Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461133	02/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Acadia-St Landry Hospital Pathology	810 South Broadway Street, Church Point, LA	

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 performed on February 14, 2023 through February 17, 2023 at Acadia St. Landry Hospital Pathology, CLIA ID # 19D0461133. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, quality control records, patient test logs, and interview with personnel, the laboratory failed to ensure one (1) of five (5) proficiency testing samples for D-dimer were tested in the same manner as patient samples in September 2022. Findings: 1. Review of the laboratory's "Proficiency Testing Policy and Procedure" revealed "Laboratory routine procedures are followed for PT sample testing, however keeping the PT provider instructions as a priority." 2. Review of the laboratory's September 2022 quality control records and patient test logs for D-dimer revealed the laboratory did not perform two (2) levels of quality control prior to proficiency testing as they would for patient testing for the following date and sample: September 13, 2022: "CPSI SURVEY 11" 3. In interview on February 16, 2023 at 9:29 am, the Compliance Personnel confirmed the identified proficiency testing sample did not have quality controls performed.

D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to ensure attestation statements were signed by testing personnel as required for four (4) of five (5) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing Policy and Procedure" under the "Handling of Survey" section revealed "The assigned testing personnel will also be required to sign and date the attestation statement." 2. Review of the laboratory's 2021 and 2022 American Proficiency Institute (API) proficiency testing records revealed the laboratory's testing personnel did not sign the attestation statements for the following four (4) events: a) 2021 Chemistry Miscellaneous 2nd event b) 2021 Chemistry Core 3rd event c) 2022 Immunology/Immunohematology 1st event: specific samples testing by personnel was not indicated d) 2022 Hematology /Coagulation 2nd event 3. In interview on February 15, 2023 at 11:31 am, General Supervisor 1 confirmed the laboratory did not have complete or signed attestation statements for the identified events.
D3015	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103 A facility that provides transfusion services must meet all of the requirements of this section and document all transfusion-related activities. This STANDARD is not met as evidenced by: Based on review of laboratory and hospital policies and procedures and patient records, as well as interview with laboratory and nursing personnel, the laboratory failed to ensure complete transfusion-related activities were documented as required by the hospital and laboratory for three (3) of three (3) patients reviewed. Findings: 1. Review of the hospital policy "Blood and Blood Components Administration Policy" and the laboratory policy "Blood Administration Policy" under section "Procurement of blood or blood product" revealed both laboratory personnel and the nurse receiving the unit from the laboratory are required to sign the "Blood Administration Signout Form." 2. Further review of hospital policy "Blood and Blood Components Administration Policy" and the laboratory policy "Blood Administration Policy" revealed the following: *Document pre-vitals (no more than 15 minutes prior to transfusion). *Enter volume transfused. *Document end vitals. *For Inpatients, resume routine vital sign checks as ordered and continued monitoring for delayed blood transfusion reactions. Document in Evident 30 minutes to 1 hour after the end

	of the transfusion in order to monitor for delayed transfusion reaction. *For Outpatients being discharged, monitor patient another hour after completion of transfusion and recheck vital signs at this time and document in Evident 30 minutes to 1 hour after the end of the transfusion in order to monitor for delayed transfusion reaction. *Summary of Documentation of Vital Signs/Assessments: DOCUMENTATION IN Electronic Health Record: 1. Document Vital Signs 15 minutes prior to transfusing patient. 2. Stay with patient for the first 15min after starting the transfusion and document a set of Vital signs. 3. Continue to monitor the patient throughout the transfusion. 4. Document vitals at 1 hour, 2 hour, 3 hour and upon completion of the transfusion. 5. Patients, are monitored and vitals are to be taken and documented 60 min after the transfusion and prior to discharge for a possible delayed transfusion reaction. 3. Review of three (3) patient charts revealed missing transfusion related documentation: a) Patient A transfused December 13, 2021. -Blood checked out of lab at 1711. *Laboratory personnel did not sign the Blood Administration Unit Signout Form. *Nursing did not document vital signs at the completion of the transfusion and 1 hour after completion of the transfusion. b) Patient B transfused November 26, 2022. -Blood checked out of lab at 0630. *Nursing personnel did not document "Time Blood Hung" in the chart. *Nursing personnel did not document "Amount of Blood Transfused" in the chart. c) Patient B transfused January 12, 2023. -Blood checked out of lab at 1532. *Nursing personnel did not document "Time Stopped" in the chart. *Nursing personnel did not document "Amount of Blood Transfused" in the chart. *Nursing did not document vital signs 1 hour after completion of the transfusion. d) Patient B transfused January 12, 2023. -Blood checked out of lab at 2253. *Nursing did not document vital signs 1 hour after completion of the transfusion. e) Patient C transfused August 11, 2022. -Blood checked out of lab at 1452. *Nursing documented pre-transfusion vital signs greater than 15 minutes before the transfusion was started. Nursing documented patient vital signs at 1415. Nursing hung the blood at 1500. *Nursing did not document vital signs 1 hour after completion of the transfusion. 4. In interview on February 16, 2023 at 3: 42 PM, the Director of Nursing confirmed that the missing information identified above was not documented in the patient charts.
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 observation, review of quality control, and interview with laboratory personnel, the laboratory failed to retain quality control records for at least two (2) years. Findings: 1. Observation by surveyors during laboratory tour on February 14, 2023 revealed the laboratory utilizes the Siemens Dimension EXL instrument. 2. Review of chemistry quality control records for the current lot in use at the time of the survey revealed the laboratory did not have records for establishing their acceptable range for MMB Level 1 and Level 3, Troponin Level 1, and BNP Level 1 and Level 3. 3. In interview on February 16, 2023 at 9:03 AM, General Supervisor 1 stated he was unable to find the quality control new lot establishment data for the analytes and levels identified above.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES

	CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Form) form, policies, personnel records, and interview with personnel, the laboratory failed to ensure procedures to assess competency for one (1) of two (2) Technical Consultants and General Supervisors reviewed were followed. Findings: 1. Review of the laboratory's CMS 209 form revealed two (2) personnel serve as Technical Consultant and General Supervisor. 2. Review of the laboratory's "Competency Policy" revealed "Documented competency assessment is required for the personnel listed as Technical Consultant/Clinical Consultant on the 209 form. This competency will be performed annually. Documented competency assessment is required for the personnel listed as General Supervisor on the 209 Form This competency will be performed annually. 3. Review of personnel records for Technical Consultant/General Supervisor 2 revealed the laboratory did not have documentation of a 2022 competency assessment for his duties as Technical Consultant and General Supervisor. 4. In interview on February 14, 2023 at 1:26 pm, General Supervisor 1 confirmed the Laboratory Director did not perform competency assessments for the duties of Technical Consultant and General Supervisor for Technical Consultant/General Supervisor 2.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, proficiency testing records, and interview with personnel, the laboratory failed to perform complete assessments for three (3) of five (5) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's "Proficiency Testing Policy and Procedure" under the "Survey Result Evaluation" section revealed "The Laboratory Manager is to perform the survey result evaluation review upon receipt of the result evaluation which includes corrective action due to sample result failures." 2. Further review of the laboratory's "Proficiency Testing Policy and Procedure" revealed the following documents: a) "Proficiency Testing Event Tracking" form b) A two-page "Action Needed Form" utilized for assessments c) "Proficiency Testing Survey Log" 3. Review of the laboratory's proficiency testing records results from the American Proficiency Institute (API) revealed the following "unacceptable" PT results: a) 2021 Immunology /Immunohematology 2nd Event: Direct Antiglobulin Test (DAT): Sample DAT-04 b) 2021 Chemistry Core 3rd Event: Alcohol: Sample ALC-13 c) 2022 Chemistry Core 1st Event: NT pro-BNP: Sample CM-01 4. Review of the laboratory's proficiency testing records revealed the laboratory did not have documentation of complete assessments for the following events: a) 2021 Immunology/Immunohematology 2nd Event: Direct Antiglobulin Test (DAT): Sample DAT-04. The laboratory did not complete page 2 of the "Action Needed Form" b) 2021 Chemistry Core 3rd Event: Alcohol: Sample ALC-13: No documentation of an assessment performed c) 2022 Chemistry Core 1st Event: NT pro-BNP: No documentation of an assessment

	performed 5. In interview on February 15, 2023 at 11:31 am, General Supevisor 1 confirmed the laboratory did not have documentation of complete assessments for the identified unacceptable PT results.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, requisitions, and interview with personnel, the laboratory failed to have a requisition that included a complete test menu for clients. Findings: 1. Review of the laboratory's test menu revealed high sensitivity troponin testing is performed. 2. In interview on February 14, 2023 at 12: 06 pm, General Supervisor 1 stated high sensitivity troponin testing began November 18, 2021. 3. Review of the laboratory's requisition revealed high sensitivity troponin was not included on the test menu. 4. In interview on February 16, 2023 at 3:28 pm, General Supervisor 1 confirmed the laboratory's requisition did not include the high sensitivity troponin test.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, client service manual, and interview with personnel, the laboratory failed to include instructions for specimen handling, transport, and stability requirements for high sensitivity troponin test. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs high sensitivity troponin testing. 2. In interview on February 14, 2023 at 12:06 pm, General Supervisor 1 stated high sensitivity troponin testing began November 18, 2021. 3. Review of the laboratory's client service manual revealed the laboratory did not include specimen handling, transport and stability requirements for the high sensitivity troponin test. 4. In interview on February 16, 2023 at 3:28 pm, Supervisor 1 confirmed the laboratory's client service manual did not include specimen handling, transport and stability requirements for the high sensitivity troponin test.
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:

	I. Based on review of laboratory policy and procedure and interview with laboratory personnel, the laboratory failed to follow their policy for establishing quality control ranges of Thyroid Stimulating Hormone (TSH), Ethanol (ETOH), and Ammonia (AMM). Findings: 1. Review of the laboratory's policy "Laboratory QC Policy" under "Establishing QC Performance (Statistical Calculations) revealed "No more than three (3) data points per day should be used to obtain the target value mean. Ensure that different shifts and different personnel are running and signing QC during the establishment time." 2. Review of the quality control mean establishment for TSH , ETOH, and AMM revealed quality control was tested more than three times per day as follows: a) TSH Levels 1 and 3: -Eleven (11) times May 16, 2022 b) ETOH Level 1, AMM Levels 1 and 3: -Six (6) times on March 8, 2022 -Twelve (12) times on March 13, 2022 c) ETOH Level 3: -Six (6) times on March 8, 2022 -Twelve (12) times on March 13, 2022 -Nine (9) times on March 14, 2022 3. In interview on February 16, 2023 at 9:03 AM, the General Supervisor 1 confirmed the laboratory ran quality control more than three times per day to establish quality control ranges. II. Based on review of laboratory policy and procedure and blood bank refrigerator circular charts, as well as interview with laboratory personnel, the laboratory failed to follow their alarm check policy for blood bank alarm testing. Findings: 1. Review of the policy "Blood Bank Alarm Check" under the section "Statement of Purpose" revealed "External alarm will sound at Nurses station. Nurses' response time is 1 minute." 2. In interview on February 16, 2023 at 11:51 AM, the General Supervisor 1 stated that the information identified above is outdated and the nurses' station does not have an alarm. 3. Further review of the policy "Blood Bank Alarm Check" under the "Procedure" section revealed that after performing the alarm check "Log the low alarm activation" and "Log the high alarm activation." 4. Review of the blood bank circular charts for monitoring of the blood bank refrigerator showed documentation of the alarm checks on the back of the chart. 5. In interview on February 16, 2023 at 11: 51 AM, the General Supervisor 1 confirmed that the alarm check was documented once the graph was removed from service and not when the alarm check was performed. 36645 III. Based on review of the laboratory's polices and interview with personnel, the laboratory failed to establish a complete policy manual. Findings: 1. Review of the laboratory's polices revealed the laboratory did not include the following: a) Normal patient mean study for Prothrombin time (PT) testing, to include but not limited to acceptable donor criteria b) New lot of controls/reagents implementation for Coagulation testing 2. In interview on February 16, 2023 at 10:21 am, General Supervisor 1 confirmed the laboratory did not have the identified procedures. IV. Based on review of the laboratory's policies, records, and interview with personnel, the laboratory failed to following their established Laboratory Information System (LIS) procedure. Findings: 1. Review of the "Laboratory LIS Verification" procedure revealed "Any result that is calculated by the LIS will be manually verified on a yearly basis. The results that the LIS calculates are as follows: Anion Gap, Albumin/Globulin Ratio, Bun/Creatinine Ratio, GFR, Globulin, Indirect Bilirubin, and LDL." 2. Review of the laboratory's records revealed the laboratory did not have documentation of an annual LIS verification for 2022. 3. In interview on February 16, 2023 at 3:28 pm, General Supervisor 1 and the Compliance personnel confirmed the laboratory did not have documentation of the annual LIS verification for 2022.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy and procedure manual and interview with laboratory personnel, the laboratory failed to ensure policies and procedures were updated to reflect current testing menu and quality control materials. Findings: 1. Review of the "Laboratory QC Policy" under the section "Quality Control Materials" revealed the following: "Bio-Rad Cardiac Markers Plus Control Levels 1 &3 CK-MB, ProBNP, Trop NOTE: i) Stable until expiration date when stored at -20C to -70C, ii) 20 day opened stability at 2-8C (except for Trop I and Myoglobin - 10 days NT-proBNP - 5 days, and Troponin T - 4days)." 2. Review of Task 1 and 3 submitted by the laboratory revealed current test menu analyte Troponin I-HS and the associated quality control Bio-Rad Cardiac Marker Plus LT. 3. In interview on February 16, 2023 at 09:03 AM, General Supervisor 1 confirmed the current testing and quality control on Task 1 and 3 was correct and the laboratory's quality control policy was not updated. II. Based on review of the laboratory's policy and procedure manual and the Troponin I High Sensitivity performance specification records, as well as interview with laboratory personnel, the laboratory failed to ensure the procedure for High Sensitivity Troponin was approved by the Laboratory Director. Findings: 1. Review of the laboratory's policy and procedure manual revealed the laboratory did not have record of a policy or procedure for High Sensitivity Troponin. 2. On February 14, 2023 at 3:24 PM, General Supervisor 1 gave surveyors a document titled "LOCI High-Sensitivity Troponin." 3. Review of the procedure for "LOCI High-Sensitivity Troponin" revealed no record of the Laboratory Director's approval and signature. 4. In interview on February 14, 2020 at 3:24 PM, General Supervisor 1 stated the policy he gave surveyors was located in his office. He confirmed the identified procedure was not included in the laboratory's policy and procedure manual available to testing personnel. He said that he thought he had a procedure for the identified test signed by the Laboratory Director but could not find it.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, review of policies, and interview with laboratory personnel, the laboratory failed to ensure that blood collection tubes and transport medium were not used beyond their expiration dates. Findings: 1. Observation by the surveyors during the tour of the laboratory on February 14, 2023 at 10:11 am revealed the following expired items in place for patient testing: In a phlebotomy tray: a. One (1) BD Vacutainer K2EDTA Ref 367841 Lot 1195782 exp 10/31/22. b. One (1) BD Vacutainer PST Gel and Lithium Heparin 83 units Ref 367962 Lot 2018936 exp 1/31 /23. c. One (1) BD Vacutainer Buff Na Citrate 0.109M 3.2% Ref 363083 Lot 2109029 exp 1/31/23. In drawer labeled Labcorp transfer tubes: a. Three (3) Capillary EDTA K lot 7074111 exp 10/2020. b. Two (2) Capillary Li Heparin Lot 8071711 exp 4/2021. In drawer labeled Wound Culture Swabs: a. Three (3) Transystem sterile transport swab 003H38 L 212001800 exp 12/31/22. b. Two (2) Transystem sterile transport swab 029B39 L 211917500 exp 12/31/22. 2. Review of the laboratory's "Expired Items Audit" revealed "Each area of the laboratory will be audited monthly by testing

	personnel and phlebotomists/lab assistants (Blood bank monitored weekly) for items near or beyond expiration date. The monthly audit will be documented on the expired items log sheet." 3. In interview on February 14, 2023 at 10:28 AM, General Supervisor 1 confirmed the expired items in the phlebotomy tray. In interview on February 14, 2023 at 11:00 AM, General Supervisor 1 confirmed the expired items in the Labcorp transfer tubes drawer. In interview on February 14, 2023 at 11:21 AM, the Testing Personnel 2 confirmed the expired items in the Wound Culture Swabs drawer. 4. In interview on February 16, 2023 at 10:20 am, General Supervisor 1 stated the laboratory did not have an expired items log with documentation of monthly checks.
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 observation, review of High Sensitivity Troponin validation records, as well as interview with laboratory personnel, the laboratory failed to verify complete performance specification for High Sensitivity Troponin (TNIH) testing on the Siemens Dimension EXL Analyzer. Findings: 1. Observation by the surveyors on February 14, 2023 revealed the laboratory utilized the Siemens Dimension EXL Chemistry Analyzer. 2. Review of the validation studies summary for High Sensitivity Troponin revealed no acceptability criteria range was clearly defined for accuracy. The summary stated "Verification of Accuracy and Precision (run-to-run, day-to-day, and operator variance): Twenty (20) points of QC were performed October 15, 2021 through November 14, 2021 and were within range." 3. Further review of the validation summary revealed that the simple precision summary was not followed. The summary stated "Verification of Within Run (Simple) Precision: Five (5) runs of Five (5) levels of Linearity Material were performed in a row on September 2, 2021 and October 14, 2021." - Raw data labeled as "Precision" had Level 1 and Level 3 written on the instrument printout and five (5) runs performed. - Raw data labeled as "Linearity" had five (5) levels and three (3) runs performed. 4. Review of the validation summary revealed that the reportable range and reference range was not clearly stated. The summary stated: -"Verification of TNIH Reportable Range was obtained from linearity material on September 2, 2021." -"Verification of Reference Range was obtained by running Twenty (20) normal patients on October 15, 2021. Normal patient questionnaires included." 5. In interview on February 15, 2023 at 9:15 AM, General Supervisor 1 stated that for accuracy "within range" meant within the package insert range. He confirmed that this was not stated on the summary. He also confirmed that the reportable and reference ranges were not stated in the summary or in the validation files.
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:
I. Based on observation, review of maintenance records, and interview with laboratory personnel, the laboratory failed to ensure daily maintenance for the Siemens Dimension EXL instrument was performed and documented for three (3) of three hundred sixty-five (365) days reviewed. Findings: 1. Observation by surveyors during the laboratory tour on February 14, 2023 revealed the laboratory utilized the Siemens Dimension EXL. 2. Review of the 2022 maintenance logs for the Siemens Dimension EXL revealed the laboratory was to perform and document the following: *Daily Maintenance -Cuvette -Reagent -HM -RMS Hydration -RMS Reagent -Empty Cuvette Waste -Run System Check 3. Further review of the maintenance logs for 2022 revealed the laboratory failed to document the daily maintenance readings for the following dates: July 27, 2022 - RMS Hydration November 1, 2022 - Cuvette, Reagent, HM, RMS Hydration, RMS Reagent December 14, 2022 - RMS Hydration, RMS Reagent 4. In interview on February 16, 2023 at 10:42 AM, General Supervisor 1 confirmed the documentation listed above was missing. He stated that service was called on July 27, 2022 but the laboratory did not document the RMS readings after service was completed. II. Based on observation, review of maintenance records, and interview with laboratory personnel, the laboratory failed to ensure the daily system check for the Siemens Dimension EXL instrument was performed and documented for two (2) of three hundred sixty-five (365) days reviewed. Findings: 1. Observation by surveyors during the laboratory tour on February 14, 2023 revealed the laboratory utilized the Siemens Dimension EXL 2. Review of the 2022 maintenance logs for the Siemens Dimension EXL revealed the laboratory was to perform and document the following: *Daily System Check -Reagent 1 -Reagent 2 -Sampler -HM -RMS -LOCI Highest Value -ABS Lot 3. Further review of the maintenance logs for 2022 revealed the laboratory failed to document the daily system check for the following dates: July 27, 2022 - RMS November 1, 2022 - Reagent 1, Reagent 2, Sampler, HM, RMS, LOCI Highest Value, ABS Lot 4. In interview on February 16, 2023 at 10:42 AM, the General Supervisor 1 confirmed the documentation listed above was missing. He stated that service was called on the July 27, 2022 but the laboratory did not document the RMS readings after service was completed. III. Based on observation, review of maintenance records, and interview with laboratory personnel, the laboratory failed to perform the EXL Quiklyte sensor change every five days as required by the manufacturer for the Siemens Dimension EXL instrument for four (4) of eighteen (18) sensor changes reviewed. Findings: 1. Observation by surveyors during the laboratory tour on February 14, 2023 revealed the laboratory utilized the Siemens Dimension EXL 2. Review of the 2022 maintenance logs for the Siemens Dimension EXL indicated the laboratory was to perform and document the following: *EXL Quiklyte sensor change (performed every five days) 3. Review of the maintenance logs for 2022 revealed the laboratory failed to document the Quiklyte sensor change for the following dates thereby exceeding five days: July 23, 2022 (put in use July 18, 2022 and replaced on July 24, 2022) September 23, 2022 (put in use September 18, 2022 and replaced September 24, 2022) November 13, 2022 (put in use November 8, 2022 and replaced November 14, 2022) November 22, 2022 (put in use November 17, 2022 and replaced November 24, 2022) 4. In interview on February 16, 2023 at 10:42 AM, the General Supervisor 1 confirmed the sensor change and documentation listed above was missing. IV. Based on observation, review of maintenance records, and interview with laboratory personnel, the laboratory failed to ensure weekly maintenance for the

	Siemens Dimension EXL instrument was performed and documented for two (2) of fifty-two (52) weeks reviewed. Findings: 1. Observation by surveyors during the laboratory tour on February 14, 2023 revealed the laboratory utilized the Siemens Dimension EXL. 2. Review of the 2022 maintenance logs for the Siemens Dimension EXL indicated the laboratory was to perform and document the following: *Weekly Maintenance -Clean outside R2 probe -Clean HM Wash Probe 3. Review of the maintenance logs for 2022 revealed the laboratory failed to document the weekly maintenance for the following weeks: September 4, 2022 - September 10, 2022 September 25, 2022 - October 1, 2022 4. Further review of the September 2022 Weekly Maintenance log revealed the comment "See QA Incident for weekly Maint being" but the laboratory was unable to provide documentation of the quality assurance for the missed weeks. 5. In interview on February 16, 2023 at 10:42 AM, General Supervisor 1 confirmed the weekly maintenance and documentation listed above was missing. V. Based on observation, review of maintenance records, and interview with laboratory personnel, the laboratory failed to ensure weekly maintenance for the Sysmex XS-1000i instrument was performed and documented for one (1) of fifty-two (52) weeks reviewed. Findings: 1. Observation by surveyors during the laboratory tour on February 14, 2023 revealed the laboratory utilized the Sysmex XS-1000i. 2. Review of the 2022 maintenance logs for the Sysmex XS-1000i indicated the laboratory was to perform and document the following: *Weekly Maintenance - Power Down IPU 3. Further review of the maintenance logs for 2022 revealed the laboratory failed to document the weekly maintenance for the week of December 11, 2022 - December 17, 2022 4. In interview on February 16, 2023 at 3:54 PM, the General Supervisor 1 confirmed the weekly maintenance and documentation listed above was missing. 36645 VI. Based on observation by surveyors, review of the laboratory's maintenance logs, and interview with personnel, the laboratory failed to ensure monthly maintenance procedures for the Chemistry analyzer were performed as required by the manufacturer for one (1) of twelve (12) months reviewed in 2022. Findings: 1. Observation by surveyors during the laboratory tour on February 14, 2023 at 10:11 am revealed the laboratory utilizes the Siemens Dimension EXL for Chemistry testing. 2. Review of the "QUIKLYTE/Weekly/Monthly Maintenance Logs" revealed the following monthly tasks: a) Replace IMT Tubing b) Clean IMT System c) Replace/clean air filters d) Stylette HM wash probes e) Replace HM Pump Head f) Clean Windows 3. Review of the "QUIKLYTE/Weekly/Monthly Maintenance Logs" for 2022 revealed the laboratory did not document the following monthly maintenance tasks for May 2022: a) Replace HM Pump Head b) Clean Windows 4. In interview on February 16, 2023 at 10:42, General Supervisor 1 confirmed the laboratory did not have documentation of performance of the identified monthly maintenance tasks for May 2022.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's corrective action documents and interview with personnel, the laboratory failed to follow their established corrective action policies regarding review and documentation. Findings: 1. Review of the laboratory's "QA Incident Form" revealed the laboratory documents the following: a) Problem/Event b)

	Resolution/Corrective Action: c) QA Monitoring (Indicator) d) Laboratory Manager signature/date e) Laboratory Director signature/date 2. Review of random selection of the laboratory's "QA Incident Forms" in 2022 revealed the laboratory did not complete documentation for the following: a) QA Incident for February 2022 regarding ISE sensor change: The laboratory did not document "QA Monitoring (Indicator)" and the Laboratory Director's review (signature). b) QA Incident for September 2022 regarding CO2: The laboratory did not document "QA Monitoring (Indicator)" and the Laboratory Director's review (signature). 3. In interview on February 15, 2023 at 11:31 am, General Supervisor 1 confirmed the laboratory did not have complete documentation and review for the identified corrective actions performed.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on temperature log review and interview with personnel, the laboratory failed to document corrective action when the laboratory's room temperature was not maintained between 18 degrees to 25 degrees Celsius as required by the laboratory for seven (7) of three hundred sixty-five (365) days reviewed. Findings: 1. Review of the laboratory's temperature logs from 2022 revealed the laboratory failed to maintain the room temperature between 18 degrees to 25 degrees Celsius per laboratory's requirements for the following dates: October 19, 2022 October 20, 2022 October 21, 2022 November 6, 2022 November 19, 2022 December 15, 2022 December 17, 2022 2. In interview on February 16, 2023, General Supervisor 1 confirmed the laboratory did not document corrective actions for the dates identified above.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and corrective action logs, as well as interview with laboratory personnel, the laboratory failed to

	document corrective actions performed when chemistry quality control was outside of acceptable limits for seven (7) of ninety-two (92) days reviewed. Findings: 1. Review of the laboratory's policy "Laboratory QC Policy" under "Trouble shooting (sic) Out of Range QC" revealed "...NOTE: Document all advice from Technical Support on Corrective Action Log (to include reference number). Include all corrective actions on the QC Corrective Action Log." 2. Further review of quality control performed January 2022, November 2022, and January 2023 revealed the following out of control runs as determined by the laboratory without corrective actions documented: 01/04/2022 - Amm Level 3 01/16/22 - LNTP Level 1 1/9/23 - HCG Level 1 1/9/23 - DGNA Level 1 1/9/23 - Ca Level 1 1/17/23 - Ca Level 1 1/24/23 - Amy Level 3 3. In interview on February 15, 2023 at 2:00 PM, General Supervisor 1 confirmed corrective action for the quality control runs listed above was not documented.
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 observation, record review, and interview with personnel, the laboratory failed to have Quality Assurance monitors in place to identify and correct quality issues in Analytic Systems. Findings: 1. The laboratory failed to ensure that blood collection tubes and transport medium were not used beyond their expiration dates. Refer to D5417. 2. The laboratory failed to maintain complete performance specification verifications for High Sensitivity Troponin (TNIH) testing on the Siemens Dimension EXL Analyzer. Refer to D5421. 3. The laboratory failed to ensure maintenance for the Siemens Dimension EXL instrument was performed and documented. Refer to D5429 I, II, III, IV, V, and VI. 4. The laboratory failed to document corrective actions performed when the laboratory's room temperature was not maintained between 18 degrees to 25 degrees Celsius per laboratory's requirements. Refer to D5781. 5. The laboratory failed to document corrective actions performed when chemistry quality control was outside of acceptable limits. Refer to D5783.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the laboratory's Quality Assessment system failed to identify and correct problems identified with the

	postanalytic system. Findings: 1. The laboratory failed to ensure the documentation of all transfusion-related activities as required by the hospital and laboratory. Refer to D3015.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) 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 observation, record review, and interview with personnel, the Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to retain quality control records for at least two (2) years. Refer to D3031. 2. The laboratory failed to have a requisition that included a complete test menu for clients. Refer to D5301. 3. The laboratory failed to include instructions for specimen handling, transport, and stability requirements for high sensitivity troponin test. Refer to D5317. 4. The laboratory failed to ensure supplies and reagents did not exceed their expiration dates. Refer to D5417. 5. The laboratory failed to document corrective action when the laboratory's room temperature was not maintained between 18 degrees to 25 degrees Celsius as required by the laboratory. Refer to D5781. 6. The laboratory failed to document corrective actions performed when chemistry quality control was outside of acceptable limits. Refer to D5783.
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 record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. 1. The laboratory failed to ensure one (1) of five (5) proficiency testing samples for D-dimer were tested in the same manner as patient samples in September 2022. Refer to D2006. 2. The laboratory failed to ensure attestation statements were signed by testing personnel as required for four (4) of five (5) proficiency testing (PT) events reviewed. Refer to D2015.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing evaluation forms were maintained. Refer to D5221.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D5401 I.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels

	of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on review of instrument maintenance records and interview with laboratory personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to ensure daily maintenance for the Siemens Dimension EXL instrument was performed and documented. Refer to D5429 I. 2. The laboratory failed to ensure the daily system check for the Siemens Dimension EXL instrument was performed and documented. Refer to D5429 II. 3. The laboratory failed to ensure EXL Quiklyte check for the Siemens Dimension EXL instrument was performed and documented. Refer to D5429 III. 4. The laboratory failed to ensure weekly maintenance for the Siemens Dimension EXL instrument was performed and documented. Refer to D5429 IV. 5. The laboratory failed to ensure weekly maintenance for the Sysmex XS-1000i instrument was performed and documented. Refer to D5429 V. 6. The laboratory failed to ensure monthly maintenance procedures for the Chemistry analyzer were performed as required by the manufacturer for one (1) of twelve (12) months reviewed in 2022. Refer to D5429 VI.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5779.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. 1. The laboratory failed to ensure procedures to assess competency for one (1) of two (2) Technical Consultants and General Supervisors reviewed were followed. Refer to D5209. 2. The Technical Consultants failed to ensure seven (7) of eight (8) testing personnel were assessed for their problem solving skills for moderate complexity testing. Refer to D6052.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy manual. Refer to D5401 III. 2. The laboratory failed to following their established Laboratory Information System (LIS) procedure. Refer to D5401 IV. 3. The laboratory failed to ensure policies and procedures were updated to reflect current testing menu and quality control materials. Refer to D5407 I. 4. The laboratory failed to have the procedure for High Sensitivity Troponin approved and signed by the Laboratory Director. Refer to D5407 II.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, personnel records, and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of Technical Consultant to one (1) of two (2) personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 form revealed the laboratory has two (2) personnel serving as Technical Consultant. 2. Review of personnel records for Technical Consultant 2 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of

	Technical Consultant to him. 3. In interview on February 14, 2023 at 1:26 pm, General Supervisor 1 confirmed the laboratory did not have written documentation of delegation of responsibilities to Technical Consultant 2.
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 observation by surveyors, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to retain quality control records for at least two (2) years. Refer to D3031. 2. The laboratory failed to establish a complete policy manual. Refer to D5401 III. 3. The laboratory failed to ensure daily maintenance for the Siemens Dimension EXL instrument was performed and documented. Refer to D5429 I. 4. The laboratory failed to ensure the daily system check for the Siemens Dimension EXL instrument was performed and documented. Refer to D5429 II. 5. The laboratory failed to ensure EXL Quiklyte check for the Siemens Dimension EXL instrument was performed and documented. Refer to D5429 III. 6. The laboratory failed to ensure weekly maintenance for the Siemens Dimension EXL instrument was performed and documented. Refer to D5429 IV. 7. The laboratory failed to ensure weekly maintenance for the Sysmex XS-1000i instrument was performed and documented. Refer to D5429 V. 8. The laboratory failed to ensure monthly maintenance procedures for the Chemistry analyzer were performed as required by the manufacturer for one (1) of twelve months reviewed in 2022. Refer to D5429 VI.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b) The technical consultant is responsible for-- (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed

	to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5781.
D6052	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills. This STANDARD is not met as evidenced by: Based on review of the laboratory's competency assessment policies, personnel records, and interview with personnel, the Technical Consultants failed to ensure seven (7) of eight (8) testing personnel were assessed for their problem solving skills for moderate complexity testing. Findings: 1. Review of the laboratory's "Competency Policy" revealed testing personnel are assessed for the following six (6) procedures: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 2. Review of the following personnel records revealed the Technical Consultants did not assess problem solving skills: a) Technical Consultant 2 (also serves as Testing Personnel): missing assessment in 2021 for Hematology (including instrument and manual differential procedures), Coagulation testing, and Chemistry testing (including instrument and urinalysis microscopic procedures) b) Testing Personnel 1: missing assessment in 2021 for Hematology testing (including instrument and manual differential procedures), Coagulation testing, and Chemistry testing (including instrument and urinalysis microscopic procedures) c) Testing Personnel 2: missing assessment for semi-annual competency (performed in 2021) for Coagulation testing, Chemistry testing (including instrument and urinalysis microscopic procedures), and manual differential procedure for Hematology testing. d) Testing Personnel 5 (previous employee): missing assessment in 2021 for Hematology testing (including instrument and manual differential procedures), Coagulation testing, and Chemistry testing (including instrument and urinalysis microscopic procedures) e) Testing Personnel 6 (previous employee): missing assessment in 2021 for Hematology instrument testing f) Technical Consultant 2: missing assessment in 2022 for Hematology testing (including instrument and manual differential procedures) g) Testing Personnel 4: missing assessment in 2022 for Hematology testing (including instrument and manual differential procedures), Coagulation testing, and Chemistry testing (including instrument and urinalysis microscopic procedures) f) General Supervisor 1: missing assessment for sem-annual competency (performed in 2022) for Hematology testing (including instrument and manual differential procedures), Coagulation testing, and Chemistry testing (including instrument and urinalysis microscopic procedures) 3. In interview on February 14, 2023 at 1:26 pm, General Supervisor 1 stated problem solving skills are assessed through the corrective action logs; however, are not documented on the competency assessment forms. General Supervisor 1 confirmed there was no documentation of assessment for problem solving skills for the identified Testing Personnel.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5401 II.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency testing evaluation forms were maintained. Refer to D5221.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. 1. The laboratory failed to have Quality Assurance monitors in place to identify and correct quality issues in Analytic Systems. Refer to D5791. 2. The laboratory's Quality Assessment system failed to identify and correct problems identified with the postanalytic system. Refer to D5793.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were documented when deviations from laboratory's policies occurred. Refer to D5781.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. 1. The laboratory failed to ensure procedures to assess competency for one (1) of two (2) Technical Consultants and General Supervisors reviewed were followed. Refer to D5209. 2. Review of the laboratory's "Competency Policy" revealed testing personnel are assessed for the following six (6) procedures: a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. b) Monitoring the recording and reporting or test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. f) Assessment of problem solving skills. 3. Review of the following personnel records revealed the Laboratory Director (who also serves as the Technical Supervisor) did not ensure testing personnel who performed blood bank testing were assessed, at a minimum for, the six (6) identified procedures: a) Technical Consultant 2 (also serves as Testing Personnel): 2021 assessment review of intermediate test results, quality control records, proficiency testing results and preventative maintenance records, director observation of maintenance, and problem solving skills was not documented b) Testing Personnel 2 for six month assessment in 2021: direct observation of maintenance and problem solving skills were not assessment b) Testing Personnel 5 (Previously employed): 2021 assessment direct observation of maintenance and problem solving skills were not documented c) Testing Personnel 6 (Previously employed): 2021 assessment direct observation of maintenance and problem solving skills were not documented d) Technical Consultant 2 (also serves as Testing Personnel): 2022 assessment of problem solving skills was not documented e) General Supervisor 1 (also serves as Testing Personnel) for six month in 2022; assessment of problem solving skills was not documented f) Testing Personnel 4: 2022 assessment of problem solving skills was not documented 4. In interview on February 14, 2023 at 1:26 pm, General Supervisor 1 confirmed there was no documentation of competency assessments for the identified procedures and Testing Personnel.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test

	results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 (Laboratory Personnel Report) form, personnel records, and interview with personnel, the Laboratory Director failed to delegate, in writing, the responsibilities of General Supervisor to one (1) of two (2) personnel reviewed. Findings: 1. Review of the laboratory's CMS 209 form revealed the laboratory has two (2) personnel serving as General Supervisor. 2. Review of personnel records for Technical Consultant 2 revealed the laboratory did not have documentation of the Laboratory Director delegating the tasks and responsibilities of General Supervisor to him. 3. In interview on February 14, 2023 at 1:26 pm, General Supervisor 1 confirmed the laboratory did not have written documentation of delegation of responsibilities of General Supervisor to Technical Consultant 2.