Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2247441	10/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Ou Health Er & Urgent Care Czech Hall	709 N Czech Hall Rd, Yukon, OK	

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 initial survey was performed on 10/03/2023 through 10/04/2023. The laboratory was found out of compliance with the following CLIA Condition: 493.1409; D6033: Technical Consultant The findings were reviewed with the laboratory director, laboratory administrative director, quality and safety manager, regulatory department director, program director, clinical manager, and point of care supervisor during an exit conference performed at the conclusion of the survey.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, and interview with the quality and safety manager, the laboratory failed to ensure a policy for alarm system checks was in place for the blood bank refrigerator during the review period of August 2022 through the current date. Findings include: (1) On 10/04/2023 at 10:45 am, the quality and safety manager stated two units of O negative packed red blood cells were routinely maintained in the blood bank refrigerator. The units were available for emergency patient transfusions; (2) Policy review revealed no policy for performing alarm checks for the blood bank refrigerator; (3) Interview with the quality and safety manager on 10/04/2023 at 10:45 am confirmed the laboratory failed to have a policy for performing alarm checks for blood product storage and alarm checks had not been performed during the review period.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the point of care (POC) supervisor, the laboratory failed to follow their written policy for verifying the stated values of control materials prior to implementation for three of three lot numbers used during the review period of 09/20/2023 through the current date. Findings include: (1) On 10/03/2023 at 10:00 am, the POC supervisor stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 hematology analyzer beginning 08/31/2022; (b) Three levels of EIGHTCHECK-3WP X-TRA QC (Quality Control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of records for three control lot numbers put into use on 09/20/2023 identified the following: (a) Low abnormal level control lot #32490710 - assayed 10 times on 09/20/2023; (b) Normal level control lot # 32490711 - assayed 10 times on 09/20/2023; (c) High abnormal level control 32490712 - assayed 10 times on 09/20/2023. (3) A review of laboratory written policy titled" Sysmex XP 300" under section E. "Starting a New Lot Controls" confirmed the laboratory did not follow their policy and stated the following: (a) "Parallel test new controls by analyzing the three levels of control a minimum of twice a day for 5 days prior to expiration of the previous lot. After a minimum of 10 data points are accumulated and values are running within assay ranges, the lot may be placed into production. The new lot will be validated prior to the current lot expiration." (4) The findings were reviewed with the POC supervisor who stated on 10/04/2023 at 09:10 am, the laboratory did not follow their written policy.
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: Based on a review of records, manufacturer's instructions, and interview with the point of care supervisor and the quality and safety manager, the laboratory failed to follow the manufacturer's instructions for verifying white blood cell flags for five of five patient reports. Findings include: (1) On 10/03/2023 at 11:00 am, the point of care supervisor stated the following: (a) Routine CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer. (2) A review of the manufacturer's operators manual stated; (a) Section 8.3 histogram flags "Various information can be obtained from the histograms. The XP-300 extracts the characteristics of the histogram and displays them as histogram flags. When histogram flags are displayed, perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following." (b) Flag [WL] - 1. Centrifuge sample and replace the plasma with equal volume of saline or Cellpack

	and repeat analysis 2. Check smear, etc. (c) Flag [T2] - 1. Check smear, etc. 2. Centrifuge sample and replace with equal volume of saline or Cellpack and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis, etc. (d) Flag [AG] - 1. Check smear, etc. (e) Flags [F1], [F2], [F3] - 1. Check smear, etc. 2. Centrifuge sample and replace with equal volume of saline or Cellpack and repeat analysis, warm sample at 37 degrees Celsius for 30 minutes and repeat analysis, etc. (3) Five patient CBC records were reviewed that contained flags. For five of five records, there was no evidence the laboratory followed the manufacturer's instructions for repeat analysis and verifying the flags as follows: (a) Sample #1027655546 - Testing performed on 09/30/2023 at 08:40 am with WL and AG flags obtained; (b) Sample #1027655546 - Testing performed on 09/30/2023 at 08:45 am with T2 and AG flags obtained; (c) Sample #1027662821 - Testing performed on 10/01/2023 at 05: 04 pm with T2 and AG flags obtained; (d) Sample #1027706733 - Testing performed on 10//02/2023 at 09:14 pm with an AG flag obtained; (e) Sample #1027707885 - Testing performed on 10/02/2023 at 11:05 pm with F1, F2, and AG flags obtained. (4) The records were reviewed with the point of care supervisor and the quality and safety manager, who stated on 10/03/2023 at 11:45 am the flags obtained for patients had not been verified as shown above.
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 a review of manufacturer's instructions, and interview with the point of care supervisor, the laboratory failed to ensure the laboratory humidity was monitored as required by the manufacturer for the Sysmex XP300 for 12 of 12 months reviewed. Findings include: (1) On 10/03/2023 at 2:00 pm the point of care (POC) supervisor stated complete blood count testing was performed using the Sysmex XP300 analyzer; (2) A review of the operator's manual for the test system identified the manufacturer required the analyzer be operated at a humidity of 30-80% with no condensation; (3) Interview with the POC supervisor on 10/03/2023 at 2:00 pm confirmed the laboratory humidity had not been monitored as required by the manufacturer.
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 a review of manufacturer's instructions, observation, and interview with the point of care (POC) supervisor, the laboratory failed to ensure three of three quality

	control materials had not exceeded their open vial expiration dates. Findings include: (1) On 10/03/2023 at 10:00 am, the POC supervisor stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 hematology analyzer; (2) Observation of the laboratory on 10/03/2023 at 10:05 am identified three levels of EIGHTCHECK-3WP X-TRA liquid controls (lot #32490710, lot #32490711, and lot #32490712) stored at 2-8 degrees Centigrade (C) which had not been dated with open dates; (3) Review of the manufacturer's package insert under the heading "Storage and shelf life after first opening" stated, "Opened and recapped vials and vials whose caps have been pierced will retain stability for 14 days if stored at 2-8C after being re-capped."; (4)The findings were discussed with the POC supervisor who stated on 10 /03/2023 at 10:22 am, the quality control materials were currently in use and had not been dated with the modified 14 days expiration date.
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 a review of records and interview with the laboratory director, the laboratory failed to verify the reference ranges for one of one new analyzer introduced into the laboratory. Findings include: (1) On 10/03/2023 at 10:00 am, the laboratory supervisor stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 hematology analyzer beginning 08/31/2023; (2) A review of the performance specification records for the new test system identified no evidence the laboratory had verified the reference ranges for each analyte (no documentation to prove where the reference ranges were derived); (3) The records were reviewed with the laboratory director who stated on 10/03/2023 at 01:40 pm, there was no documentation to prove the reference ranges had been verified for each of the CBC analytes. 48517 Based on a review of records and interview with the point of care supervisor, the laboratory failed to utilize the demonstrated reportable ranges for the epoc blood gas analyzer that was put in use on 08/31/2022. Findings include: (1) On 10/03/2023 at 1:20 pm, the point of care supervisor stated the laboratory began testing on the Siemens epoc analyzer for Blood Gas (pH, pCO2, pO2) testing on 08/31/2022; (2) A review of the performance specification records for the analyzer identified the laboratory had demonstrated the following reportable ranges: (a) pCO2 - 3.1-116 (b) pO2 - 34.2-591.0 (3) Interview with the point of care supervisor 10/03/2023 at 1:30 pm confirmed the laboratory was using the following manufacturer's reportable ranges instead of the ranges that had been demonstrated by the laboratory: (a) pCO2 - 5-150 (b) pO2 - 10-750
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of manufacturer's instructions, maintenance records, and interview with the point of care (POC) supervisor and the laboratory director, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures during the review period of 09/01/2022 through 09/30/2023. Findings include: (1) On 10/03/2023 at 10:00 am, the POC supervisor stated CBC (Complete Blood Count) testing was performed using the Sysmex XP-300 hematology analyzer beginning 08/31/2023; (2) A review of the manufacturer's instruction manual titled, "Sysmex XP 300 Instructions for Use", Chapter 12, section 12-1 required the following maintenance procedures: (a) Weekly "Clean SRV (Sample Rotor Valve) tray" (b) Monthly "Clean RBC and WBC TD (transducer), and Clean Waste Chamber" (c) Every Three Months "Clean SRV" (3) A review of maintenance logs from 09/01/2022 through 09/30/2023 identified the following: (a) Weekly: (i) Not documented as performed between 09/13/2022 and 10/01/2022 (ii) Not documented as performed between 11/05/2022 and 11/22/2023 (iii) Not documented as performed between 12/19/2023 and 01/26/2023 (iv) Not documented as performed between 03/18/2023 and 03/29/2023 (v) Not documented as performed between 03/29/2023 and 05/10/2023 (vi) Not documented as performed between 05/10 /2023 and 07/17/2023 (vii) Not documented as performed between 07/17/2023 and 08 /01/2023 (viii) Not documented as performed between 08/01/2023 and 08/27/2023 (b) Monthly: (i) Not documented as performed until 10/01/2022 (ii) Not documented as performed between 01/26/2023 and 03/01/2023 (iii) Not documented as performed between 04/01/2023 and 06/01/2023 (iv) Not documented as performed between 07/31 /2023 and 09/30/2023 (c) Every Three Months: (i) Not documented as performed between 09/01/2022 and 09/30/2023 (4) The records were reviewed with the laboratory director who stated on 10/03/2023 at 01:26 pm, maintenance procedures had not been documented as performed as shown above.
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 a review of records and interview with the point of care supervisor, the laboratory failed to perform QC (quality control) as stated in the IQCP (Individualized Quality Control Plan) for prothrombin time (PT)/international normalized ratio (INR) testing. Findings include: (1) On 10/03/2023 at 12:00 pm, the point of care supervisor stated the laboratory performed PT/INR testing beginning 08/31/2022 and an IQCP had been developed for the Hemochron Signature Elite test system; (2) A review of the QCP (Quality Control Plan) for the Hemochron Signature Elite revealed two levels of QC materials were to be tested on a weekly basis and with new lot numbers

	of reagents; (3) A review of QC records from January 2023 through September 2023 identified that QC testing had not been performed as stated in the QCP as follows: (a) PT/INR - There was no documentation to prove QC had been performed between: (i) 7 /05/2023 and 7/15/2023 (ii) 8/28/2023 and 9/11/2023 (4) The records were reviewed with the point of care supervisor who stated on 10/03/2023 at 12:00 pm, QC had not been performed as stated above.
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 a review of records and interview with the point of care (POC) supervisor, the laboratory failed to verify the stated values of the control materials before they were put into use for three of three lot numbers utilized during the review period of 04 /01/2023 through 04/30/2023. Findings include: (1) On 10/03/2023 at 10:00 am, the POC supervisor stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Sysmex XP-300 hematology analyzer beginning 08/31 /2022; (b) Three levels of EIGHTCHECK-3WP X-TRA QC (Quality Control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) A review of records for three control lot numbers identified no evidence the provided ranges were verified before the lot numbers were put into use for three of three lot numbers as follows: (a) Low control lot #30810710, Normal control lot #30810711, and High control lot #30810712 used from 04/01/2023 through 04/30/2023; (3) The findings were reviewed with the POC supervisor who stated on 10/03/2023 at 11:57 am the manufacturer's ranges had not been verified before the above lot numbers had been put into use.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the

	point of care supervisor, the laboratory failed to provide documentation the manufacturer's specifications had been followed for establishing quality control ranges for PT/INR testing for 2 of 2 lot numbers. Findings include: (1) On 10/03/2023 at 12:00 pm, the point of care supervisor stated; (a) The Hemochron Signature Elite analyzer was used to perform PT (Prothrombin Time)/ INR (International Normalized Ratio) testing using the Citrate PT cuvettes; (b) Normal and abnormal controls were tested on a weekly basis and with new lot numbers of cuvettes. (2) A review of the manufacturer's instructions (package inserts) for the control materials stated, "Accriva recommends that each institution establish its own expected range of response based on the mean +/- 2 standard deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test results should produce a coefficient of variation of approximately 14% or less for coagulation control tests"; (3) A review of quality control records for lot changes performed in 2023 revealed the laboratory had not followed the manufacturer's instructions as follows: (a) Normal Control Lot #B3DNC006, put into use on 07/28/2023 - There was no evidence the laboratory had established it's own means and standart deviations, and determined the coefficients of variation; (b) Abnormal Control Lot #B3DNC005, put into use on 07 /28/2023 - There was no evidence the laboratory had established it's own means and standart deviations, and determined the coefficients of variation;. (4) The findings were discussed with the point of care supervisor who stated on 10/03/2023 at 12:00 pm, the laboratory did not maintain documentation to prove the manufacturer's instructions had been followed.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a review of records, Quidel Triage assay data sheet, and interview with the point of care supervisor, the laboratory failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for one of one patient report. Findings include: (1) On 10/04/2023 at 10:50 am, the point of care supervisor stated Urine Drug Screen testing was performed using the Triage Meter Pro; (2) A review of the Triage test assay data sheet stated, "This test provides only a preliminary test result. Clinical consideration and professional judgement must be applied to any drug of abuse test results, particularly in evaluating a preliminary positive result. A more specific gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectroscopy/mass spectroscopy (LC/MS/MS), and high performance liquid chromatography (HPLC) are common methods."; (3) A review of one patient report with urine drug screen test results reported on 06/10/2023 identified the report did not include a disclaimer with the manufacturer's statement that the

	results were preliminary and guidance on obtaining a confirmed analytical result; (4) The findings were discussed with the point of care supervisor who stated on 10/04 /2023 at 10:50 am, the patient report did not include the disclaimer.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the point of care supervisor, the laboratory director failed to ensure enrollment and participation in a proficiency testing program for one of one event in 2022. Findings include: (1) On 10/03/2023 at 10:30 am, the point of care supervisor stated the following: (a) Complete Blood Count (CBC) testing was performed using the Sysmex XP 300 analyzer begining on 08/31 /2022; (b) Blood gas testing was performed using the Siemens epoc analyzer begining on 08/31/2022. (2) A review of proficiency testing records revealed no evidence the laboratory had enrolled in proficiency testing until 11/5/2022 for one of one event (2022 third event); (3) During an interview on 10/03/2023 at 10:30 am, the point of care supervisor stated the laboratory did not enroll in proficiency testing until 11/5 /2022.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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. This CONDITION is not met as evidenced by: Based on a review of records and interview with the quality and safety manager, the technical consultant failed to provide technical supervision in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) The technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for two of eight testing persons.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the

	laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the quality and safety manager, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for two of eight competency evaluations. Findings include: (1) On 10/04/2023, a review of records for eight persons performing moderate complexity testing during September 2022 through the current date identified the following for two of eight testing persons: (a) Testing Person #7 - The 09/27/2023 annual competency evaluation had been performed by an individual who did not meet the regulatory requirements of a technical consultant; (b) Testing Person #9 - The 09/27/2023 semi-annual competency evaluation had been performed by an individual who did not meet the regulatory requirements of a technical consultant. (2) The records were reviewed with the quality and safety manager who confirmed via email following the survey on 10/10/2023 at 01:30 pm, the evaluations had been performed by an individual who did not meet the qualifications of a technical consultant.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the point of care (POC) supervisor and quality and safety manager, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for two of eight testing persons performing testing from June 2022 through the current date. Findings include: (1) A review of personnel records for eight persons performing moderate complexity testing identified the following for two of eight persons: (a) Testing Person #1 - The initial training was completed on 08/24 /2022. There was no evidence a semiannual evaluation had been performed between 08/24/2022 and 09/30/2023; (b) Testing Person #18 - The initial training was completed on 06/07/2022. There was no evidence a semiannual evaluation had been performed between 06/07/2022 and 09/12/2023. (2) The records were reviewed with the POC supervisor who stated on 10/04/2023 at 11:00 am, a semiannual competency evaluation had not been performed.