Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2287003	05/07/2024
Name of Provider or Supplier	**Street Address, City, State**	
Concord Life Sciences, Llc Dba Principle	9840 Lorene Lane, San Antonio, TX	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Abbott iSTAT analyzer, review of patient test samples from 4/15/2024 to 05/05/2024, and staff interview, the laboratory failed to ensure samples were testing within the manufacturer's required time for 2 of 15 samples. The findings included: 1. A review of the manufacturer's instructions for the Abbot iSTAT (Art: 714258-000V, Rev. Date: 18-OCT-2021) under the section titled "Test Timing" determined: "Within 30 minutes of collection Samples collected with anticoagulant for the measure of sodium, potassium, chloride, glucose, BUN/UREA, creatinine, hematocrit, troponin I, CK-MB, beta-hCG and BNP." 2. A sampling of patient test samples from 4/15/2024 to 05/05/2024 identified 2 of 15 patients whose samples were tested more than 30 minutes after collection. They were: a) Specimen ID: 33141 Test date: 04/15/2024 Collected: 04/15/2024 4:08 pm Tested: 04/15/2024 4:46 pm Elapsed time: 38 minutes Tests performed: sodium potassium chloride glucose BUN creatinine b) Specimen ID: 132844 Test date: 04/29 /2024 Collected: 04/29/2024 3:18 pm Tested: 04/29/2024 4:02 pm Elapsed time: 44

	minutes Tests performed: sodium potassium chloride glucose BUN creatinine 3. The laboratory was asked to provide documentation of performing testing within the manufacturer's requirements. No documentation was provided. 4. The laboratory director confirmed the findings after reviewing the records on 05/07/2024 at 1200 hours in the conference room.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, review of manufacturer's instructions and staff interview, the laboratory failed to provide overall quality in analytic systems. The findings include: 1. The laboratory failed to have documentation of verifying results with flags following manufacturer's instructions on 2 of 2 hematology results (refer to D5411 I). 2. The laboratory failed to have documentation of monitoring the temperature of 6 of 6 shipments received to ensure the cartridges were not exposed to temperature outside the manufacturer's acceptable range (refer to D5411 II). 3. The laboratory failed to have documentation of verifying patient normal ranges for 40 of 40 hematology tests, 7 of 7 basic metabolic panel tests, and 1 of 1 b-type natriuretic peptide tests (refer to D5421). 4. The laboratory failed to have documentation of monitoring quality control values over time for 4 of 4 hematology control lots, 3 of 3 troponin control lots, 4 of 4 basic metabolic panel control lots, and 4 of 4 b-type natriuretic peptide control lots (refer to D5441). 5. The laboratory failed to have documentation of developing a Risk assessment and Quality Assurance Plan as part of its Individualized Quality Control Plans control testing on 1 of 1 PixCell Hemoscreen analyzers and 3 of 3 Abbott iSTAT analyzers (refer to D5445). 6. The laboratory failed to have documentation of verifying 4 of 4 hematology control lots, 3 of 3 troponin control lots, 4 of 4 basic metabolic panel control lots, and 4 of 4 b-type natriuretic peptide control lots prior to use (refer to D5469). 7. The laboratory failed to have a quality assurance plan which could identify and correct issues in analytic systems (refer to D5791).
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of the manufacturer's instructions for the PixCell HemoScreen analyzer, review of patient records from 04/30/2024 to 05/04/2024 and staff interview, the laboratory failed to have documentation of verifying results with flags

	following manufacturer's instructions on 2 of 2 hematology results. The findings included: 1. A review of the operating manual for the PixCell HemoScreen analyzer (Ref: US-EL-00002) under the section titled "10.2 Flags Requiring Further Review" determined: a) FLAG: Asterisk (*) "Parameter: WBC, NEUT#/LYMP#/MONO# /EOS#/BASO#/NEUT%/LYMP%/MONO%/EOS%/BASO% Interpretation: The sample may contain the following abnormal cells: Nucleated RBCs (NRBCs), Immature Granulocytes (IGs), Blast cells, Atypical Lymphoctes, Band Forms. Results are displayed." 2. A sampling of patient test records from 04/30/2024 to 05/04/2024 identified 2 of 17 patient reports with flagged results which were reported to the provider. They were: a) Date: 04/30/2024 Specimen ID: 802004 Flag: * Parameters: NEUT#/LYMP#/MONO#/EOS#/BASO#/NEUT%/LYMP%/MONO%/EOS% /BASO% b) Date: 05/03/2024 Specimen ID: 805792 Flag: * Parameters: NEUT# /LYMP#/MONO#/EOS#/BASO#/NEUT%/LYMP%/MONO%/EOS%/BASO% 3. The laboratory was asked to provide documentation of verifying the results listed above. No documentation was provided. 4. The laboratory manager confirmed the finding in an interview conducted on 05/07/2024 at 1330 hours in the conference room. II. Abbott iSTAT analyzer, review of reagent log sheet from November 2023 to March 2024, and staff interview, the laboratory failed to have documentation of monitoring the temperature of 6 of 6 shipments received to ensure the cartridges were not exposed to temperature outside the manufacturer's acceptable range. The findings included: 1. A review of the manufacturer's instructions for the Abbott iSTAT (Art: 714258-000V, Rev. Date: 18-OCT-2021) determined: "Fill out records of receipt and forward with material to refrigeration. Read the temperature strip without delay since it will change with exposure to room temperature. Do not use cartridges and contact iSTAT Technical Support within 24 hours if window 3 or window 4 are colored... record the temperature strip reading" 2. A review of the laboratory's reagent log sheet from November 2023 to March 2024 identified the laboratory received 5 shipments of cartridges. They were: a) Date: 11/24/2023 Lots: 301161, 321163 b) Date: 01/27/2024 Lots: 011176, 031176 c) Date: 02/22/2024 Lot: 23067 d) Date: 02/27/2024 Lots: 061179, 041179 e) Date: 03/09/2024 Lots: 031171, 011171 f) Date: 03/31/2024 Lots: 031171,01171 3. The laboratory was asked to provide documentation of recording the temperature of each shipment to ensure it was received within the required temperature range. No documentation was provided. 4. The laboratory director confirmed the findings after her review of the records in an interview conducted on 05 /07/2024 at 1440 hours in the conference room. Key WBC: white blood cell RBC: red blood cell NEUT: neutrophil LYMP: lymphocyte MONO: monocyte EOS: eosinophil BASO: basophil
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 review of the manufacturer's instructions for the R&D Systems CBC-PIX hematology controls, surveyor observation of control material currently in use, review of the laboratory's quality control records from 04/04/2024 to 05/07/2024, review of patient test records from 04/15/2024 to 05/07/2024 and staff interview, the laboratory failed to ensure expired control material was not used on 2 of 2 quality control testing days. The findings include: 1. A review of the manufacturer's instructions for the

	R&D Systems CBC-PIX hematology controls (IS182-002 Rev. 10/21) under the section titled "Stability and Storage" determined: "Opened vials are stable for 14 days, provided they are handled properly." 2. Surveyor observation of control material currently in use in the laboratory on 05/07/2024 at 1400 hours identified the follow: CBC-PIX controls Lot: PIX240605 Levels: Low, Normal, High In use date: 03/20 /2024 3. A review of the laboratory's quality control records from 04/04/2024 to 5/17 /2024 determined the expired control material was tested on the following 2 days: 04 /15/2024 05/06/2024 4. A review of patient test records from 04/15/2024 to 05/07 /20204 identified 328 patient samples tested when expired control material was in use (see patient alias list #1). 5. The laboratory director confirmed the findings in an interview conducted on 05/07/2024 at 1410 hours in the conference room.
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: Based on review of the laboratory's verification studies for the PixCell Hemoscreen analyzer, review of the laboratory's verification studies for the Abbott iSTAT analyzers, review of patient test reports, and staff interview, the laboratory failed to have documentation of verifying patient normal ranges for: A) 40 of 40 hematology tests B) 7 of 7 basic metabolic panel tests C) 1 of 1 b-type natriuretic peptide tests The findings include: A) 40 of 40 hematology tests 1. A review of the laboratory's verification studies for the PixCell Hemoscreen analyzer performed in 09/2024 identified the laboratory failed to have documentation of verifying patient normal ranges. 2. A review of the patient testing reports for hematology identified the following patient normal ranges were in use: a) Male WBC: 4.2 - 9.1 RBC: 4.63 - 6.08 Hemoglobin: 13.7 - 17.5 Hematocrit: 40.1 - 51.0 MCV: 79.0 - 102.0 MCH: 25.6 - 32.3 MCHC: 32.2 - 35.5 RDW: 11.6 - 14.4 Platelet: 163 - 337 MPV: 8.0 - 12.0 Neutrophil#: 1.78 - 5.38 Lymphocyte#: 1.32 - 3.57 Monocyte#: 0.30 - 0.82 Eosinophil#: 0.04 - 0.54 Basophil#: 0.01 - 0.08 Neutrophil%: 34.0 - 67.9 Lymphocyte%: 21.8 - 53.1 Monocyte%: 5.3 - 12.2 Eosinophil%: 0.8 - 7.0 Basophil%: 0.2 - 1.2 b) Female WBC: 4.0 - 10.0 RBC: 3.93 - 5.22 Hemoglobin: 11.2 - 15.7 Hematocrit: 34.1 -44.9 MCV: 79.0 - 102.0 MCH: 25.6 - 32.3 MCHC: 32.2 - 35.5 RDW: 11.6 - 14.4 Platelet: 182 - 369 MPV: 8.0 - 12.0 Neutrophil#: 1.56 - 6.13 Lymphocyte#: 1.18 - 3.74 Monocyte#: 0.24 - 0.86 Eosinophil#: 0.04 - 0.36 Basophil#: 0.01 - 0.08 Neutrophil%: 34.0 - 71.1 Lymphocyte%: 19.3 - 51.7 Monocyte%: 4.7 - 12.5 Eosinophil%: 0.7 - 5.8 Basophil%: 0.1 - 1.2 3. The laboratory was asked to provide documentation of verifying the listed patient normal ranges. No documentation was provided. 4. The laboratory stated it performed 2465 hematology tests annually. 5. The laboratory director confirmed the findings in an interview conducted on 05/07/2024 at 1215 hours in the conference room. B) 7 of 7 basic metabolic tests 1. A review of the laboratory's verification studies for the Abbott iSTAT analyzers performed in 01/2024 and 002/2024 identified the laboratory failed to have documentation of verifying patient normal ranges. 2. A review of the patient

	testing reports for hematology identified the following patient normal ranges were in use: Sodium: 136 - 145 Potassium: 3.5 -5.1 Chloride: 98.0 - 107.0 CO2: 23 - 31 Glucose: 82 - 115 BUN: 8 - 26 Creatine: 0.72 - 1.25 3. The laboratory was asked to provide documentation of verifying the listed patient normal ranges. No documentation was provided. 4. The laboratory stated it performed 1576 tests annually. 5. The laboratory director confirmed the findings in an interview conducted on 05/07/2024 at 1215 hours in the conference room. B) 1 of 1 b-type natriuretic peptide tests 1. A review of the laboratory's verification studies for the Abbott iSTAT analyzers performed in 01/2024 and 002/2024 identified the laboratory failed to have documentation of verifying patient normal ranges. 2. A review of the patient testing reports for hematology identified the following patient normal ranges were in use: BNP: 0 - 100 3. The laboratory was asked to provide documentation of verifying the listed patient normal ranges. No documentation was provided. 4. The laboratory stated it performed 248 tests annually. 5. The laboratory director confirmed the findings in an interview conducted on 05/07/2024 at 1215 hours in the conference room. Key: WBC: white blood cell RBC: red blood cell MCV: mean corpuscular volume MCH: mean corpuscular hemoglobin MCHC: mean corpuscular hemoglobin concentration RDW: red cell distribution width MPV: mean platelet volume CO2: carbon dioxide BUN: blood urea nitrogen
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from October 2023 to April 2024, and staff interview, the laboratory failed to have documentation of monitoring quality control values over time for 4 of 4 hematology control lots, 3 of 3 troponin control lots, 4 of 4 basic metabolic panel control lots, and 4 of 4 b-type natriuretic peptide control lots. The findings include: 1. A review of the laboratory's R&D Systems CBC-PIX hematology control records from October 2023 to April 2024 identified the following 4 lots were used by the laboratory: Lot: 240205 Lot: 240605 Lot: 231205 Lot: 231005 2. A review of the laboratory's troponin control records from January 2024 to April 2024 identified the following 3 lots were used by the laboratory: Lot: 301163 Lot: 321168 Lot: 301161 3. A review of the laboratory's basic metabolic panel control records from January 2024 to April 2024 identified the following 4 lots were used by the laboratory: Lot: 011171 Lot: 031171 Lot: 031164 Lot: 011164 4. A review of the laboratory's b-type natriuretic peptide control records from January 2024 to April 2024 identified the following 3 lots were used by the laboratory: Lot: 041179 Lot: 061179 Lot: 041158 Lot: 061158 5. The laboratory was

	asked to provide documentation of monitoring quality control values over time. No documentation was provided. 6. The laboratory director confirmed the findings in an interview conducted on 05/17/2024 at 1250 hours in the conference room.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control program, review of the laboratory's quality control records from October 2023 to May 2024, and staff interview, the laboratory failed to have documentation of developing a Risk assessment and Quality Assurance Plan as part of its Individualized Quality Control Plans control testing on 1 of 1 PixCell Hemoscreen analyzers and 3 of 3 Abbott iSTAT analyzers. The findings included: 1. A review of the laboratory's Quality Control Program (approved by the laboratory director on 02/01/2024) under the section titled "Quality Control Guidelines" revealed: a) Hemoscreen: "Hemoscreen CBC analyzer will have 3 levels of controls run for each new lot number of test cartridges, each new shipment of cartridges, every 30 days." And, b) iSTAT: "iSTAT Chem8+, Troponin I, and BNP cartridges will have 2 levels of controls are [sic] run with each new lot number or reagents and every thirty days after IQCP evaluation is completed." 2. A review of the laboratory's quality control records from October 2023 to May 2024 revealed the laboratory performed quality control testing on the PixCell Hemoscreen and three Abbott iSTATs as stated in the Quality Control Program. 3. The laboratory was asked to provide documentation of completing the risk assessments and developing the quality assurance plan for each of the analyzers and the tests performed to support the modification of the frequency of the control testing. No documentation was provided. 4. The laboratory director confirmed the findings in an interview conducted on 5/07 /2024 at 1315 hours in the conference room.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must

	document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from October 2023 to April 2024, and staff interview, the laboratory failed to have documentation of verifying 4 of 4 hematology control lots, 3 of 3 troponin control lots, 4 of 4 basic metabolic panel control lots, and 4 of 4 b-type natriuretic peptide control lots prior to use. The findings include: 1. A review of the laboratory's R&D Systems CBC-PIX hematology control records from October 2023 to April 2024 identified the following 4 lots were used by the laboratory: Lot: 240205 Lot: 240605 Lot: 231205 Lot: 231005 2. A review of the laboratory's troponin control records from January 2024 to April 2024 identified the following 3 lots were used by the laboratory: Lot: 301163 Lot: 321168 Lot: 301161 3. A review of the laboratory's basic metabolic panel control records from January 2024 to April 2024 identified the following 4 lots were used by the laboratory: Lot: 011171 Lot: 031171 Lot: 031164 Lot: 011164 4. A review of the laboratory's b-type natriuretic peptide control records from January 2024 to April 2024 identified the following 3 lots were used by the laboratory: Lot: 041179 Lot: 061179 Lot: 041158 Lot: 061158 5. The laboratory was asked to provide documentation of verifying the new lots prior to use. No documentation was provided. 6. The laboratory director confirmed the findings in an interview conducted on 05/17 /2024 at 1250 hours in the conference room.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, review of manufacturer's instructions and staff interview, the laboratory's quality assessment plan failed to identify and correct problems in analytic systems. The findings include: 1. The laboratory's quality assessment plan failed to ensure results with flags were verified following manufacturer's instructions on 2 of 2 hematology results (refer to D5411 I). 2. The laboratory's quality assessment plan failed to ensure the laboratory documented the temperature of 6 of 6 shipments received to ensure the cartridges were not exposed to temperature outside the manufacturer's acceptable range (refer to D5411 II). 3. The laboratory's quality assessment plan failed to ensure patient normal ranges were verified for 40 of 40 hematology tests, 7 of 7 basic metabolic panel tests, and 1 of 1 b-type natriuretic peptide tests (refer to D5421). 4. The laboratory's quality assessment plan failed to ensure quality control values were monitored over time for 4 of 4 hematology control lots, 3 of 3 troponin control lots, 4 of 4 basic metabolic panel control lots, and 4 of 4 b-type natriuretic peptide control lots (refer to D5441). 5. The laboratory's quality assessment plan failed to ensure a Risk assessment and Quality Assurance Plan were developed as part of its Individualized Quality Control Plans control testing on 1 of 1 PixCell Hemoscreen analyzers and 3 of 3 Abbott iSTAT analyzers (refer to D5445). 6. The laboratory's quality assessment plan failed to

	ensure 4 of 4 hematology control lots, 3 of 3 troponin control lots, 4 of 4 basic metabolic panel control lots, and 4 of 4 b-type natriuretic peptide control lots were verified prior to use (refer to D5469).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Control Program, review of the laboratory's quality control records, and staff interview, the laboratory director failed to ensure a quality control program was developed and followed to assure quality. The findings included: 1. The laboratory director failed to ensure expired control material was not used (refer to D5417). 2. The laboratory director failed to ensure quality control values were monitored over time for 4 of 4 hematology control lots, 3 of 3 troponin control lots, 4 of 4 basic metabolic panel control lots, and 4 of 4 b-type natriuretic peptide control lots (refer to D5441). 3. The laboratory director failed to ensure a Risk assessment and Quality Assurance Plan were developed as part of its Individualized Quality Control Plans control testing on 1 of 1 PixCell Hemoscreen analyzers and 3 of 3 Abbott iSTAT analyzers (refer to D5445). 4. The laboratory director failed to ensure 4 of 4 hematology control lots, 3 of 3 troponin control lots, 4 of 4 basic metabolic panel control lots, and 4 of 4 b-type natriuretic peptide control lots were verified prior to use (refer to D5469).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's records, review of manufacturer's instructions and staff interview, the laboratory director failed to ensure the laboratory had a quality assessment plan which could identify and correct problems in analytic systems (refer to D5791).
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed

	specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the technical consultant failed to include the assessment of previously analyzed specimens, internal blind testing samples or external proficiency testing samples as part of 10 of 10 competency assessments. The findings include: 1. A review of the laboratory's personnel records from October 2023 to May 2025 determined the technical consultant performed 10 competency assessment on personnel performing moderate complexity testing. 2. A review of the competency assessments determined the assessment of previously analyzed specimens, internal blind testing samples or external proficiency testing samples was not included in the assessments. 3. The laboratory was asked to provide documentation of the missing assessment. No documentation was provided. 4. The laboratory director confirmed the findings in an interview conducted on 05/07/2024 at 0950 hours in the conference room.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, the technical consultant failed to include the assessment of problem solving skills as part of 10 of 10 competency assessments. The findings include: 1. A review of the laboratory's personnel records from October 2023 to May 2025 determined the technical consultant performed 10 competency assessment on personnel performing moderate complexity testing. 2. A review of the competency assessments determined the assessment of problem solving skills was not included in the assessments. 3. The laboratory was asked to provide documentation of the missing assessment. No documentation was provided. 4. The laboratory director confirmed the findings in an interview conducted on 05/07/2024 at 0950 hours in the conference room.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the review of the laboratory's submitted Form CMS 209, review of personnel records, and staff interview, the laboratory failed to have documentation of education to qualify 1 of 10 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor

	of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on the review of the laboratory's submitted Form CMS 209, review of personnel records, and staff interview, the laboratory failed to have documentation of education to qualify 1 of 10 testing personnel. The findings included: 1. A review of the laboratory's submitted Form CMS 209 determined the laboratory identified 10 testing personnel. 2. A review of the laboratory's personnel records determined the laboratory failed to have documentation of education to qualify 1 of 10 testing personnel. The personnel without documentation of education was (as listed on Form CMS 209): Testing personnel number 7 3. The laboratory was asked to provide documentation of education for testing personnel number 7. No documentation was provided. 4. The laboratory director confirmed the findings in an interview conducted on 05/07/2024 at 0950 hours in the conference room.