Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475908	04/29/2021
Name of Provider or Supplier	**Street Address, City, State**	
Creek Nation Community Hospital	1800 E Coplin Rd, Okemah, 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 recertification survey was performed on 04/26,27,28,29/2021. The findings were reviewed with the laboratory director, director of laboratory services, laboratory manager, technical consultant #2, testing person #1, testing person #2, testing person #8, laboratory phlebotomist, four laboratory consultants, administrative director, chief operating officer, and director of quality during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to maintain quality control records for at least 2 years for four of four control lot numbers. Findings include: MULTI-CHEM QUALITY CONTROL MATERIAL (1) On 04/29/2021 at 01:00 pm, technical consultant #2 stated to surveyor #2: (a) The laboratory performed routine chemistry testing using the Abbott Architect 4100 (some examples of the analytes tested: Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Amylase, Calcium, Chloride, Cholesterol, CO2, Creatinine, Direct Bilirubin, Glucose, Sodium, Magnesium, Potassium); (b) Two levels of QC (Quality Control) materials were performed each day of patient testing for routine chemistry testing. (2) Surveyor #2 reviewed two Multi-Chem QC lot numbers, Lot# 16701171 - Level one and Lot# 16701173 - Level three. On 04/29/2022 at 01:10 pm, surveyor #2 asked technical consultant #2 for the laboratory's documentation of how their means and limits of acceptability, and the dates the materials were put into use for patient testing.

	Technical consultant #2 stated on 04/29/2021 at 01:30 pm, the QC materials were put into use in January 2019, however there was no documentation to prove how the means and acceptable limits were established; (3) Surveyor #2 then requested QC printouts from the analyzer, with the means and limits the laboratory was currently using to determine acceptability of QC results. Although it appeared to surveyor #2 (by reviewing the laboratory's control ranges, printed from the analyzer) that the laboratory had established the means and limits of acceptability, there was no documentation to substantiate how the means and limits had been derived; (4) Surveyor #2 reviewed the findings with technical consultant #2. Technical consultant #2, stated on 04/29/2021 at 02:10 pm, although the laboratory had established their means and limits when the new lot numbers were put into use, the records had not been maintained for at least 2 years. HEMOGLOBIN A1C AND BNP QUALITY CONTROL RECORDS (1) On 04/29/2021 at 01:00 pm, technical consultant #2 stated to surveyor #2: (a) The laboratory performed Hemoglobin A1c and BNP (Brain Natriuretic Peptide) testing using the Abbott Architect 4100 analyzer; (b) Two levels of quality control materials were performed each day of patient testing. (2) On 04/29 /2021, surveyor #2 reviewed BNP quality control records between July 2019 through March 2020 but could not located quality control records for the following: (a) July 2019 - A1c quality control lot# 9042 level two; (b) November 2019 - BNP quality control lot# 23696 level two. (3) Surveyor #2 reviewed the records with technical consultant #2. Technical consultant #2 stated on 04/29/2021 at 01:45 pm the laboratory did not maintain quality control records for two years.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory consultant and laboratory manager, the laboratory failed to review and evaluate proficiency testing results for three of 28 events. Findings include: (1) On 04/26/2021, the surveyor reviewed 2019, 2020, and 2021 proficiency testing records. The following biases were identified (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Second 2019 Chemistry Core Event (i) Glucose - five of five results exhibited a negative bias (aa) Sample CH-11 - SDI of -5.5 (bb) Sample CH-12 - SDI of -6.2 (cc) Sample CH-13 - SDI of -4.6 (dd) Sample CH-14 - SDI of -4.9 (ee) Sample CH-15 0 SDI of -4.3 (b) First 2020 Chemistry Core Event (i) Glucose - three of five results exhibited a negative bias (aa) Sample CH-02 - SDI of -4.3 (bb) Sample CH-04 - SDI of -2.1 (cc) Sample CH-05 - SDI of -2.9 (c) Second 2020 Chemistry Core Event (i) AST (Aspartate Aminotransferase) - three of five results exhibited a negative bias (aa) Sample CH-07 - SDI of -2.0 (bb) Sample CH-09 - SDI of -2.1 (cc) Sample CH-10 - SDI of -2.3 (ii) Direct Bilirubin - three of five results exhibited a negative bias (aa) Sample CH-08 - SDI of -2.7 (bb) Sample CH-09 - SDI of -2.4 (cc) Sample CH-10 - SDI of -2.7 (iii) Glucose - four of five results exhibited a negative bias (aa) Sample CH-07 - SDI of -4.1 (bb) Sample CH-08 - SDI of -2.5 (cc) Sample CH-09 - SDI of -4.9 (dd) Sample CH-10 - SDI of -2.9 (iv) Lipase - five of five exhibited a positive bias (aa) Sample CH-06 - SDI of 7.4 (bb) Sample CH-07 - SDI of 9.1 (cc) Sample CH-08 - SDI of 7.6 (dd) Sample CH-09 - SDI of 9.4 (ee) Sample CH-10 - SDI of 7.4 (2) The surveyor could not locate evidence in the records proving the biases had been identified and addressed; (3) The records were

	reviewed with the laboratory consultant and the laboratory manager. The laboratory manager stated on 04/26/2021 at 02:40 pm the biases had not been addressed as indicated above.
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 the policy and procedure manual and interview with the laboratory manager, the laboratory failed to follow written procedures for the Helmer Platelet Agitator for four of four quarterly clean and maintenance; and failed to follow written procedures for establishing initial QC ranges for two of two lot numbers. Findings include: HELMER PLATELET AGITATOR PF96i QUARTERLY CLEAN AND MAINTENANCE (1) On 04/26/2021 at 10:55 am, the laboratory manager stated to surveyor #2: (a) The laboratory used the Helmer Platelet Agitator PF96i to store platelets ordered for patient transfusion. (2) On 04/28/2021, surveyor #2 reviewed the policy for the Helmer Platelet Agitator PF96i quarterly clean and maintenance which stated: (a) "Test the Motion Alarm" (b) "Clean the fan located on the underside of base" (c) "Clean the shelves of Platelet Agitator with Caviwipe" (2) On 04/28/2021, surveyor #2 reviewed the 2019, 2020, and 2021 Helmer Platelet Agitator PF96i quarterly clean and maintenance records and identified the following: (a) 2019 quarterly clean and maintenance records had not been documented as performed. (3) Surveyor #2 review the records with the laboratory manager. The laboratory manager stated on 04/28/2021 at 02:47 pm, the laboratory did not follow the laboratory's quarterly clean and maintenance written procedure in 2019 as indicated above. ESTABLISH QUALITY CONTROL RANGES (1) On 04/29/2021 at 01:00 pm, technical consultant #2 stated to surveyor #2: (a) The laboratory performed TSH (Thyroid Stimulating Hormone) testing using the Abbott Architect 4100 analyzer ; (2) Surveyor #2 reviewed the laboratory's written policy and procedure titled, "Chemistry Policy", which stated under the section, "D. For Abbott Architect Ci4100": (a) "1. To establish initial QC (Quality Control) ranges for each new lot number of control, analyze a minimum of 20 samples, preferably over several days. Establish the mean and SD for each analyte for each level.". (3) Surveyor #2, reviewed QC records for two lot numbers and identified the following: (a) Bio-Rad Liquichek Immunoassay lot# 85231 (level one) mean and SD was established using 15 analyzed samples and put into use on 01/01/2021; (b) Bio-Rad Liquichek Immunoassay lot# 85233 (level two) mean and SD was established using 15 analyzed samples and put into use on 01/01/2021. (3) Surveyor #2 reviewed the records with technical consultant #2. Technical consultant #2 stated on 04/29/21 at 01:55 pm, the laboratory had not followed the laboratory's written procedure for establishing initial QC ranges
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 consultant, the laboratory failed to ensure the validation had been reviewed and evaluated by the laboratory for one of one new test kit. Findings include: (1) On 04/26/2021 at 01:55 pm, the laboratory consultant stated to surveyor #1 the laboratory began performing Qualitative Serum Pregnancy testing using the OSOM hCG Combo test on 03/08 /2021; (2) Surveyor #1 reviewed the validation data for test system. There was no documentation the laboratory had reviewed and evaluated the validation data to approve the new test method; (3) Surveyor #1 reviewed the records with the laboratory consultant who stated on 04/26/2021 at 02:42 pm, there was no documentation to prove that the validation data had been reviewed and evaluated by the laboratory. (NOTE: The interpretive guidelines at 493.1253(b)(1) state, "The laboratory is responsible for verifying the performance specifications of each nonwaived unmodified FDA-cleared or approved test system that it introduces, prior to reporting patient test results." In addition, the interpretive guidelines state, "Prior to introducing a test for routine patient testing, the laboratory must review and evaluate the verification data.")
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 records, manufacturer's instructions, and interview with the laboratory consultant and laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for one of four months. Findings include: (1) On 04/26/2021 at 10:00 am, the laboratory consultant and laboratory manager stated to surveyor #2: (a) The laboratory performed urinalysis testing using the Clinitek Advantus. (2) On 04/27/2021, surveyor #2 reviewed the manufacturer's maintenance requirements as stated on the maintenance logs. The daily maintenance requirements were as follows: (a) Daily (i) Clean Push Bar (ii) Discard used reagent strips (iii) Clean fixed platform (iv) Clean moving table (v) Clean hold down plate from fixed platform (vi) Inspect the calibration bar for scratches, or marks (3) Surveyor #2 then reviewed maintenance records for four months (January 2021 through April 2021). The following was identified: (a) There was no evidence the daily maintenance had been performed as follows: (i) Between 03/25/2021 and 03/27 /2021 (ii) Between 03/27/2021 and 04/01/2021 (4) Surveyor #2 reviewed the records with the laboratory consultant and the laboratory manager. The laboratory manager stated on 04/27/2021 at 01:45 pm, the daily maintenance had not been documented as performed as indicated above.
D5435	MAINTENANCE AND FUNCTION CHECKS

	CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory manager, the laboratory failed to follow their written protocol for ensuring the centrifuge was functioning properly for two of five function checks. Findings include: (1) On 04/26/2021 at 10:00 am, the laboratory manager stated the following to surveyor #1: (a) Urine sediment examinations were performed in the laboratory; (b) Patient specimens had been processed in the Horizon 614V Drucker centrifuge at a speed of 1500-2000 rpm (revolutions per minute) for 5 minutes until 03/31/2021, when the laboratory obtained a new centrifuge. (2) Surveyor #1 reviewed the policy titled, "Maintenance and Function Checks" which stated, "Function checks for RPM and timer accuracy are performed by the MCNDH Net Facilities Department twice a year or as specified by the equipment manufacturer"; (3) Surveyor #1 reviewed the centrifuge records from May 2019 through March 2021. The records showed that, although the centrifuge speed and timer checks had been performed twice annually, the results for the speed and timer checks performed on 11/13/2020 and 03/23/2021 had not been documented to ensure the centrifuge was processing specimens at the appropriate speed and time; (4) Surveyor #1 reviewed the findings with the laboratory manager who stated on 04/26/2021 at 11:30 am, the results for two of the centrifuge speed and timer checks had not been documented as stated above.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (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 laboratory manager, the laboratory failed to perform at least two levels of control testing each day patient specimens were tested for two of 20 patients. Findings include: (1) On 04/26/2021 at 11:40 am, the laboratory manager stated to surveyor #2: (a) The laboratory performed D-Dimer testing and CKMB testing using the Alere Triage Meter analyzer ; (b) Two levels (low and high) of quality control (QC) materials were to be tested each day of patient testing. (2) On 04/29/2021, surveyor #2 reviewed QC and patient records for testing performed between January 2020 through February 2021. It was identified QC testing had not been performed each day of patient testing for two of 20 days of patient testing: (a) D-Dimer testing (i) Patient (37200500155) teasing performed on 02

	/15/2020 at 02:24 pm. (b) CKMB (i) Patient (37210060071) testing performed on 01 /30/2021 at 09:12 pm (3) Surveyor #2 reviewed the records with the laboratory manager. The laboratory manager stated on 04/29/2021 at 11:50 am QC testing had not been documented as performed each day of patient testing as indicated above.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 laboratory consultant, the laboratory failed to perform a negative and positive control material each day of Qualitative Serum Pregnancy testing for one of four days. Findings include:, (1) On 04 /26/2021 at 01:55 pm, the laboratory consultant stated to surveyor #1 the laboratory began performing Qualitative Serum Pregnancy testing using the OSOM hCG Combo test on 03/08/2021; (2) Surveyor #1 reviewed quality control (QC) and patient records from 03/08/2021 through 04/08/2021, which showed that QC had not been performed on one of four days. The specific day was 03/28/2021; (3) Surveyor #1 reviewed the findings with the laboratory consultant who stated on 04/26/2021 at 02:40 pm, QC testing had not been performed each day of patient testing.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of written policies and interview with the director of nursing, the laboratory failed to ensure that written policies provided safety for individuals being transfused for five of 15 units of packed red blood cells. Findings include: (1) On 04 /26/2021 at 10:55 am, the laboratory manager stated to surveyor #2 the laboratory stored units of PRBC (packed red blood cells) in the blood bank refrigerator. The units were to be used for patient transfusions; (2) On 04/28/2021, surveyor #2 reviewed the hospital policy regarding transfusion reactions. The policy titled, "Administration of Blood & Blood Products" under the section titled, "N. Document vital signs as follows:", stated: (a) "1. Pre-transfusion" (b) "2. 5 minutes after start time" (c) "3. 15 minutes after start time" (d) "4. 60 minutes after start time" (e) "5.

	And every 60 minutes thereafter until transfusion is complete." (f) "6. Post transfusion" (3) Surveyor #2 reviewed records for 15 units of PRBCs (Packed Red Blood Cells) that had been transfused between 02/24/2019 through 04/25/2021 for six patients, and identified the following: (a) 5 minutes after start time (i) Patient# 80097053 - Transfused with one unit PRBC (unit# W091020372543) on 10/12/2020. The transfusion started at 02:04 pm and the first vital was documented at 04:45 pm (two hours 45 minutes later); (ii) Patient# 80097053 - Transfused with one unit PRBC (unit# W091020361350) on 10/12/2020. The transfusion started at 04:58 pm and the first vital was documented at 06:28 pm (one hour 30 minutes later). (b) 15 minutes after start time (i) Patient# 80090076 - Transfused with one unit PRBC (unit# W091020226609) on 06/03/2020. The transfusion started at 12:45 am, vitals were taken at 12:50 am and 01:20 am (30 minutes later); (ii) Patient# 80042825 - Transfused with one unit PRBC (unit# W091020298771) on 08/13/2020. The transfusion started at 08:37 pm, vitals were taken at 08:43 pm, 08:50 pm, and 10:15 pm (one hour 38 minutes later); (iii) Patient# 80042825 - Transfused with one unit PRBC (unit# W09102089668) on 09/17/2020. The transfusion started at 03:02 pm, vitals were taken at 03:07 pm and 04:32 pm (one hour 25 minutes later). (4) Surveyor #2 reviewed the findings with the director of nursing. The director of nursing stated on 04/28/2021 at 03:05 pm the written policy and procedure for blood administration had not been followed as indicated above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on a review of records, and interview with the laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different analyzers. Findings include: (1) On 04 /26/2021 at 10:30 am, the laboratory manager stated to surveyor #2 (a) BUN (Blood Urea Nitrogen), Calcium, Chloride, Creatinine, Glucose, Potassium, and Sodium testing were performed on two analyzers as follows: (i) The Abbott Architect 4100 analyzer as the primary analyzer; (ii) The Abbott iSTAT analyzer (serial number #343109) using the Chem 8+ cartridge as the back-up analyzer. (b) Troponin I and CKMB testing were performed on two analyzers as follows: (i) The Abbott Architect 4100 analyzer as the primary analyzer; (ii) Alere Triage Meter as the back-up analyzer. (c) D-Dimer testing was performed on two analyzers as follows: (i) The ACL TOP as the primary analyzer; (ii) Alere Triage Meter as the back-up analyzer. (2) On 04/27/2021, surveyor #2 reviewed the comparison data for the analyzers and identified the following: (a) BUN (Blood Urea Nitrogen), Calcium, Chloride, Creatinine, Glucose, Potassium, and Sodium testing (i) For testing performed from January 2020 through the second day of the survey (04/27/2021), there was no evidence the relationship between the analyzers had been evaluated twice in 2020 and to date in 2021. The relationship between the analyzers had been evaluated on 11/20 /2020 (not prior to that date and after that date). (b) Troponin I and CKMB testing (i) For testing performed from November 2018 through the second day of the survey (04 /27/2021), there was no evidence the relationship between the analyzers had been

	evaluated twice in 2019 and twice in 2020. The comparison had not been evaluated between 11/16/2018 and 12/29/2020. (c) D-Dimer testing (i) For testing performed from November 2018 through the second day of the survey (04/27/2021), there was no evidence the relationship between the analyzers had been evaluated twice in 2019 and twice in 2020. The comparison had not been evaluated between 11/20/2018 and 03 /29/2021. (3) Surveyor #2 reviewed the records with the laboratory manager who stated on 04/27/2021 at 01:35 pm, the relationship between the analyzers had not been evaluated twice annually as indicated above.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory consultant and laboratory manager, the laboratory failed to make appropriate reference ranges available for two of two reagent lot number changes; the laboratory failed to make appropriate reference ranges available for two of two patient SARS-CoV-2 antibody patient reports. Findings include: REAGENT LOT NUMBER CHANGES - NORMAL REFERENCE RANGE (1) On 04/26/2021 at 10:00 am, the laboratory manager stated surveyor #2 the laboratory performed PT/INR (Prothrombin Time /International Normalized Ratio) PTT (Partial Thromboplastin Time) testing on the ACL Top analyzer. In addition the following reagents were put into use on 03/01 /2021: (a) Recombinplastin PT reagent lot# N1099299 (b) SynthASil PTT Reagent lot# N1199759 (2) Surveyor #2 reviewed the PT and PTT reagent implementation records and identified the laboratory had verified the following: (a) PT normal reference interval of 9.9 - 12.7 seconds; (b) PTT normal reference interval of 28.4 - 40.62 seconds. (3) Surveyor #2 then reviewed a patient PT and PTT report dated 04/24 /2021 at 08:29 pm with the following: (a) PT normal reference range of 9.7-12.5 seconds; (b) PTT normal reference range of 26.9 - 37.7 seconds. (4) Surveyor #2 surveyor reviewed the findings with the laboratory consultant and laboratory manager. On 04/26/2021 at 02:55 pm, the laboratory manager stated that although the laboratory had established a PT and PTT normal reference interval with the PT and PTT reagent lot change, the laboratory had not implemented the change into the laboratory's computer information system. SARS-CoV-2 ANTIBODY PATIENT REPORT (1) On 04/26/2021 at 10:10 am, the laboratory manager stated surveyor #2 the laboratory performed SARS-CoV-2 antibody (IgG) testing on the Abbott Architect 4100 analyzer; (2) On 04/29/2021, surveyor #2 reviewed two patient SARS-CoV-2 antibody reports dated 02/25/2021 at at 03:28 pm and 04/08/2021 at 04:17 pm. The patient reports did not include a normal reference range for IgG antibody; (3) The report was reviewed with the laboratory manager, who stated on 04/29/2021 at 02:40 pm, the two patient reports did not include a normal reference range as indicated above.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory consultant and laboratory manager, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for one of 28 events. Findings include: (1) On 04/26/2021, surveyor #2 reviewed 2019, 2020, and 2021 proficiency testing events. For one of 28 events, the attestation statements had been signed approximately two months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows: (a) Third 2020 Hematology/Coagulation Event - The sample testing had been completed on 11/20/2020, and the attestation statement had not been signed by the laboratory director/designee until 01/31/2021. (2) Surveyor #2 reviewed the findings with the laboratory consultant and laboratory manager. The laboratory manager stated on 04/26 /2021 at 02:35 pm the attestations had been signed approximately two months after the proficiency samples had been tested. Surveyor #2 explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.