| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 32D2162469 | 02/12/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Elite Primary Care Llc | 530 N Telshor Blvd Ste A, Las Cruces, NM | |

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

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
|---|---|
| **D0000** | A initial survey was completed on February 12, 2025 at Elite Primary Care. Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F.R. 493.1250 Condition: Analytic Systems 42 C.F.R. 493.1441 Condition: High Complexity Laboratory Director 42 C.F.R. 493.1447 Condition: Technical Supervisor 42 C.F.R. 493.1459 Condition: General Supervisor 42 C.F.R. 493.1409 Condition: Technical Consultant 42 C.F.R. 493.1487 Condition: High Complexity Testing Personnel |
| **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.<br><br>This CONDITION is not met as evidenced by:<br>Based on the ARK Ethyl Glucuronide (ETG) assay package insert, the laboratory's performance verification study, a FUO (forensic use only) Assay letter, Emit II Plus specialty drug and the Emit II Plus Oxycodone quality control package inserts, patient test results, and interview with Testing Personnel 1, (TP1) and the Siemens Technical Applications Specialist, the laboratory failed to meet analytic system requirements for toxicology testing from July 2024 through February 2025 as evidenced by: 1. The laboratory failed to accurately perform performance verification to ensure the laboratory could result quantitative test results. Refer to D5421 2. The laboratory failed to accurately perform performance verification to include specificity and |

| | |
|---|---|
| | sensitivity for one forensic use only analyte (ETG). Refer to D5423 3. The laboratory failed to run at least 2 quantitative quality control materials per day of patient testing. Refer to 5447 |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, review of the laboratory's Sample Collection and Handling Policy, ARK Diagnostics, Inc. ARK Ethyl Glucuronide Assay (EtG) manufacturer's instructions (MI), ARK Diagnostics, Inc. ARK Fentanyl II Assay (Fent) manufacturer's instructions, SYVA EMIT II Plus Amphetamines Assay (Amp) manufacturer's instructions, and interview with Testing Personnel 1 (TP1), the laboratory failed to follow the manufacturer's instructions for specimen storage and testing requirements during July 2024 to February 2025. Findings included: 1. During tour of the laboratory on 02/12/2025 at 10:33 am, observed no centrifuge present. 2. Review of the laboratory's Sample Collection and Handling Policy stated "Samples should be stored at the appropriate temperature and conditions as specified by the protocol." 3. Review of EtG MI and Fent MI indicated urine samples must be stored refrigerated and specimens with high turbidity or visible particulate matter must be centrifuged prior to testing. 4. Review of AMP MI indicated specimens with high turbidity must be centrifuged prior to testing. 5. During interview on 02/12/2025 at 11: 11 am with TP1, they stated samples are stored at room temperature for 1 day before testing, are not checked for turbidity or particulate matter, and that the laboratory does not use a centrifuge. This confirmed the above findings. 6. The laboratory reports an estimated 2000 toxicology tests annually. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on direct observation, review of ARK Diagnostics, Inc. ARK Ethyl Glucuronide Assay (EtG) manufacturer's instructions (MI); ARK Diagnostics, Inc. ARK Fentanyl II Assay (Fent) manufacturer's instructions; SYVA EMIT II Plus Amphetamines Assay (Amp) manufacturer's instructions; refrigerator temperature log; Beckman Au480 analyzer operations manual; lack of documentation, and interview with Testing Personnel 1 (TP1); the laboratory failed to record the temperature of the |

| | |
|---|---|
| | storage refrigerator for 15 days in July 2024, and monitor temperature and humidity for Au480 Analyzer room for July 2024 through February 2025. Findings included: 1. During tour of laboratory on 02/12/2025 at 10:33 am, reagents for EtG, Fent, and Amp assays were observed being stored in the refrigerator. 2. Review of Etg, Fent, and Amp MI, revealed the reagents must be stored refrigerated (2 -8Celcius(C)). 3. Review of refrigerator temperature logs revealed no temperature was recorded for 15 of 31 days in July 2024 (July 17 through July 31, 2024). 4. Review of the Au480 Serial Number 2023080781 operators manual stated: a. "When the system is in operation, make sure the following requirements are met: i. The temperature of the installation room is between 18C and 32C ii. The temperature does not fluctuate more than +2C. iii. The humidity is between 20% Relative Humidity (RH) and 80% RH with no condensation." 5. The laboratory was asked to provide documentation of temperature monitoring for Au480 analyzer room. No documentation was provided. 6. Interview on 02/12/2025 at 10:55 am with TP1 indicated temperature and humidity for instrument room was not recorded for July 2024 to February 2025 which confirmed the above findings. 7. The laboratory reports an estimated 2000 toxicology tests annually. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 the laboratory's performance verification study, patient reports, and interview with a Siemens Technical Applications Specialist, the laboratory failed to accurately perform performance verification studies to ensure the laboratory could result quantitative test results for 14 of 14 analytes tested on the Beckman Coulter Au80 chemistry analyzer from July 2024 to February 2025. Findings included: 1. A review of the laboratory's performance verification study completed 12/20/2023, revealed the laboratory failed to ensure the performance specifications for accuracy and precision were completed for quantitative results. 2. A random sampling of patient reports reviewed from February 11, 2025, revealed patient results were given a quantitative value with the following reference range for all analytes tested; Reference Range = -9999999 - 100 3. During a phone interview on 02/12/2025 at 1:25 pm with the Siemens Technical Applications Specialist that performed the performance verification study for the laboratory, they stated, "The study only verified the instrument to report out qualitative results", confirming the above findings. 4. The laboratory reported performing 2000 urine toxicology test annually. |
| **D5423** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(2)<br><br>(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a |

| | |
|---|---|
| | test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the ARK Ethyl Glucuronide (ETG) assay package insert, the laboratory's performance verification study, a FUO (forensic use only) Assay letter, patient reports, and interview with a Siemens Technical Applications Specialist, the laboratory failed to accurately perform performance verification to include sensitivity and specificity for one forensic use only test on the Beckman Coulter Au80 chemistry analyzer from July 2024 to February 2025. Findings included: 1. A review of the ARK ETG assay package insert stated the assay is for "criminal justice and forensic use only" 2. A Review of the laboratory's performance verification study completed 12/20/2023, listed only accuracy and precision for qualitative results as performance specifications verified during the performance verification. 3. A review of a letter titled "FUO Assays" sent by Siemens Healthineers, states, "by signing the letter the facility acknowledges and understands the following: 1. [The analyte ETG] is not approved or cleared by the FDA for any purpose: 2. [The analyte ETG] is not intended for any invitro diagnostic treatment purposes ..." The laboratory director signed and dated the acknowledgment letter 11/02/2023. 4. The laboratory reported approximately 2000 ETG patient reports from July 2024 through February 2025. 5. During a phone interview on 02/12/2025 at 1:25 pm with the Siemens Technical Applications Specialist, they stated, "An acknowledgement letter about the FUO assay was sent to the laboratory and was returned signed by the laboratory director.", which confirmed the above findings. |
| **D5447** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(i)(g)<br><br>(d)(3)(i) Each quantitative procedure, include two control materials of different concentrations;<br><br>This STANDARD is not met as evidenced by:<br>Based on Emit II Plus specialty drug and the Emit II Plus Oxycodone quality control package inserts, patient test results, and interview with Testing Personnel 1 (TP1), the laboratory failed to run at least 2 quantitative quality control (QC) materials per day of patient testing for 14 of 14 analytes on the Beckman Coulter Au80 chemistry analyzer from July 2024 to February 2025. Findings included: 1. A review of the Emit II Plus specialty drug and the Emit II Plus Oxycodone quality control package inserts revealed the intended use for the quality control material is to provide positive and negative cutoff values. 2. A random sampling of patient reports reviewed from February 11, 2025, revealed patient results were given a quantitative value with the following reference range for all analytes tested; Reference Range = -9999999 - 100 3. An interview on 02/12/2025 at 1:10 pm with TP 1 confirming the above findings. 4. The laboratory reported performing 2000 toxicology test annually. |
| **D5781** | CORRECTIVE ACTIONS |

| | |
|---|---|
| | CFR(s): 493.1282(b)(1)<br><br>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's Incident Reporting and Investigation Policy, lack of documentation, and interview with Testing Personnel 1 (TP1), the laboratory failed to document corrective actions taken from July 2024 through February 2025. Findings included: 1. Review of the laboratory's Incident Reporting and Investigation Policy stated, "Corrective actions must be documented and tracked to ensure that preventative measures are effective." 2. The laboratory was asked to provide documentation of corrective actions taken from July 2024 through February 2025, no documentation was provided. 3. During an Interview on 02/12/2025 at 11:50 with TP1, they indicated corrective action are not documented which confirmed the above findings. 4. The laboratory reports an estimated 2000 toxicology tests annually |
| **D6033** | TECHNICAL CONSULTANT-MODERATE COMPLEXITY<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 the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, the laboratory's Training and Competency Policy, lack of documentation and interview with Testing Personnel 2 (TP2), the laboratory failed to designate a qualified technical consultant (TC) to ensure all TC responsibilities were met as evidence by: 1. The technical consultant failed to meet the qualification requirements. Refer to D6109 2. The technical consultant failed to perform competency assessments for all testing personnel. Refer to D6121 |
| **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 (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 1 year of laboratory training or experience, or both, in nonwaived 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)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, and interview with testing personnel 2 (TP2), the laboratory failed to ensure 1 of 1 technical consultant (TC) met the qualification requirements from July 2024 through February 2025. Findings included: 1. A review of the CMS-209 revealed 1 personnel designated as the TC. 2. A review of personnel and education records revealed the personnel listed as the TC only had a high school diploma and did not meet the qualification requirements to qualify as TC. 3. An interview at 02/12/2025 at 10:00 am with TP 2 confirmed the above findings. 4. The laboratory reported performing 2000 toxicology test annually. |
| **D6046** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)<br><br>(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's Training and Competency Policy, lack of documentation and interview with Testing Personnel 2 (TP2), the Technical Consultant failed to perform competency assessments for 2 of 2 testing personnel for July 2024 to February 2025. Findings include: 1. A review of the laboratory's Training and Competency Policy stated, "All personnel must sign off on training and competency assessments, which will be documented in their personnel files." 2. The Laboratory was asked to provide competency assessment records for testing personnel during July 2024 to February 2025 when laboratory testing began. No records were provided. 3. During an interview on 02/12/2025 at 10:25 with TP2, they stated that competency assessments have not been performed for testing personnel which confirmed the above findings. 4. The laboratory reported an estimated 2000 toxicology tests annually. |
| **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 the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, ARK Ethyl Glucuronide (ETG) assay package insert, the laboratory's performance verification study, patient reports, and interview with Testing Personnel 2 (TP2) and a Siemens Technical Applications Specialist the laboratory director failed to provide overall direction and management of the laboratory as evidence by: 1. The laboratory director failed to meet the qualification requirements to oversee a high complexity laboratory. Refer to D6078 2. The laboratory director failed to ensure performance verification studies were done accurately for the analytes reported by the laboratory. Refer to D6086 3. The laboratory director failed to ensure all personnel meet the qualification requirements for their designated roles. D6102 |
| **D6078** | LABORATORY DIRECTOR QUALIFICATIONS<br>CFR(s): 493.1443<br><br>The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 (b)(2)(i) Be a doctor of medicine, a 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 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) |

| | |
|---|---|
| | Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of Pathology.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, and interview with testing personnel 2 (TP2), the laboratory failed to ensure the laboratory director (LD) met the qualification requirements to manage and direct a laboratory performing high complexity testing from July 2024 through February 2025. Findings included: 1. A review of the CMS-209 revealed 1 personnel designated as the LD. 2. A review of personnel and education records revealed the personnel listed as the LD had a Masters in Nursing and no documented experience or training in a high complexity laboratory, which did not meet the qualification requirements to qualify as a laboratory director over a high complexity laboratory. 3. An interview at 02/12/2025 at 10:00 am with TP 2 confirmed the above findings. 4. The laboratory reported performing 2000 toxicology test annually. |
| **D6086** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(ii)<br><br>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the ARK Ethyl Glucuronide (ETG) assay package insert, the laboratory's performance verification study, a FUO (forensic use only) Assay letter, patient reports, and interview with Testing Personnel 2 (TP2) and a Siemens Technical Applications Specialist, the laboratory director failed to ensure performance verification studies were accurately performed to include specificity and sensitivity for one forensic use only analyte (ETG) and to ensure the laboratory could result quantitative test results for 14 of 14 analytes for urine toxicology testing on the Beckman Coulter Au80 chemistry analyzer from July 2024 to February 2025. Refer to D5421 and D5423 |

| | |
|---|---|
| **D6102** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(12)<br><br>(e)(12) 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 the review of the Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, and interview with testing personnel 2 (TP2), the laboratory director failed to ensure all personnel met the qualification requirements for their designated roles and failed to designate a technical supervisor and general supervisor from July 2024 through February 2025. Findings included: 1. A review of the CMS-209 revealed 1 personnel listed as the technical consultant, 2 testing personnel listed to perform high complexity testing, and no personnel designated as the technical supervisor or general supervisor. 2. A review of personnel and education records revealed the personnel designated as technical consultant and high complexity testing personnel did not meet the qualification requirements to qualify for those roles. 3. An interview at 02/12/2025 at 10:00 am with TP 2 confirmed the above findings. 4. The laboratory reported performing 2000 toxicology test annually. |
| **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 the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, the laboratory's Training and Competency Policy, lack of documentation and interview with Testing Personnel 2 (TP2), the laboratory failed to designate a qualified technical supervisor (TS) to ensure all TS responsibilities were met as evidence by: 1. The laboratory failed to designate a technical supervisor that met the qualification requirements. Refer to D6109 2. The technical supervisor failed to perform competency assessments for all testing personnel. Refer to D6121 |
| **D6109** | TECHNICAL SUPERVISOR QUALIFICATIONS<br>CFR(s): 493.1449<br><br>The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical supervision for each of the specialties and subspecialties of service in which the laboratory performs high complexity tests or procedures. The director of a laboratory performing high complexity testing may function as the technical supervisor provided he or she meets the qualifications specified in this section. |

| | |
|---|---|
| | This STANDARD is not met as evidenced by:<br>Based on the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, and interview with testing personnel 2 (TP2), the laboratory failed to designate a technical supervisor (TS) that met the qualification requirements from July 2024 through February 2025. Findings included: 1. A review of the CMS-209 revealed the laboratory failed to designate a TS. 2. A review of personnel and education records revealed no personnel met the qualifications requirements to qualify as a TS. 3. An interview at 02/12/2025 at 10:00 am with TP 2 confirmed the above findings. 4. The laboratory reported performing 2000 toxicology test annually. |
| **D6121** | TECHNICAL SUPERVISOR RESPONSIBILITIES<br>CFR(s): 493.1451(b)(8)(i)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to-- (b)(8)(i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;<br><br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's Training and Competency Policy, lack of documentation and interview with Testing Personnel 2 (TP2), the Technical Supervisor failed to perform competency assessments for 2 of 2 testing personnel for July 2024 to February 2025. Findings include: 1. A review of the laboratory's Training and Competency Policy stated, "All personnel must sign off on training and competency assessments, which will be documented in their personnel files." 2. The Laboratory was asked to provide competency assessment records for testing personnel during July 2024 to February 2025 when laboratory testing began. No records were provided. 3. During an interview on 02/12/2025 at 10:25 with TP2, they stated that competency assessments have not been performed for testing personnel which confirmed the above findings. 4. The laboratory reported performing 2000 toxicology test annually. |
| **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 the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, and interview with testing personnel 2 (TP2), the laboratory failed to designate a general supervisor (GS) that met the qualification requirements from July 2024 through February 2025. 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 (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, biological, clinical or medical 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)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (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 (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g).<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, and interview with testing personnel 2 (TP2), the laboratory failed to designate a general supervisor (GS) that met the qualification requirements from July 2024 through February 2025. Findings included: 1. A review of the CMS-209 revealed the laboratory failed to designate a GS. 2. A review of personnel and education records revealed no personnel met the qualifications requirements to qualify as a GS. 3. An interview at 02/12/2025 at 10:00 am with TP 2 confirmed the above findings. 4. The laboratory reported performing 2000 toxicology test annually. |
| **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: |

| | |
|---|---|
| | Based on the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, and interview with testing personnel 2 (TP2), the laboratory failed to ensure 2 of 2 testing personnel were qualified as high complexity testing personnel. 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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of Centers for Medicare & Medicaid Services Laboratory Personnel Report form 209 (CMS-209), personnel and education records, and interview with testing personnel 2 (TP2), the laboratory failed to ensure 2 of 2 testing personnel were qualified as high complexity testing personnel for July 2024 to February 2025. Findings included: 1. A review of the CMS-209 revealed 2 testing personnel designated to perform high complexity testing. 2. A review of personnel and education records revealed the 2 testing personnel did not meet the qualification |

| | |
|---|---|
| | requirements to perform high complexity testing. 3. An interview on 02/12/2025 at 10: 00 am with TP 2 confirmed the above findings. 4. The laboratory reported performing 2000 toxicology test annually. |