFF 2 hematology analyzer. Semiannual competency records revealed a partially completed competency was evaluated on 01 /2022. The Laboratory Director failed to ensure the above listed testing personnel received the appropriate training in moderate complexity testing prior to patient testing. 3. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director confirmed the above findings. During an interview on 01/23/2024 at 3:40 pm, TP-1 stated that no training was provided for him since he had previous experience on the Sysmex XN-330 hematology analyzer and the AU-480 chemistry analyzer. |
| **D6031** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(13)<br><br>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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process;<br><br>This STANDARD is not met as evidenced by: |

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| | Based on surveyor observation, review of laboratory policy and procedure manual, and confirmed in interview, the Laboratory Director failed to ensure policies were established and followed for three of three specialties reviewed (Chemistry, Hematology and Toxicology) in January 2024, as evidenced by: 1. The laboratory failed to have a policy in place for performing LCMS Toxicology analysis for 40 of 40 analytes from 2019-2023. (Refer to D5403, I) 2. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Beckman Coulter AU480 chemistry analyzer for 28 of 28 analytes performed in 2023. (Refer to D5403, II) 3. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Sysmex XN-330 hematology analyzer for five of five analytes performed in 2023. (Refer to D5403, III) |
| **D6032** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(14)<br><br>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)(14) Specify, in writing, the responsibilities and duties of each consultant and 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 results reporting, and whether consultant or director review is required prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, CMS 209 form, laboratory personnel records, and confirmed in interview, the Laboratory Director failed to specify in writing the responsibilities and duties four of four Testing Persons (TP-1, TP-2, TP-3, TP-4) performing moderate complexity testing and one of two Technical Consultants (TC-2). Findings included: 1. Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Personnel Duties ... 4. Have a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform; whether supervision is required for specimen processing, test performance, or results reporting; and whether consultant or director review is required prior to reporting patient test results." Review of laboratory policy titled "Personnel Manual Protocol" revealed: "Procedure ... Personnel records ... The personnel manual shall include the following documents on all personnel ... Signed and dated description of current duties and responsibilities as specified by the lab director. Procedures the individual is authorized to perform. Whether supervision is required for specimen processing, test performance or result reporting. Whether supervisory or director review is required to report patient test results [sic]" 2. Review of the CMS 209 form listed TP-1, TP-2, TP-3, TP-4 performing moderate complexity testing and TC-2 as a moderate complexity consultant. 3. Review of personnel records for revealed no delegation of duties for TP-1. The laboratory director did not specify, in writing, which procedures TP-1 was authorized to perform. Review of personnel records for TP-2 and TP-4 revealed a delegation of "Testing Personnel." Further review of the form revealed the form was signed by a person who was NOT the laboratory director. The laboratory director did not specify, in writing, which procedures TP-2 and TP-4 were authorized to perform. Review of personnel records for TP-3 revealed a delegation of "Testing Personnel." Further review of the form |

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| | revealed the form was not signed by the laboratory director. The laboratory director did not specify, in writing, which procedures TP-3 was authorized to perform with /without supervision. Review of personnel records for revealed no delegation of duties for TC-2. The laboratory director did not specify, in writing, which procedures TC-2 was authorized to perform. 4. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and confirmed in interview with staff, the technical consultant failed to provide overall technical and scientific oversight for three of three specialties (Chemistry, Hematology and Toxicology (moderate complexity)) in 2023, as evidenced by: 1. The laboratory failed to ensure one of two Technical Consultants (TC-2) were qualified by education to provide technical consultation for each of the specialties of service in which the laboratory performed moderate complexity tests. (Refer to D6035) 2. The technical consultant failed to ensure quality of laboratory services for the preanalytic and analytic phases of testing for three of three specialties reviewed (Chemistry, Hematology and Toxicology) from 2019-2023. (Refer to D6036) |
| **D6035** | TECHNICAL CONSULTANT QUALIFICATIONS<br>CFR(s): 493.1411<br><br>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) |

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| | Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to one of two Technical Consultants (TC-2) were qualified by education to provide technical consultation for each of the specialties of service in which the laboratory performed moderate complexity tests. Findings included: 1. Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Personnel Duties 1. Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results." 2. Review of the CMS-209 form listed TC-2 technical consultant providing oversight for moderate complexity testing. 3. Review of personnel records for TC-2 included an Associate in Applied Science Degree in Medical Technology, Baccalaureate in Health Services Administration, and Master's in Business Administration. The educational documents did not meet the qualifications for serving as a technical consultant. 4. During an electronic mail correspondence on 01/24/2024 at 4:24 pm, the Laboratory Director confirmed the above findings. |
| **D6036** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413<br><br>The technical consultant is responsible for the technical and scientific oversight of the laboratory.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of manufacturer's instructions, laboratory policy, and study for storage of coagulation specimens, the technical consultant failed to ensure quality of laboratory services for the preanalytic and analytic phases of testing for three of three specialties reviewed (Chemistry, Hematology and Toxicology) from 2019-2023, as evidenced by: 1. The laboratory failed to follow manufacturer's instructions for specimen storage prior to analysis for 7 of 15 serum CO2 patient specimens reviewed in January 2024. (Refer to 5311) 2. The laboratory failed to have a policy in place for performing LCMS Toxicology analysis for 40 of 40 analytes from 2019-2023. (Refer to D5403, I) 3. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Beckman Coulter AU480 chemistry analyzer for 28 of 28 analytes performed in 2023. (Refer to D5403, II) 4. The laboratory failed to have a quality control (QC) policy in place for performing patient analysis on the Sysmex XN-330 hematology analyzer for 5 of 5 analytes performed in 2023. (Refer to D5403, III) 5. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage for four of four QC vials |

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| | observed in January 2024. (Refer to D5413, I) 6. The laboratory failed to follow manufacturer's instructions for quality control (QC) storage for 18 of 18 QC vials observed in January 2024. (Refer to D5413, II) 7. The laboratory failed to follow manufacturer's instructions for operating temperature of the AU480 chemistry analyzer for six of six months in 2023 (July-December). (Refer to D5413, III) 8. The laboratory failed to label XN-L Check Hematology QC (Quality Control) material with revised expiration date for three of three control vials reviewed in January 2024. (Refer to D5415) 9. The laboratory failed to ensure the normal range for five of five CBC analytes (WBC, RBC, HGB, HCT, PLT) were verified by the laboratory's studies in 2022 (April). (Refer to D5421) 10. The laboratory failed to document a complete and approved establishment study for LCMS toxicology testing for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). (Refer to D5423) 11. The laboratory failed to document weekly maintenance for 10 of 24 weeks reviewed in 2023 (July-December). (Refer to D5431) 12. The laboratory failed to have documentation of performing calibration verification every 6 months for 40 of 40 analytes tested on the LCMS analyzer from 2019-2023. (Refer to D5439, I) 13. The laboratory failed to document review of chemistry QC records for errors over time for 28 of 28 analytes performed on the Beckman Coulter AU480 chemistry analyzer in 2022 and 2023. (Refer to D5441) 14. The laboratory failed to document corrective actions when freezer temperatures failed to fall in the acceptable range for 22 of 40 days reviewed in 2023 (October-December). (Refer to D5781) |
| **D6048** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(ii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies, annual competency assessments, and staff interview, the technical consultant failed to monitor the recording and reporting of test results for one of two annual competency assessments performed on the ACT DIFF 2 hematology analyzer in 2022. Findings included: 1. Review of laboratory policy titled "Technical Supervisor/Consultant Responsibilities" revealed: "Position: Technical Supervisor ... Identifies training needs and ensures testing personnel receive regular in-service training. Evaluates the competency of all testing personnel on an ongoing basis. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation." Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ..." Review of laboratory policy titled "Competency Assessment for Testing Personnel" revealed: "Procedure Competency Assessment will include one or more of the following: 1. Direct observation of routine test performance, including patient preparation (if applicable), specimen handling, processing, testing and result reporting [sic] 2. Performance of instrument maintenance and function checks. 3. Assessment of test performance with previous analyzed specimen (proficiency testing samples, blind samples or previously analyzed samples) [sic] 4. Written assessment with ability to |

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| | refer to manuals or reference books to solve problems. 5. Problem solving skills. 6. Report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills." 2. A review of the laboratory's annual competency assessments performed in 2022 revealed the technical consultant failed to monitor the recording and reporting of test results for Testing Person-2 on the ACT DIFF 2 hematology analyzer. 3. During an interview on 01/23 /2024 at 2:32 pm, the Office Manager confirmed the above findings. |
| **D6049** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(iii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies, annual competency assessments, and staff interview, the technical consultant failed to include the review of preliminary results, worksheets, quality control, proficiency testing and preventive maintenance for one of two annual competency assessments performed on the ACT DIFF 2 hematology analyzer in 2022. Findings included: 1. Review of laboratory policy titled "Technical Supervisor/Consultant Responsibilities" revealed: "Position: Technical Supervisor ... Identifies training needs and ensures testing personnel receive regular in-service training. Evaluates the competency of all testing personnel on an ongoing basis. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation." Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ..." Review of laboratory policy titled "Competency Assessment for Testing Personnel" revealed: "Procedure Competency Assessment will include one or more of the following: 1. Direct observation of routine test performance, including patient preparation (if applicable), specimen handling, processing, testing and result reporting [sic] 2. Performance of instrument maintenance and function checks. 3. Assessment of test performance with previous analyzed specimen (proficiency testing samples, blind samples or previously analyzed samples) [sic] 4. Written assessment with ability to refer to manuals or reference books to solve problems. 5. Problem solving skills. 6. Report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills." 2. A review of the laboratory's annual competency assessments performed in 2022 revealed the technical consultant failed to include the review of preliminary results, worksheets, quality control, proficiency testing and preventive maintenance for Testing Person-2 on the ACT DIFF 2 hematology analyzer. 3. During an interview on 01/23/2024 at 2:32 pm, the Office Manager confirmed the above findings. |
| **D6050** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(iv)<br><br>The procedures for evaluation of the competency of the staff must include, but are not |

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| | limited to direct observation of performance of instrument maintenance and function checks.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies, annual competency assessments, and staff interview, the technical consultant failed to evaluate the direct observation of instrument maintenance and function checks for one of two annual competency assessments performed on the ACT DIFF 2 hematology analyzer in 2022. Findings included: 1. Review of laboratory policy titled "Technical Supervisor/Consultant Responsibilities" revealed: "Position: Technical Supervisor ... Identifies training needs and ensures testing personnel receive regular in-service training. Evaluates the competency of all testing personnel on an ongoing basis. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation." Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ..." Review of laboratory policy titled "Competency Assessment for Testing Personnel" revealed: "Procedure Competency Assessment will include one or more of the following: 1. Direct observation of routine test performance, including patient preparation (if applicable), specimen handling, processing, testing and result reporting [sic] 2. Performance of instrument maintenance and function checks. 3. Assessment of test performance with previous analyzed specimen (proficiency testing samples, blind samples or previously analyzed samples) [sic] 4. Written assessment with ability to refer to manuals or reference books to solve problems. 5. Problem solving skills. 6. Report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills." 2. A review of the laboratory's annual competency assessments performed in 2022 revealed the technical consultant failed to evaluate the direct observation of instrument maintenance and function checks for Testing Person-2 on the ACT DIFF 2 hematology analyzer. 3. During an interview on 01/23/2024 at 2:32 pm, the Office Manager confirmed the above findings. |
| **D6051** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(v)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies, annual competency assessments, and staff interview, the technical consultant failed to assess test performance through testing previous specimens, blind test samples, or external PT samples for one of two annual competency assessments performed on the ACT DIFF 2 hematology analyzer in 2022. Findings included: 1. Review of laboratory policy titled "Technical Supervisor /Consultant Responsibilities" revealed: "Position: Technical Supervisor ... Identifies training needs and ensures testing personnel receive regular in-service training. |

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| | Evaluates the competency of all testing personnel on an ongoing basis. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation." Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ..." Review of laboratory policy titled "Competency Assessment for Testing Personnel" revealed: "Procedure Competency Assessment will include one or more of the following: 1. Direct observation of routine test performance, including patient preparation (if applicable), specimen handling, processing, testing and result reporting [sic] 2. Performance of instrument maintenance and function checks. 3. Assessment of test performance with previous analyzed specimen (proficiency testing samples, blind samples or previously analyzed samples) [sic] 4. Written assessment with ability to refer to manuals or reference books to solve problems. 5. Problem solving skills. 6. Report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills." 2. A review of the laboratory's annual competency assessments performed in 2022 revealed the technical consultant failed to assess test performance through testing previous specimens, blind test samples, or external PT samples for Testing Person-2 on the ACT DIFF 2 hematology analyzer. 3. During an interview on 01/23/2024 at 2:32 pm, the Office Manager confirmed the above findings. |
| **D6052** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(vi)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies, annual competency assessments, and staff interview, the technical consultant failed to assess problem solving skills for one of two annual competency assessments performed on the ACT DIFF 2 hematology analyzer in 2022. Findings included: 1. Review of laboratory policy titled "Technical Supervisor/Consultant Responsibilities" revealed: "Position: Technical Supervisor ... Identifies training needs and ensures testing personnel receive regular in-service training. Evaluates the competency of all testing personnel on an ongoing basis. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation." Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ..." Review of laboratory policy titled "Competency Assessment for Testing Personnel" revealed: "Procedure Competency Assessment will include one or more of the following: 1. Direct observation of routine test performance, including patient preparation (if applicable), specimen handling, processing, testing and result reporting [sic] 2. Performance of instrument maintenance and function checks. 3. Assessment of |

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| | test performance with previous analyzed specimen (proficiency testing samples, blind samples or previously analyzed samples) [sic] 4. Written assessment with ability to refer to manuals or reference books to solve problems. 5. Problem solving skills. 6. Report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills." 2. A review of the laboratory's annual competency assessments performed in 2022 revealed the technical consultant failed to assess problem solving skills for Testing Person-2 on the ACT DIFF 2 hematology analyzer. 3. During an interview on 01/23/2024 at 2:32 pm, the Office Manager confirmed the above findings. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies, Centers for Medicare and Medicaid Services (CMS) 209 form, testing personnel records, and staff interview, the technical consultant failed to evaluate and document the performance for three of four Testing Persons (TP-2, TP-3, TP-4) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Findings included: 1. Review of laboratory policy titled "Technical Supervisor/Consultant Responsibilities" revealed: "Position: Technical Supervisor ... Identifies training needs and ensures testing personnel receive regular in-service training. Evaluates the competency of all testing personnel on an ongoing basis. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation." Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ..." Review of laboratory policy titled "Personnel Manual Protocol" revealed: "Procedure ... Personnel records ... The personnel manual shall include the following documents on all personnel ... Competency assessments" 2. Review of the CMS 209 form revealed TP-2, TP-3, TP-4 as testing persons performing moderately complex laboratory testing. 3. Review of personnel records revealed a hire date for TP-2 as 06/01/2021 and no initial training documentation on the ACT DIFF 2 hematology analyzer. Refer to D6029. Further review of personnel records revealed a competency assessment performed on 01/2022. There was no evidence of a second semiannual competency assessment (due 06/2022) during the first year the individual tested patient specimens. Review of personnel records revealed a hire date for TP-3 as 01/13 /2023 and no initial training documentation on the ACT DIFF 2 hematology analyzer. Refer to D6029. Further review of personnel records revealed no evidence of semiannual competency assessments during the first year the individual tested patient specimens. Review of personnel records revealed a hire date for TP-4 as 11/11/2021 and no initial training documentation on the ACT DIFF 2 hematology analyzer. Refer to D6029. Further review of personnel records revealed a partially completed competency assessment performed on 01/2022. Refer to D6048, D6049, D6050, |

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| | D6051, D6052. There was no evidence of a second semiannual competency assessment (due 06/2022) during the first year the individual tested patient specimens. The laboratory was asked to provide documentation for competency assessments for TP-2, TP-3, TP-4. No documentation of competency assessments was provided. 4. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director confirmed the above findings. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policies, testing personnel records, and staff interview, the technical consultant failed to evaluate and document the annual competency assessments for two of four Testing Persons (TP-2, TP-4) responsible for moderate complexity testing. Findings included: 1. Review of laboratory policy titled "Technical Supervisor/Consultant Responsibilities" revealed: "Position: Technical Supervisor ... Identifies training needs and ensures testing personnel receive regular in-service training. Evaluates the competency of all testing personnel on an ongoing basis. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation." Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ..." Review of laboratory policy titled "Personnel Manual Protocol" revealed: "Procedure ... Personnel records ... The personnel manual shall include the following documents on all personnel ... Competency assessments" 2. Review of personnel records revealed annual competency assessment was not performed for TP-2 and TP-4 in 2023. 3. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director confirmed the above findings. |
| **D6055** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of manufacturer instructions, laboratory policies, instrument verification studies, personnel files, and confirmed in interview, the Technical Consultant failed to evaluate and document the performance of two of four testing personnel (TP2, TP4) following the implementation of a new test methodology in |

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| | April 2022. Findings included: 1. Review of the Sysmex XN-330 implementation binder revealed: "Section 4 Training Checklists and Competencies Proper training of the laboratory personnel is critical to the success of implementing any new process or analyzer." 2. Review of laboratory policy titled "Technical Supervisor/Consultant Responsibilities" revealed: "Position: Technical Supervisor ... Identifies training needs and ensures testing personnel receive regular in-service training. Evaluates the competency of all testing personnel on an ongoing basis. Evaluates and documents performance of individuals responsible for testing at six months and twelve months in the first year of employment and yearly thereafter, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated for the new test methodology or instrumentation." Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ... Personnel Duties ... 2. Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered and have demonstrated that they can perform all testing operations reliably to provide and report accurate results." 3. Review of the verification studies revealed the addition of Sysmex XN-330 hematology analyzer in April 2022. 4. Review of testing personnel files indicated that testing performance had not been evaluated and documented prior to reporting patient test results for TP-2 and TP-4. The laboratory was asked to provide documentation of training, and none was provided. 5. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director confirmed the above findings. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of the laboratory's records, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to provide overall management of the laboratory for one of one high complexity specialty (Toxicology) from 2019-2024, as evidenced by: 1. The Laboratory Director failed to ensure testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in high complexity testing, for five of five years from 2019-2023. (Refer to D6079) 2. The Laboratory Director failed to ensure the laboratory provided quality services for analytic and postanalytic systems of toxicology testing for five of five years from 2019-2023. (Refer to D6082) 3. The Laboratory Director failed to ensure documentation of a complete and approved establishment study for LCMS toxicology testing for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). (Refer to D6086) 4. The Laboratory Director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality, for one of one high complexity specialty (Toxicology) from 2019-2023. (Refer to D6094) 5. The Laboratory Director failed to ensure that one of one Testing Persons (TP-5) received the appropriate training in high complexity testing prior to patient testing. (Refer to D6102) 6. The Laboratory |

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| | Director failed to specify in writing the responsibilities and duties one of one Testing Persons (TP-5) performing high complexity testing, one of one Technical Supervisors (TS-1) and one of one General Supervisors (GS-1). (Refer to D6107) |
| **D6079** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(a)(b)<br><br>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory documentation, patient specimen logs, patient final reports, and confirmed in interview, the Laboratory Director failed to ensure testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in high complexity testing, for five of five years from 2019-2023, as evidenced by: 1. The laboratory failed to perform twice annual accuracy verification for 40 of 40 non-regulated analytes in 2022 and 2023. (Refer to D5217) 2. The laboratory failed to have a policy in place for performing LCMS Toxicology analysis for 40 of 40 analytes from 2019-2023. (Refer to D5403, I) 3. The laboratory failed to document a complete and approved establishment study for LCMS toxicology testing for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). (Refer to D5423) 4. The laboratory failed to have documentation of performing calibration verification every 6 months for 40 of 40 analytes tested on the LCMS analyzer from 2019-2023. (Refer to D5439, I) 5. The laboratory failed to have a system in place for ensuring patient test records were readily available for 47 of 47 patient specimens observed in January 2024. (Refer to D5803) |
| **D6082** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory establishment study, laboratory policy, and confirmed in interview, the Laboratory Director failed to ensure the laboratory provided quality services for analytic and postanalytic systems of toxicology testing for five of five years from 2019-2023, as evidenced by: 1. The laboratory failed to have a policy in place for performing LCMS Toxicology analysis for 40 of 40 analytes from 2019-2023. (Refer to D5403, I) 2. The laboratory failed to document a complete and |

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| | approved establishment study for LCMS toxicology testing for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). (Refer to D5423) 3. The laboratory failed to have documentation of performing calibration verification every 6 months for 40 of 40 analytes tested on the LCMS analyzer from 2019-2023. (Refer to D5439, I) |
| **D6086** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(ii)<br><br>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policy, LCMS establishment study, patient final reports, and confirmed in interview, the Laboratory Director failed to perform analytic sensitivity to include interfering substances for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). (Refer to D5423) |
| **D6094** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policy, environmental records, QC records, and confirmed in interview, the Laboratory Director failed to ensure quality assessment programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality, for one of one high complexity specialty (Toxicology) from 2019-2023, as evidenced by: 1. The laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the pre-analytic phase of testing for one of one high complexity specialty (Toxicology) performed from February 2019 to January 2024. (Refer to D5393) 2. The laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the analytical phase of testing for one of one high complexity specialty (Toxicology) performed from February 2019 to January 2024. (Refer to D5793) 3. The laboratory failed to have an effective QA (quality assessment) procedure in place to identify and correct problems in the postanalytical phase of testing for one of one high complexity specialty (Toxicology) performed from February 2019 to January 2024. (Refer to D5893) |
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate |

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| | results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, lack of training documentation, and confirmed in interview the Laboratory Director failed to ensure that one of one Testing Persons (TP-5) received the appropriate training in high complexity testing prior to patient testing. Findings included: 1. Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Position: Laboratory Director (Test Complexity: Moderate and High) The laboratory director is responsible for the overall operation of the lab and the competency of all laboratory personnel, and is responsible for the following ... Personnel Duties ... 2. Ensure that prior to testing patient specimens, all personnel have the appropriate education and experience, and receive the appropriate training for the type and complexity of services offered and have demonstrated that they can perform all testing operations reliably to provide and report accurate results." Review of laboratory policy titled "Personnel Manual Protocol" revealed: "Procedure ... Personnel records ... The personnel manual shall include the following documents on all personnel ... Initial training documentation" 2. During an interview 01/23/2024 at 4:10 pm, the Laboratory Director stated that TP-5 had been hired "two to three months ago." He further stated that there was no training provided for TP-5. The Laboratory Director failed to ensure TP-5 received the appropriate training in high complexity testing prior to patient testing. |
| **D6107** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(15)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, CMS 209 form, laboratory personnel records, and confirmed in interview, the Laboratory Director failed to specify in writing the responsibilities and duties one of one Testing Persons (TP-5) performing high complexity testing, one of one Technical Supervisors (TS-1) and one of one General Supervisors (GS-1). Findings included: 1. Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Personnel Duties ... 4. Have a written list of responsibilities of each individual in the laboratory that specifies the level of activity each is authorized to perform; whether supervision is required for specimen processing, test performance, or results reporting; and whether consultant or director review is required prior to reporting patient test results." Review of laboratory policy titled "Personnel Manual Protocol" revealed: "Procedure ... Personnel records ... The personnel manual shall include the following documents on all personnel ... Signed and dated description of current duties and responsibilities as specified by the lab director. Procedures the individual is authorized to perform. Whether supervision is required for specimen processing, test performance or result reporting. Whether supervisory or director review is required to report patient test results [sic]" 2. Review of the CMS 209 form listed TP-5 performing high complexity testing TP-5 was also |

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| | delegated as TS-1 and GS-1. 3. Review of personnel records for revealed no delegation of duties for TP-5/TS-1/GS-1. The laboratory director did not specify, in writing, which procedures TP-5/TS-1/GS-1 was authorized to perform. 4. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director confirmed the above findings. Word key: CMS: Centers for Medicare and Medicaid Services |
| **D6108** | LABORATORY TECHNICAL SUPERVISOR<br>CFR(s): 493.1447<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to employ one of one Technical Supervisor (TS-1) who met qualifications to provide technical oversight of high complexity testing, as required. Refer to D6111. |
| **D6111** | TECHNICAL SUPERVISOR QUALIFICATIONS<br>CFR(s): 493.1449<br><br>(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 laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to employ one of one technical supervisor (TS-1) who met qualifications to provide technical oversight of high complexity testing, as required. Findings included: 1. Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Personnel Duties 1. Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results." Review of laboratory policy titled "Personnel Manual Protocol" revealed: "Procedure ... Personnel records ... The personnel manual shall include the following documents

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| | on all personnel ... Copy of academic degree or transcript" 2. Review of the CMS-209 form listed TS-1 as a technical supervisor for providing oversight of high complexity testing. 3. Review of personnel records for TS-1 included a foreign Doctor of Philosophy (PhD) without a United States (US) equivalency evaluation. The educational documents did not meet the qualifications for serving as a TS. The laboratory was asked to provide a US equivalency evaluation, and none was provided. 4. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director confirmed the above findings. |
| **D6115** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(2)<br><br>The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.<br><br>This STANDARD is not met as evidenced by:<br>Based on surveyor observation, review of laboratory policy, LCMS establishment study, patient final reports, and confirmed in interview, the Technical Supervisor failed to perform analytic sensitivity to include interfering substances for 40 of 40 analytes performed in 2019 (February-December), 2020-2023 (January-December), and 2024 (January). (Refer to D5423) |
| **D6141** | GENERAL SUPERVISOR<br>CFR(s): 493.1459<br><br>The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure one of one General Supervisor (GS-1) met the requirements to provide supervision of high complexity testing. Refer to D6143. |
| **D6143** | GENERAL SUPERVISOR QUALIFICATIONS<br>CFR(s): 493.1461<br><br>(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(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 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; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years |

of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493. 1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c) (4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c) (5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5) (ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:
Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure one of one General Supervisor (GS-1) met the requirements to provide supervision of high complexity testing. Findings included: 1. Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Personnel Duties 1. Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results." Review of laboratory policy titled "Personnel Manual Protocol" revealed: "Procedure ... Personnel records ... The personnel manual shall include the following documents on all personnel ... Copy of academic degree or transcript" 2. Review of the CMS-209 form listed GS-1 as a general supervisor for providing oversight of high complexity testing. 3. Review of personnel records for GS-1 included a foreign Doctor of Philosophy (PhD) without

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| | a United States (US) equivalency evaluation. The educational documents did not meet the qualifications for serving as a GS. The laboratory was asked to provide a US equivalency evaluation, and none was provided. 4. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director confirmed the above findings. |
| **D6168** | TESTING PERSONNEL<br>CFR(s): 493.1487<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure one of one testing persons (TP-5) met the requirements to perform high complexity testing. Refer to D6171. |
| **D6171** | TESTING PERSONNEL QUALIFICATIONS<br>CFR(s): 493.1489(b)<br><br>(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 |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, CMS (Centers for Medicare and Medicaid Services) 209 form, personnel records, and interview with staff, the laboratory failed to ensure one of one testing persons (TP-5) met the requirements to perform high complexity testing. Findings included: 1. Review of laboratory policy titled "Laboratory Director Responsibilities" revealed: "Personnel Duties 1. Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise, and accurately perform tests and report test results." Review of laboratory policy titled "Personnel Manual Protocol" revealed: "Procedure ... Personnel records ... The personnel manual shall include the following documents on all personnel ... Copy of academic degree or transcript" 2. Review of the CMS-209 form listed TP-5 as performing high complexity testing. 3. Review of personnel records for TP-5 included a foreign Doctor of Philosophy (PhD) without a United States (US) equivalency evaluation. The educational documents did not meet the qualifications for serving as a high complexity testing person. The laboratory was asked to provide a US equivalency evaluation, and none was provided. 4. During an interview on 01/23/2024 at 3:28 pm, the Laboratory Director confirmed the above findings. |