

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 23D2068079	<b>(X3) Date Survey Completed</b> 10/14/2024
<b>Name of Provider or Supplier</b> Vitruvian Health	<b>Street Address, City, State</b> 431 Swartz Ct, Ste 200, Ionia, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An unannounced complaint investigation was completed on October 14, 2024 at Vitruvian Health by the State of Michigan Licensing and Regulatory Affairs Department. During the investigation, it was determined the laboratory was out of compliance with the following condition-level deficiencies: 493.1230 Condition: General laboratory systems 493.1250 Condition: Analytic systems 493.1441 Condition: Laboratories performing high complexity testing; laboratory director 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor
<b>D5200</b>	<p><b>GENERAL LABORATORY SYSTEMS</b> CFR(s): 493.1230</p> <p>Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to establish competency assessment policies (refer to D5209) and failed to verify the accuracy of its Thermo Scientific Indiko Plus analyzer and Applied Biosystems MDS Sciex analyzer (refer to D5217).</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,</p>

consultant competency.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the technical supervisor, the laboratory failed to establish competency assessment policies for 13 (September 2023 to October 2024) of 13 months reviewed. Findings include: 1. A review of the laboratory's Form CMS-209 revealed the laboratory employed one testing personnel. 2. A review of the competency assessment documentation for the testing personnel performed on 9/16/23 revealed it had been performed as a self-assessment. 3. The surveyor requested the laboratory's competency assessment policy on 10/14/24 and it was not made available. 4. An interview on 10/14/24 at 1:45 pm with the technical supervisor confirmed the laboratory had not established competency assessment policies.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**  
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the technical supervisor, the laboratory failed to verify the accuracy of its Thermo Scientific Indiko Plus analyzer and Applied Biosystems MDS Sciex analyzer for 13 (September 2023 to October 2024) of 13 months reviewed. Findings include: 1. A review of the laboratory's test menu revealed it tests the following analytes not listed under Subpart I: a. Oxycodone b. Fentanyl c. Opioids d. Benzodiazepine e. Barbiturates f. Amphetamine g. Benzoylcegonine h. Methadone i. 6-MAM j. 7-Aminoclonazepam k. Alphahydroxyalprazolam l. Alprazolam m. Amphetamine n. Butalbital o. Carisoprodol p. Codeine q. Diazepam r. EDDP s. Ethyl sulfate t. Gabapentin u. Hydrocodone v. Hydromorphone w. Ketamine x. Meprobamate y. Methamphetamine z. Mitragynine aa. Morphine bb. Naloxone cc. Norbuprenorphine dd. Nordiazepam ee. Norfentanyl ff. Norhydrocodone gg. Norketamine hh. Noroxycodone ii. Oxymorphone jj. Pregabalin kk. Tapentadol ll. Tramadol mm. Urine specific gravity nn. Urine pH oo. Urine creatinine 2. A review of the laboratory's twice annual verification of accuracy documentation revealed a lack of records between September 2023 to October 2024 to verify accuracy of its Thermo Scientific Indiko Plus toxicology testing and Applied Biosystems MDS Sciex toxicology testing. 3. An interview on 10/14/24 at 2:35 pm with the technical supervisor confirmed the laboratory had not verified the accuracy of its Thermo Scientific Indiko Plus toxicology testing and Applied Biosystems MDS Sciex toxicology testing.

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
. Based on observation, record review, and interviews, the laboratory failed to have a procedure manual to include specimen collection, labeling, acceptability, rejection criteria, and control procedures (refer to D5403), failed to monitor and document temperatures of its laboratory, specimen and reagent refrigerator, and reagent freezer (refer to D5413), failed to label its reagents, solutions, control materials, and calibration materials with the identity, preparation and expiration dates (refer to D5415), failed to ensure reagents, control materials, and calibration materials were not used beyond expiration dates (refer to D5417), failed to verify performance specifications for its Thermo Scientific Indiko Plus analyzer prior to using it for patient testing (refer to D5421), and failed to perform and document instrument maintenance for its Thermo Scientific Indiko Plus analyzer (refer to D5433).

**D5403**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the technical supervisor, the laboratory failed to have a procedure manual to include specimen collection, labeling, acceptability, rejection criteria, and control procedures for 13 (September 2023 to October 2024) of 13 months reviewed. Findings include: 1. A review of the laboratory's procedure manuals revealed a lack of test procedures including specimen collection, labeling, acceptability, rejection criteria, and control procedures. 2. An interview on 10/14/24 at 2:46 pm with the technical supervisor confirmed specimen collection, labeling, acceptability, rejection criteria, and control procedure components were not included in the procedure manuals.

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interview with the testing personnel, the laboratory failed to monitor and document temperatures of its laboratory, specimen and reagent refrigerator, and reagent freezer for two (9/28/24 and 10/13/24) of two testing dates reviewed. Findings include: 1. The surveyor observed the laboratory on 10/14/24 at 11:08 am and the space felt warm. There was a refrigerator with reagents, controls, calibrators, and patient specimens as well as a freezer with standards inside. 2. A review of the laboratory's temperature monitoring revealed a lack of documentation for 9/28/24 and 10/13/24. 3. A review of patient testing records revealed a total of 78 patient urine samples were tested on 9/28/24 and 170 patient urine samples were tested on 10/13/24 using the laboratory's Thermo Scientific Indiko Plus analyzer and Applied Biosystems MDS Sciex analyzer. 4. An interview on 10/14/24 at 3:42 pm with the testing personnel confirmed temperatures were not documented.

**D5415**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

. Based on observation and interview with the Clinical Outreach Director, the laboratory failed to label its reagents, solutions, control materials, and calibration materials with the identity, preparation and expiration dates for seven reagents observed. Findings include: 1. The surveyor observed the following reagents, control materials, and calibration materials without either the identity, preparation or expiration dates on 10/14/24 at 11:08 am: a. An unlabeled urine cup with urine inside. b. An unlabeled glass vial with a black top with clear fluid inside. c. A brown vial with a black top with "IS MCS mix." d. An unlabeled brown vial with a black top with a white label. e. IMCSzyme bottle lot #R24-01001. f. A box labeled "Interval Standards" g. A box with 73 small vials with no list of contents, preparation, and expiration dates. 2. A review of patient testing records revealed a total of 78 patient urine samples were tested on 9/28/24 and 170 patient urine samples were tested on 10/13/24 using the laboratory's Thermo Scientific Indiko Plus analyzer and Applied Biosystems MDS Sciex analyzer. 3. An interview on 10/14/24 at 11:35 am with the Clinical Outreach Director confirmed the reagents and supplies listed above did not include identity, preparation, or expiration dates.

**D5417**

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other

supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

. Based on observation and interviews, the laboratory failed to ensure reagents, control materials, and calibration materials were not used beyond their expiration dates for 43 items observed. Findings include: 1. The surveyor observed the following expired reagents, control materials, and calibration materials on 10/14/24 at 11:08 am: a. A glass vial with a black top and clear fluid inside labeled "LS/LMCS 7/15/24." b. Room Temperature Buffer with the expiration date of "01/2024." c. DRI pH-Detect calibrator pH 11 with the expiration date of 5/31/24. d. DRI Creatinine-Detect calibrator 2.0 mg/dL with the expiration date of 5/31/24. e. DRI Creatinine-Detect calibrator 20.0 mg/dL Calibrator with the expiration date of 5/31/24. f. DRI Drugs of Abuse Low Calibrator with the expiration date of 6/30/24. g. DRI Multi-Drug Urine Calibrator 2 with the expiration date of 9/30/24. h. MAS DOA Total Liquid Assayed Drugs of Abuse Control 2 expired 4/22/24. i. MAS DOA Total Liquid Assayed Drugs of Abuse Control 3 expired 3/22/24. j. MAS DOA Total Liquid Assayed Drugs of Abuse Control 4 expired 7/28/24. k. MAS DOA Total Liquid Assayed Drugs of Abuse Control 5 expired 7/28/24. l. DRI Creatinine-Detect 1.3 mg/dL control expired 5/31/24. m. DRI Creatinine-Detect 23.0 mg/dL control expired 5/31/24. n. DRI pH-Detect pH 3.6 control expired 9/30/24. o. DRI pH-Detect pH 7.0 control expired 5/31/24. p. Methyl Alcohol, Absolute expired 10/31/23. q. Three bottles of Honeywell LC-MS Water expired on 5/6/24. r. "Needle rinse" attached to the Applied Biosystems MDS Sciex analyzer with the expiration date of 6/16/24. s. "MPA" attached to the Applied Biosystems MDS Sciex analyzer with the expiration date of 7/26/24. t. "M3P" attached to the Applied Biosystems MDS Sciex analyzer with the expiration date of 7/26/24. u. A glass vial labeled "Stock" with the expiration date of 9/16/24. v. A box labeled "Internal Standard Top Methanol Stocks" expiration date of 9/16/24. w. A box labeled "Top Stock" with the expiration date of 8/15/23. x. A box labeled "Standards Chemical Kit with Low/High Concentration PPGs" with 18 bottles inside with the expiration date of 8/31/23. y. DRI Multidrug Urine Calibrator 1 with the expiration date of 6/30/24. z. Benzodiazepine Enzyme Immunoassay reagent with the expiration date of 2/29/24. 2. A review of patient testing records revealed a total of 78 patient urine samples were tested on 9/28/24 and 170 patient urine samples were tested on 10/13/24 using the laboratory's Thermo Scientific Indiko Plus analyzer and Applied Biosystems MDS Sciex analyzer. 3. An interview on 10/14/24 at 11:35 am with the Clinical Outreach Director confirmed the reagents and supplies listed above had exceeded expiration dates.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

	<p>. Based on record review and interview with the testing personnel, the laboratory failed to verify performance specifications for its Thermo Scientific Indiko Plus analyzer prior to using it for patient testing for 13 (September 2023 to October 2024) of 13 months the instrument has been in use. Findings include: 1. A review of the laboratory's Thermo Scientific Indiko Plus analyzer's verification of performance specifications revealed a lack of laboratory director's review and approval. 2. An interview on 10/14/24 at 2:16 pm with the testing personnel revealed the verification of performance specifications had not been performed by the laboratory.</p>
<p><b>D5433</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on record review, and interview with the testing personnel, the laboratory failed to perform and document instrument maintenance for its Thermo Scientific Indiko analyzer for two (9/28/24 and 10/13/24) of two testing dates reviewed. Findings include: 1. A review of the laboratory's "Indiko Plus SOP" revealed a section titled "Service" stating, "Following the first run of every month, perform the monthly maintenance highlighted in the Indiko Maintenance Form. Following every run, perform the weekly maintenance and disengage the reagent wheel, storing it in the fridge. After each run, perform shutdown operations using the Thermo bleach solution. WashSol must be selected in a rack, controls and placed in a rack. Clear daily files after each run." 2. A review of the laboratory's maintenance logs revealed a lack of documentation of maintenance performed for 9/28/24 and 10/13/24. 3. A review of patient testing records revealed a total of 78 patient urine samples were tested on 9/28/24 and 170 patient urine samples were tested on 10/13/24 using the laboratory's Thermo Scientific Indiko Plus analyzer. 4. An interview on 10/14/24 at 3: 42 pm with the testing personnel confirmed maintenance was not documented.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p> <p>. Based on observation, record review, and interviews, the laboratory director failed to ensure compliance with 493.61 Requirements for a certificate of accreditation to comply with the requirements of the approved accreditation program (refer to D6079), failed to ensure the laboratory verified performance specifications for its Thermo Scientific Indiko Plus analyzer prior to using it for patient testing (refer to D6082), failed to ensure quality assessment programs were established (refer to D6094), failed</p>

to ensure the laboratory verified the accuracy of its using the laboratory's Thermo Scientific Indiko Plus testing and Applied Biosystems MDS Sciex testing (refer to D6095), failed to ensure remedial actions were taken then expired reagents, controls, calibrators, and supplies were used to perform patient testing (refer to D6096), failed to ensure the technical supervisor was qualified (refer to D6101), failed to ensure competency assessment policies were established to assess its laboratory staff (refer to D6103), and failed to ensure the procedure manual included specimen collection, labeling, acceptability, rejection criteria, and control procedures (refer to D6106).

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(a)(b)

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.

This STANDARD is not met as evidenced by:  
. Based on record review and interview with the Clinical Outreach Director, the laboratory director failed to assure compliance with 493.61 Requirements for a certificate of accreditation to comply with the requirements of the approved accreditation program for two (9/28/24 and 10/13/24) of two total testing dates since the laboratory was required to cease testing using its Applied Biosystems MDS Sciex quantitative urine toxicology analyzer on 6/11/24. Findings include: 1. A review of the 6/11/24 letter to the laboratory from their accreditation organization, The Commission on Office Laboratory Accreditation (COLA), revealed a section stating, "At the time of survey, you were informed that the laboratory was being referred to the Staff Technical Accreditation Team (STAT) for decision on serious issues identified by the Surveyor. The documents required, which are listed below, should be marked with your COLA ID and sent to COLA within 30 days from the date of this letter. The laboratory is required to cease patient drug confirmation testing performed on the LCMS analyzer." and "Prior to resuming patient testing, the laboratory must adhere to the below requests and submit the following documentation. If it is acceptable, COLA will notify the laboratory when you may resume patient testing." 2. A review of patient testing records revealed a total of 78 patient urine samples were tested on 9/28/24 and 170 patient urine samples were tested on 10/13/24 using the laboratory's Thermo Scientific Indiko Plus qualitative toxicology analyzer and Applied Biosystems MDS Sciex quantitative urine toxicology analyzer. 3. An interview on 10/14/24 at 10:31 am with the Clinical Outreach Director revealed the laboratory had not come back into compliance with their accreditation organization COLA and had not received notification testing could resume.

**D6082**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(1)

The laboratory director must ensure that testing systems developed and used for each

	<p>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.</p> <p>This STANDARD is not met as evidenced by:  . Based on record review and interview, the laboratory director failed to ensure the laboratory verified performance specifications for its Thermo Scientific Indiko Plus analyzer prior to using it for patient testing. Refer to D5421.</p>
<b>D6094</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  . Based on record review and interview with the technical supervisor, the laboratory director failed to ensure quality assessment programs were established for 13 (September 2023 to October 2024) of 13 months reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of quality assessment program. 2. An interview on 10/14/24 at 3:00 pm with the technical supervisor a quality assessment program had not been established.</p>
<b>D6095</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by:  . Based on record review and interview, the laboratory director failed to ensure the laboratory verified the accuracy of its Thermo Scientific Indiko Plus analyzer and Applied Biosystems MDS Sciex analyzer. Refer to D5217.</p>
<b>D6096</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(7)</p> <p>The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.</p> <p>This STANDARD is not met as evidenced by:  Based on observation and interview, the laboratory director failed to ensure remedial actions were taken then expired reagents, controls, calibrators, and supplies were used to perform patient testing. Refer to D5417.</p>
<b>D6101</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(11)</p>

The laboratory director must 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 in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory director failed to ensure the technical supervisor was qualified. Refer to D6111.

**D6103**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(13)

The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory director failed to ensure competency assessment policies were established. Refer to D5209.

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to ensure the procedure manual included specimen collection, labeling, acceptability, rejection criteria, and control procedures. Refer to D5403.

**D6108**

**LABORATORY TECHNICAL SUPERVISOR**

CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:

. Based on record review and interview with the technical supervisor, the laboratory failed to ensure the technical supervisor was qualified (refer to D6111), failed to verify performance specifications for its Thermo Scientific Indiko Plus analyzer prior to using it for patient testing (refer to D6115), and failed to evaluate the competency of testing personnel (refer to D6120).

## TECHNICAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1449

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited

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

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

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

individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (l)(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 (l)(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 record review and interview with the technical supervisor, the laboratory failed to ensure the Technical Supervisor was qualified for one technical supervisor listed on Form CMS-209. Findings include: 1. A review of the laboratory's Form CMS-209 revealed the laboratory had selected one technical supervisor. 2. A review of the technical supervisor's personnel records revealed a lack of documentation supporting their qualifications for serving as technical supervisor in the specialty of chemistry. 3. An interview on 10/14/24 at 3:52 pm with the technical supervisor confirmed documentation of qualifications to serve as technical supervisor in the specialty of chemistry were not available.

**D6115**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
 CFR(s): 493.1451(b)(2)

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.

This STANDARD is not met as evidenced by:  
 . Based on record review and interview, the Technical Supervisor failed to verify performance specifications for its Thermo Scientific Indiko Plus analyzer prior to using it for patient testing. Refer to D5421.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
 CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain

their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the technical supervisor failed to evaluate the competency of testing personnel. Refer to D5209.