Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0305030	11/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Evergreen Medical Center	101 Crestview Ave, Evergreen, AL	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey was conducted on 11/2-11/3/2021 at Evergreen Medical Center. Based on a lack of validation documentation for the current lot number of HemosIL Prothrombin Time (PT) reagent, a review of instructions in the product insert and laboratory procedures, and interviews with the Laboratory Manager (also the Technical Consultant), the surveyor determined the laboratory failed to perform and document the validation for the current Lot # N0201886 of PT reagent, including establishing a normal patient mean, and manually checking the INR (International Normalized Ratio) calculation on the instrument. Due to the potential for serious injury or death when the INR is incorrectly calculated, the surveyor called an Immediate Jeopardy (IJ) situation on 11/3/2021 at 2:30 PM. [Refer to D5400, D5411, D6076 and D6086.] The surveyor provided the IJ template to the Technical Consultant, and received a voluntary statement, on 11/03/2021 at 2:58 PM, to suspend testing for PT/INR, until analytic processes are remediated. .
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on a review of American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Laboratory Manager (also the Technical Consultant), the Laboratory Director failed to sign the attestation statements for 36 of 36 PT surveys, and testing personnel failed to sign three of 36 attestation statements from the 2018 thru 2021 PT survey review period. The findings include: 1. A review of the 2018 - 2021 API PT records revealed the Laboratory Director (or a designee) had failed to sign attestation statements for 36 of 36 surveys. The testing analysts had also failed to sign three 2018 Event #2 surveys: Core Chemistry, Hematology and

	Immunohematology / Immunology. 2. During an interview with the Laboratory Manager on 11/2/2021 at 2:45 PM, the surveyor reviewed the instructions on the attestation statement requiring the Laboratory Director (or designee) and testing personnel to sign the document. The Manager confirmed the laboratory personnel has failed to follow these instructions. .
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Laboratory Manager (also the Technical Consultant), the surveyor determined the laboratory failed to implement mechanisms to monitor, assess and correct problems identified when the laboratory received scores less than 100% (percent) on the PT surveys. This was noted to occur on 36 of 36 surveys reviewed during the 2018 - 2021 PT survey period. The findings include: 1. A review of the 2018-2021 API Proficiency Testing records revealed no quality assessment procedure or mechanism to investigate and correct problems when the laboratory received scores less than 100%. The laboratory had failed to implement a strategy to prevent: A) Clerical errors: a) 2018 Event #3 Hematology--Wet Prep with a failing score of 0%, b) 2018 Event #3 Bacteriology--Clostridium difficile with a score of 80%, c) 2019 Event #3 Chemistry--Theophylline with a score of 80%, d) 2020 Event #1 Chemistry--BNP (Beta-type Natriuretic Peptide) with a score of 80% e) 2021 Event #3 Chemistry--Arterial Blood Gas pH with a score of 80% B) Flagged result errors: 2020 Event #1 Chemistry--Erroneous flagged results for Gentamycin were reported resulting in a failing score of 60% C) "Failure to participate" errors: 2018 Event #2 Immunohematology-DAT (Direct Antiglobulin Testing) and all tests on 2020 Event #3 Chemistry 2. A further review of the API evaluations revealed significant negative biases in the SDI (Standard Deviation Index) results for the electrolytes in the 2020 Event #1 Chemistry survey; Sodium had a failing score of 20%, however the laboratory failed to note the significance of the biases and implement reviews to ensure patient testing was not impacted. 3. The surveyor noted results less than 100% were generally repeated with no documentation of further Quality Assurance investigation of the calibration dates, presence of quality control shifts and trends, reagent age or other factors that can affect results, to determine when the problem originated and whether patient testing was affected. The surveyor also noted the proficiency testing records were not reviewed for completeness; the Laboratory Director (or Designee) had failed to sign 36 of 36 attestation statement, and the testing analysts had failed to sign 3 of 36 statements. (Refer to D2009.) Survey review to ensure records were retained together was also a noted problem. 4. During an interview on 11/2/2021 at 2:45 PM, the surveyor reviewed and confirmed the above noted concerns with the Laboratory Manager. The surveyor explained the laboratory needed a mechanism (such as a procedure or worksheet) to document their investigations and determine the cause of any results less than 100%, especially when a failure has occurred. The Manager confirmed the laboratory did not have this. .
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 a review of laboratory records and interviews with the Laboratory Manager / Technical Consultant, the laboratory failed to: 1) Ensure new lot numbers of Prothrombin Time reagent were not utilized until a validation was performed and documented (including establishing a normal patient mean and the manual check of the INR). [Refer to D5411 and D6086.] 2. Ensure Hematology calibrations were performed every six months, and Hematology QC was performed before patient testing resumed. [Refer to D5437.] 3. Ensure Calibration Verification was performed and documented every six months. [Refer to D5439.] 4. Ensure a method to monitor and document shifts and trends over time for the Chemistry/Toxicology/C-Reactive Protein and Coagulation QC was performed. [Refer to D5441.] 5. Ensure the inspection of the audible alarm system for the Blood Bank refrigerator, and Fresh Frozen Plasma freezer was performed and documented; and ensure Immunohematology QC was performed each day of patient testing. [Refer to D5551 and D5555.] 6. Ensure procedures verifying the manufacturer's performance specifications on the Beckman Coulter DxC 700AU were reviewed and approved by the Laboratory Director before patient testing began. [Refer to D6086.] .
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 lack of validation documentation for the current lot number of HemosIL Prothrombin Time (PT) reagent, a review of instructions in the product insert and laboratory procedures, and interviews with the Laboratory Manager (also the Technical Consultant), the surveyor determined the laboratory failed to perform and document the validation for the current Lot # N0201886 of PT reagent, including establishing a normal patient mean, and manually checking the INR (International Normalized Ratio) calculation on the instrument. This was noted on one of one lot numbers of PT reagent in use. The findings include: 1. During the entrance tour on 11 /2/2021 at approximately 10:15 AM, the Laboratory Manager stated coagulation testing (PT [Prothrombin Time] and PTT [Partial Thromboplastin Time]) was performed on the IL (Instrumentation Laboratory) ACL Elite. The surveyor requested a review of the current lot number of PT reagent with the ISI (International Sensitivity Index) programmed in the analyzer. At 11:35 AM the Laboratory Manager provided the "LIQUID SETUP REPORT" printed from the ACL Elite, which documented the PT Reagent Lot number as "N0201886", and the ISI as "1.610". The surveyor noted

	this matched the information on the HemosIL product insert taken from the PT reagent box in the refrigerator. 2. A review of the manufacturer's instructions on the HemosIL reagent insert under "Instrument / test procedures" revealed, "Enter the ISI value from the insert and establish the mean of the Normal Range with each new lot number". 3. A review of the Beckman Coulter "INR CALCULATION - ACL ELITE PRO" procedure revealed, "This procedure is performed ... With a change of the thromboplastin lot number." The "Principles of the Procedure" section specified the INR equals the ratio of the patient's PT to the normal patient mean raised to the ISI (International Sensitivity Index) of the thromboplastin used, including the following: ... "Note that each lot number of reagent will have a unique ISI value and mean of normal reference interval...". 4. A review of the undated laboratory procedure, "Normal Mean Population" revealed, "Normal population range (reference range) consists of data generated from a group of individuals to be free of any abnormalities. The establishment of a normal population mean must be accurate because it plays an important part in establishing the equivalency of different laboratories INR [International Normalized Ratio] values. ... Procedure: Draw 20 patients with normal PT". 5. During the routine review of records at approximately 8:45 AM on 11/3/2021, the surveyor requested the validation documentation for the latest lot number of PT reagent, including the data used to calculate the normal patient mean, new quality control (QC) ranges, and the manual check of the instrument's INR calculation. 6. At 9:40 AM on 11/3/2021, the surveyor noted the Laboratory Manager had not located the validation studies for PT reagent lot number N0201886. The surveyor then asked for a review of the current reference value in the ACL Elite analyzer. At 9:45 AM the surveyor noted it was 12.5 seconds, and asked how this value was established; the Laboratory Manager stated she believed the testing personnel ran the Normal QC multiple times, and calculated the mean. After review of the above procedures, the Manager confirmed the testing personnel failed to follow the "Normal Mean Population" procedure. The surveyor stated they needed to review the validation data to confirm that. 7. At 10:25 AM on 11/3/2021, the surveyor asked if the laboratory included a manual check of the instrument's INR calculation whenever a new lot number of reagent was validated; the Manager was not aware this was a requirement, and did not know how to manually check the INR calculation. 8. At approximately 2: 25 PM on 11/3/2021 the Laboratory Manager was still unable to locate validation records for PT reagent lot number N0201886. The Manager had not determined who had performed the validation studies, or when the lot number was first used for patient testing. At 2:30 PM on 11/3/2021, the surveyor declared an Immediate Jeopardy due to the laboratory's failure to perform and document the validation for the current Lot # N0201886 of PT reagent, including establishing a normal patient mean as per laboratory procedure, and manually checking the INR calculation on the instrument. The surveyor provided the IJ template to the Technical Consultant, and received a voluntary statement, on 11/03/2021 at 2:58 PM, to suspend testing for PT/INR, until analytic processes are remediated. .
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii)

	Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on reviews of the Beckman Coulter DxH 600 Hematology analyzer calibration, linearity, and quality control records, and an interview with the Laboratory Manager (also the Technical Consultant), the surveyor determined the laboratory failed to follow the manufacturer's instructions: 1) to perform calibrations every six months; the laboratory failed to perform one of two calibrations due in 2019 and one of two due in 2020; and 2) to verify calibrations by running quality controls (QC) before patient testing resumed on 2/21/2020 and on 10/27/2021. The findings include: 1. A review of calibration and calibration linearity records for the Beckman Coulter DxH 600 Hematology analyzer revealed the following: A) A calibration linearity was performed on 1/4/2019; there was no record of a calibration or calibration linearity the second half of 2019. B) A calibration linearity was performed on 2/21/2020; there was no record of a calibration or calibration linearity the second half of 2020. C) A calibration were also performed on 2/21/2020 at 2:00 PM; there was no record of QC after the calibration until 2/22/2020 at 1:23 AM. D) A calibration was performed on 10 /27/2021 at 3:31 PM; there was no record of QC after the calibration until 10/28/2021 at 2:22 AM. 2. During an interview and review of the records on 11/3/2021 at 10:45 AM, the Laboratory Manager reviewed and confirmed the above noted findings. When asked about the required calibration frequency, the Laboratory Manager confirmed calibration (or calibration linearity) should be performed every six months, and QC should be performed before patient testing resumed. The surveyor then asked if any patient CBC's (Complete Blood Counts) were performed; the Manager stated four patient CBC's were performed after the 2/21/2020 calibration, and nine patient CBCs were performed after the 10/27/2021 calibration. .
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on a review of the calibration verification (C/V) records for the Beckman Coulter DxC 700AU Chemistry analyzer and an interview with the Laboratory Manager (also the Technical Consultant), the laboratory failed to perform C/V's every six months as required by CLIA regulations. The laboratory failed to perform two of two C/V's due in 2020. The findings include: 1. A review of Beckman Coulter DxC 700AU Chemistry analyzer records revealed calibration verification for all analytes was performed during the installation on 4/30/2019 thru 5/8/2019. The next record of C/V on analytes calibrated with less than three calibrators was 22 months later in March 2021. There was no documentation of the two C/V's due in 2020. 2. During an interview on 11/3/2021 at 8:40 PM, the Laboratory Manager confirmed she had been unable to perform C/V's in 2020. .
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 a lack of quality control records and an interview with the Laboratory Manager (also the Technical Consultant), the laboratory failed to document a method to monitor shifts and trends over time for the Chemistry/Toxicology/C-Reactive Protein for the September 2021 quality control (QC), and for six months of Normal coagulation QC in 2020. The findings include: 1. A review of the September 2021 QC records for the Beckman Coulter DxC 700AU analyzer revealed only a summation of the monthly QC data for the individual analytes on a "Quality Control" chart. The laboratory had no records documenting the monitoring of QC shifts and trends over time. (Examples include printing Levey-Jennings [L-J] charts periodically, or submitting data to a QC company's Interlaboratory Quality Assurance Program [IQAP] with documentation of review). 2. A review of the Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) QC performed on the IL (Instrumentation Laboratory) ACL Elite revealed only the daily QC values for the Normal level QC performed 7/1-11/29/2020 and 12/2-12/30/2020. The laboratory had no records documenting the monitoring of Normal QC shifts and trends over time. 3. During an interview on 11/3/2021 at 3:30 PM, the surveyor asked how the laboratory monitored the Chemistry QC for shifts and trends. The Laboratory Manager stated each month she compared the actual QC values to the expected "base values", and reviewed the Biorad Unity reports electronically. The surveyor explained the laboratory needed documentation of review of QC for shifts and trends, especially when proficiency testing failures occurred. (Refer to D5291.) The surveyor then requested the L-J charts for the July-December 2020 Normal PT and PTT QC; the Manager confirmed the L-J charts were not in the binder, and did not provide the records during the survey. .

D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (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 four months of Immunohematology (Blood Bank) logs and an interview with the Laboratory Manager (also the Technical Consultant), the laboratory failed to document quality control (QC) results for ABO, Rh, and unexpected Antibody Detection on two days in January and August 2021. The findings include: 1. A review of the Immunohematology (Blood Bank) logs revealed no documentation of ABO, Rh, and unexpected Antibody Detection QC on 1/19/2021 (one patient tested for ABO, Rh, and unexpected Antibody Detection) and 8/11/2021 (two patients tested). 2. During an interview on 11/3/2021 at 2:08 PM, Laboratory Manager/ Technical Consultant confirmed the testing personnel had failed to document the Immunohematology QC for the above dates.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (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 Immunohematology (Blood Bank) records and an interview with the Laboratory Manager (also the Technical Consultant), the laboratory failed to document inspection of the audible alarm system for the Blood Bank refrigerator the first quarter of 2021, and failed to implement a procedure documenting inspection of the audible alarm system for the Fresh Frozen Plasma (FFP) freezer since the previous survey on 7/26/2018. The findings include: 1. A review of the quarterly "Alarm Checks" on the refrigerator where red blood cell units were stored revealed documentation of the high and low temperature alarm checks on 12/20/2020; the next alarm check was on 7/2/2021. There was no documentation of an alarm check the first quarter of 2021. 2. A review of the 2018-2021 Immunohematology records revealed no documentation of audible alarm checks on the FFP freezer. 3. During an interview on 11/3/2021 at 2:08 PM, Laboratory Manager/ Technical Consultant confirmed the laboratory had missed the alarm check on the refrigerator, and had not performed alarm checks on the FFP freezer. .

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 a review of laboratory records, quality assurance documentation and interviews with the Laboratory Manager (also the Technical Consultant), the surveyor determined the laboratory failed to implement effective quality assessment reviews to identify and correct problems identified in the analytical systems. The findings include: 1. A review of quality assurance documentation revealed the laboratory routinely performed monthly quality assurance activities, however the reviews were inadequate to discover and correct problems in the following areas: A. Prothrombin Time Reagent Validation--Failure to implement a mechanism to ensure new lot numbers of Prothrombin Time reagent were not utilized until a validation was performed (including establishing a normal patient mean and the manual check of the INR), documented and approved. [Refer to D5400, D5411, D6076 and D6086.] B. Hematology Calibrations--Failure to implement a mechanism to ensure calibrations were performed every six months and QC was performed before patient testing resumed. [Refer to D5437.] C. Calibration Verification (C/V)--Failure to implement a mechanism ensuring analytes calibrated with less than three calibrators had C/V performed and documented every six months. [Refer to D5439.] D. Quality Control (QC)--Failure to document a method to monitor shifts and trends over time for the Chemistry/Toxicology/C-Reactive Protein QC and Normal Coagulation QC [Refer to D5441.] E. Immunohematology Audible Alarm Checks and QC--Failure to document inspection of the audible alarm system for the Blood Bank refrigerator, and Fresh Frozen Plasma freezer; and failure to perform Immunohematology QC each day of patient testing [Refer to D5551 and D5555.] F. New Instrumentation Validation Approval--Failure to document the Laboratory Director's review and approval of procedures verifying the manufacturer's performance specifications before patient testing began on the Beckman Coulter DxC 700AU [Refer to D6013.] 2. In the exit summation on 11/3/2021 at approximately 4:55 PM, the surveyor reviewed and confirmed the above quality assurance concerns with the Laboratory Manager. .
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 laboratory records and interviews with the Laboratory Manager (also the Technical Consultant), the Technical Consultant failed to ensure: 1) New lot numbers of Prothrombin Time reagent were not utilized until a validation was performed and documented (including establishing a normal patient mean and the manual check of the INR). 2). Hematology calibrations were performed every six months, and Hematology QC was performed before patient testing resumed. 3).

	Calibration Verification was performed and documented every six months. 4). A method to monitor and document shifts and trends over time for the Chemistry /Toxicology/C-Reactive Protein and Coagulation QC was performed. The findings include: 1. Refer to D6036.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on a review of laboratory records and interviews with the Laboratory Manager (also the Technical Consultant), the Technical Consultant failed to provide technical oversight to ensure: 1) New lot numbers of Prothrombin Time reagent were not utilized until a validation was performed and documented (including establishing a normal patient mean and the manual check of the INR). 2). Hematology calibrations were performed every six months, and Hematology QC was performed before patient testing resumed. 3). Calibration Verification was performed and documented every six months. 4). A method to monitor and document shifts and trends over time for the Chemistry/Toxicology/C-Reactive Protein and Coagulation QC was performed. The findings include: 1. Refer to D5411. 2. Refer to D5437. 3. Refer to D5439. 4. Refer to D5441.
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 reviews of personnel files and interviews with the Laboratory Manager (also the Technical Consultant), the Technical Consultant failed to perform and document the semi-annual competency evaluation for two of six new Testing Personnel (TP) hired since the previous survey on 7/26/2018. The findings include: 1. A review of the Form CMS-209 (Laboratory Personnel Report) revealed six new Testing Personnel (TP #2, #3, #4, #5, #6, and #10) hired since the previous survey on 7/26/2018. 2. A review of personnel files revealed no semiannual competency assessments for the following: A) TP #2 with documentation of training on 11/17/2018; there was no documentation of competency until 12/30/2019. B) TP #4 was hired 8/16/2018; an "August 2019" evaluation was signed by the Technical Consultant, with no date. A "2020" evaluation was signed by the TP; there was no signature of the person who had performed the evaluation. An August 2020 was signed by the TP; there was no signature of the person who had performed the evaluation. A "2021" evaluation was signed by the TP; there was no signature of the person who had performed the evaluation. 3. During an interview on 11/2/2021 at 12:30 PM, the surveyor reviewed the competency evaluations with the Laboratory Manager / Technical Consultant, who confirmed the above noted findings. .
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on reviews of personnel files and interviews with the Laboratory Manager (also the Technical Consultant), the Technical Consultant failed to perform and document the annual competency evaluation for three of ten Testing Personnel (TP) listed on the Form CMS-209 (Laboratory Personnel Report). The findings include: 1. A review of personnel files for TP listed on the Form CMS-209 revealed no annual competency assessments for the following: A) TP #1: No 2020 documentation of competency B) TP #3: No 2020 documentation of competency C) TP #4: Competencies were incomplete and did not specify when and by whom the evaluation was performed, as follows: TP #4 was hired 8/16/2018; the "2020", "August 2020", and "2021" evaluations were signed and dated by TP#4, however there was no signature of the person who had performed the evaluations. 2. During an interview on 11/2/2021 at 12: 30 PM, the surveyor reviewed the competency evaluations with the Laboratory Manager / Technical Consultant, who confirmed the above noted findings. .
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on a lack of validation documentation for the current lot number of HemosIL Prothrombin Time (PT) reagent, a review of instructions in the product insert and laboratory procedures, a review of Beckman Coulter DxC 700 AU installation procedures, and interviews with the Laboratory Manager (also the Technical Consultant), the surveyor determined the Laboratory Director failed to: 1) ensure the laboratory performed and documented the validation for the current Lot # N0201886 of PT reagent, including establishing a normal patient mean, and manually checking the INR (International Normalized Ratio) calculation on the instrument. This was noted on one of one lot numbers of PT reagent in use; and 2) document review and approval of the Beckman Coulter DxC 700 AU installation procedures as verification of the manufacturer's performance specifications before patient testing began. This affected one of one new instruments performing moderate-complexity tests. The findings include: 1. Refer to D5411 and D6086. .
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

	This STANDARD is not met as evidenced by: Based on a lack of validation documentation for the current lot number of HemosIL Prothrombin Time (PT) reagent, a review of instructions in the product insert and laboratory procedures, a review of Beckman Coulter DxC 700 AU installation procedures, and interviews with the Laboratory Manager (also the Technical Consultant), the surveyor determined the Laboratory Director failed to: 1) ensure the laboratory performed and documented the validation for the current Lot # N0201886 of PT reagent, including establishing a normal patient mean, and manually checking the INR (International Normalized Ratio) calculation on the instrument. This was noted on one of one lot numbers of PT reagent in use; and 2) document review and approval of the Beckman Coulter DxC 700 AU installation procedures as verification of the manufacturer's performance specifications before patient testing began. This affected one of one new instruments performing moderate-complexity tests. The findings include: 1. Refer to D5411 concerning a lack of validation documentation for the current lot number of HemosIL Prothrombin Time (PT) reagent. 2. Beckman Coulter DxC 700 AU installation procedures: A). A review of the 4/30-5/8/2019 validation records for the Beckman Coulter DxC 700AU Chemistry analyzer, revealed no documentation (signature and date) of the Laboratory Director's review and approval of the procedures verifying the manufacturer's performance specifications. Patient testing began in May 2019. B). During a review of the records, and an interview on 11/3/2021 at 8:30 AM, the Laboratory Manager reviewed and confirmed the above noted findings. SURVEYOR ID#32558 Licensure and Certification Surveyor