Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0461133	06/24/2021
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 Certification Survey was performed at Acadia St. Landry Hospital -CLIA # 19D0461133 on June 21, 2021 through June 24, 2021. Acadia St. Landry Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 400.200 CONDITION: Reporting of SARS-COV-2 Test Results 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories Performing Moderate Complexity Testing: Technical Consultant
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: I. Based on observation by surveyor, review of manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to providers or patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Observation by surveyor during laboratory tour on June 22, 2021 at 10:33 am revealed the laboratory utilizes the CareStart COVID-19 Antigen tests for SARS COV-2 testing. 2. Review of the manufacturer's instructions for use under the "Conditions of Authorization of the Laboratory" section revealed "Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. In interview on June 22, 2021 at 12:57 pm, the Technical Consultant stated fact sheets are not given to patients or providers. 4. Review of the laboratory's test menu revealed the laboratory performs 275 SARS COV-2 tests annually. II. Based on review of

	manufacturer's instructions, patient final test reports, test menu, and interview with personnel, the laboratory failed to include the Food and Drug Administration (FDA) Emergency Use Authorization statement on SARS COV-2 patient final reports. Findings: 1. Review of the manufacturer's instructions for the CareStart revealed the following statement: "This product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by laboratories certified under the CLIA that meet the requirements to perform moderate, high or waived complexity tests." 2. Review of random selection of patient final reports for SARS COV-2 revealed the laboratory did not include the identified Emergency Use Authorization statement on patient final reports. 3. In interview on June 22, 20121 at 1:23 pm, the Technical Consultant confirmed the laboratory's patient final reports for SARS COV-2 did not include the identified statement. 4. Review of the laboratory's test menu revealed the laboratory performs 275 SARS COV-2 tests annually.
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of the laboratory's COVID reports and interview with personnel, the laboratory failed to report ninety one (91) COVID patient test results to the state as required. Findings: 1. Observation by surveyor during laboratory tour on June 22, 2021 at 10:33 am, the laboratory utilizes the CareStart COVID-19 Antigen tests for SARS COV-2 testing. 2. In interview on June 22, 2021 at 12:07 pm, the Technical Consultant stated the laboratory does not report any COVID-19 results to the state. 3. In further interview on June 22, 2021 at 12:57 pm, the Technical Consultant stated the laboratory began testing COVID samples in-house on February 13, 2021. 4. Review of the laboratory's "CARESTART COVID-19 ANTIGEN" patient logs for May 2021 and June 2021 revealed the laboratory did not report positive or negative results for the following patients: Patient 10076920 Patient 10077141 Patient 10077258 Patient 10077422 Total of thirty three (33) patients tested in May 2021 and June 2021. 4. In interview on June 24, 2021 at 8:55 am, the Technical Consultant stated as of June 24, 2021 the laboratory tested ninety one (91) COVID-19 samples.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of nursing administration policies, laboratory policies, and interview with personnel, the laboratory failed to define specific criteria for suspected

	transfusion reactions. Findings: 1. Review of the laboratory's "Transfusion Reaction" procedure revealed "The nurse will monitor for common signs and symptoms of a transfusion reaction: Hemolytic or incompatibility reaction-most sever, Bacterial contamination, Allergic Reaction, Febrile, non-hemolytic reaction (temperature elevation of 2 degrees F). Common signs and symptoms: abnormal bleeding, chest /back pain, chills, coughing, cyanosis, dyspnea, facial flushing, fever (a temperature elevation of 2 degrees F is considered a reportable symptom of a suspected reaction), headache, heat at infusion site, hemoglobinuria, hypotension, itching, myalgia, nausea, oliguria/anuria, pulmonary edema, rales, rash, uneasy feelings, urticaria (hives) , wheezing." 2. Review of the nursing department's "Adverse Transfusion Reactions" policy, revealed the following signs and symptoms of a possible transfusion reaction: "localized urticarial (hives), pruitis, rash, dyspnea, wheezing, tachypnea, cyanosis, blood pressure changes greater than or equal to 20 mm/HG in 2 consecutive readings, tachycardia, nausea, vomiting, cramping, rigors, temperature changes great [sic] than or equal to 2 degrees Fahrenheit in 2 consecutive readings, flank pain, unexplained bleeding, hemoglobinuria, chills, oliguria." 3. Review of the nursing department's "Blood and Blood Product Administration" policy (revised "5 /2017") under step "12." revealed the following: a) "If a patient's temperature increases or decreases by 2 degrees Fahrenheit in two consecutive readings, stop blood, notify MD, and initiate Management of Possible Transfusion Reaction" b) "If the patient's blood pressure decreases by 50 mm/Hg in two consecutive readings and is NOT symptomatic, observe the patient and recheck the BP in 10 minutes. If the BP still has a 50 mm/Hg difference, stop blood and notify MD. Document any BP change explanation (ie. up to bathroom)." 4. Review of the nursing department's "Blood Administration Record" under the "Initiate Blood Transfusion Reaction Protocol and Report for the Following Positive Findings:" section revealed the following: "Was there a Temperature increase by 2 F? Was there a B/P increase or decrease of 20 mm /Hg in 2 consecutive readings?" 5. Review of the nursing department's " Blood Transfusion Documentation Review/Check-List" revealed the following: a)" Increase of temperature by 2 degrees F" b) "BP increase or decrease of 20 mm/Hg in 2 consecutive readings" 6. Further review of the "Nursing" department procedures and forms for transfusion reactions revealed the clinical symptoms for suspected transfusion reactions did not match the laboratory's criteria. 7. In interview on June 24, 2021 at 3:30 pm, the Director of Nursing stated the laboratory's previous Laboratory Director approved the transfusion reactions policies and forms. The Director of Nursing further stated the nursing department's "Adverse Transfusion Reaction" policy is no longer in use. The Director of Nursing stated she was unsure of why the change in blood pressure differed in the policies. The Director of Nursing confirmed the nursing department's criteria for transfusion reactions did not match the laboratory's criteria.
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 policy and interview with personnel, the laboratory failed to ensure the personnel competency assessment policy included frequency of performance for the Technical Consultant and General Supervisor.

	Findings: 1. Review of the "Laboratory Competency" policy revealed the laboratory did not include frequency of performance of assessment of duties for the Technical Consultant and General Supervisor. 2. In interview on June 23, 2021 at 11:50 am, the Technical Consultant confirmed the policy did not include frequency of performance of competency assessment by the Laboratory Director for his duties as Technical Consultant and General Supervisor .
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 collection instructions and interview with personnel, the laboratory failed to establish detailed written instructions for providers regarding specimen transport. Findings: 1. Review of the collection instructions (requisition and "Tube Colors" form) revealed the laboratory did not include the following instructions for providers: a) Specimen storage and preservation b) Conditions for specimen transportation. 2. In interview on June 23, 2021 at 11:22 am, Testing Personnel 1 confirmed the laboratory's instructions to providers did not include written instructions for specimen storage and transport.
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 observation by surveyor, record review, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 I. 2. The laboratory failed to perform the platelet poor plasma studies annually per policy for one (1) of two (2) years reviewed. Refer to D5401 II. 3. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 4. The laboratory failed to ensure policies and procedures were updated to current instrumentation. Refer to D5407. 5. The laboratory failed to document the appropriate expiration date of the saline utilized for blood bank testing as required. Refer to D5415. 6. The laboratory failed to have complete reference range studies for D-dimer. Refer to D5421 I. 7. The laboratory failed to have complete reference range studies for Hemoglobin A1C (HGB A1C). Refer to D5421 II. 8. The laboratory failed to perform positive and negative controls for Acetone testing for one (1) of five (5) months reviewed. Refer to D5449. 9. The laboratory failed to utilize control material relative to the specific drug of abuse cut-off values per manufacturer requirements for urine drug screen (UDS) testing. Refer to D5479. 10. The laboratory

	failed to perform two (2) levels of controls every eight (8) hours of patient testing for Coagulation testing for two (2) of 151 days reviewed. Refer to D5545. 11. The laboratory failed to ensure the pathologist (Laboratory Director) reviewed blood products released for emergency release for one (1) of one (1) patients reviewed. Refer to D5553. 12. The laboratory failed to perform quarterly blood bank refrigerator alarm checks for two (2) of nine (9) quarters reviewed. Refer to D5555 I. 13. The laboratory failed to monitor the blood bank refrigerator's temperature for the storage of blood products for two (2) of four (4) weeks in January 2020. Refer to D5555 II. 14. The laboratory failed to take corrective action when QC values were unacceptable for Coagulation testing for two (2) of fourteen (14) days reviewed in February 2021. Refer to D5783 I. 15. The laboratory failed to take corrective action when QC values were unacceptable for Chemistry testing for one (1) of twenty nine (29) days reviewed in February 2020. Refer to D5783 II. 16. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
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 the laboratory's policies and procedures, and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written policies and procedures that included the following: a) Reporting of SARS COV-2 test results to state public health agency b) Manual INR checks to include procedure and frequency 2. In interview on June 22, 2021 at 1:23 pm, the Technical Consultant confirmed the laboratory did not have a policy related to reporting SARS COV-2 results to the state public health agency. 3. In interview on June 23, 2021 at 10:50 am, Testing Personnel 1 confirmed the laboratory's policies /procedures did not include manual INR check. II. Based on review of the laboratory's policies, platelet poor plasma records, and interview with personnel, the laboratory failed to perform the platelet poor plasma studies annually per policy for one (1) of two (2) years reveiwed. Findings: 1. Review of the laboratory's "Platelet Poor Plasma" policy revealed "Platelet Poor Plasma verification shall be performed annually or as necessary when changes in centrifugation equipment are performed." 2. Review of the laboratory's platelet poor plasma records for 2019 and 2020 revealed the laboratory did not perform platelet poor plasma studies for 2019. 3. In interview on June 24, 2021 at 10:33 am, the laboratory's compliance personnel stated the Technical Consultant could not find the laboratory's platelet poor plasma studies for 2019.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, and interview with personnel, the laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include detailed instructions for the following: a) Quality Control, to include but not limited to, type, number and identity of controls for Coagulation and urine drug screen testing 2. In interview on June 23, 2021 at 1:20 pm, the Technical Consultant confirmed the laboratory's quality control policies did not include the identified information.
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: Based on review of the laboratory's procedures and interview with personnel, the laboratory failed to ensure policies and procedures were updated to current instrumentation. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have current policies for the following: a) Quality Assessment (QA) policy to include the laboratory's current coagulation instrumentation. 2. In interview on June 24, 2021 at 3:30 pm, the Technical Consultant confirmed the laboratory's identified policy did not include current instrumentation.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of the laboratory's blood bank records and interview with personnel,

	the laboratory failed to document the appropriate expiration date of the saline utilized for blood bank testing as required. Findings: 1. In interview on June 14, 2021 at 3:30 pm, the laboratory's Compliance personnel stated the saline utilized for blood bank testing is good for thirty (30) days after opening. The Compliance personnel further stated the laboratory is not documenting the correct expiration date. 2. Review of the laboratory's blood bank worksheets for 2021, 2020, and November 2019 revealed the laboratory recorded the saline expiration dates incorrectly for the following dates: November 21, 2019: Saline lot 334016, expiration date documented as "10/2/20" October 6, 2020: Saline lot 2006215, expiration date documented as "8/25/21" February 21, 2021: Saline lot 2029408, expiration date documented as "4-14-22" February 23, 2021: Saline lot 2029408, expiration date documented as "4/14/22" February 26, 2021: Saline lot 2029408, expiration date documented as "4/14/22"
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: I. Based on observation by surveyor, review of the laboratory's performance verification studies, test menu, and interview with personnel, the laboratory failed to have complete reference range studies for D-dimer. Findings: 1. Observation by surveyor during the laboratory tour on June 22, 2021 at 10:33 am revealed the laboratory utilizes the Sysmex CA-660 instrument for D-dimer testing. 2. Review of the laboratory's summary for the Sysmex CA-660 analyzer performance verification studies stated "Verification of Reference Ranges was obtained from running 40 normal patients. Normal patient questionnaires included." The Laboratory Director approved/signed the performance verification studies January 29, 2021. 3. Review of the laboratory's performance verification studies revealed the laboratory did not include the raw data for the reference range studies. 4. In interview on June 24, 2021 at 9:31 am, the Technical Consultant confirmed the laboratory did not have complete studies. 5. Review of the laboratory's test menu revealed the laboratory performs ninety four (94) tests annually. II. Based on observation by surveyor, review of the laboratory's performance verification studies, test menu, and interview with personnel, the laboratory failed to have complete reference range studies for Hemoglobin A1C (HGB A1C). Findings: 1. Observation by surveyor during the laboratory tour on June 22, 2021 at 10:33 am revealed the laboratory utilizes the Dimension EXL for HGB A1C. 2. Review of the summary for the Siemens Dimension performance verification studies for HGB A1C revealed reference range studies were not included. The Laboratory Director approved/signed the performance verification studies January 25, 2021. 3. Review of the laboratory's performance verification studies revealed the laboratory did not complete the reference studies for HGB A1C. 4. In interview on June 24, 2021 at 9:31 am, the Technical Consultant confirmed the laboratory did not have complete studies. 5. Review of the laboratory's test menu revealed the laboratory performs 1060 HGB A1C tests annually. .

D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policies, manufacturer's package insert, test menu, quality control records, patient logs, and interview with personnel, the laboratory failed to perform positive and negative controls for Acetone testing for one (1) of five (5) months reviewed. Findings: 1. Observation by surveyor during laboratory tour on June 22, 2021 at 10:33 am, the laboratory utilizes K-check tables for acetone testing. 2. Review of the laboratory's quality control policy revealed "Serum/Plasma Ketone (Acetone): A positive and negative control performed each day (every 24 hours) prior to patient testing. Patient testing may be performed anytime within the 24 hour period." 3. Review of the manufacturer's package insert under "Quality Control (AC) for serum, plasma, or whole blood: Laboratories should follow the applicable government regulations an local guidelines for quality control." 4. Review of the laboratory's "Acetest" logs revealed "Quality Control Performed Once Per Calendar Day of Patient Testing." 5. Review of the laboratory's quality control records for December 2020 through April 2021 revealed the laboratory did not perform quality control in December 2020. 6. Further review of the laboratory's December 2020 records for Acetest revealed the following dates and patients did not have quality control performed: December 4, 2020: Patient 10070511 December 18, 2020: Patient 10071010 7. In interview on June 24, 2021 at 10:33 am, the Technical Consultant confirmed the laboratory did not perform QC for Acetest testing in December 2020. 8. Review of the laboratory's test menu revealed the laboratory performs fifty (50) acetone tests annually.
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, manufacturer's package insert, and interview with personnel, the laboratory failed to utilize control material relative to the specific drug of abuse cut-off values per manufacturer requirements for urine drug screen (UDS) testing. Findings: 1. Observation by surveyor during the laboratory tour on June 22, 2021 at 10:33 am revealed the laboratory utilizes the Siemens Dimension EXL instrument for urine drug testing for the following analytes: amphetamine, barbiturates, benzodiazepines, cocaine, methadone, opiates, PCP, and THC. 2. Review of the "Laboratory QC Policy" revealed "Chemistry Dimension EXL; QC is to be performed each day (every 24 hours) prior to patient testing. Patient testing may be performed anytime within the 24

	hours period. " The laboratory did not indicate the specific control levels utilized for quality control. 3. In interview on June 23, 2021 at 11:50 am, the Technical Consultant stated the laboratory runs calibrator level 0 (negative: 0 ng/mL) and level 5 (positive: 800 ng/mL) for QC. The Technical Consultant stated the qualitative results are reported for patients. 4. Review of the manufacturer's package insert revealed the following: "At least once each day of use, analyze a positive and a negative control relative to the cutoff concentration of drug using a suitable urine based control material. Qualitative Mode: The results from a drug analysis can be reported qualitatively as negative or positive relative to the cutoff." 5. Further review of the manufacturer's package insert revealed the following cut-off values: Amphetamines: 300 ng/mL or 500 ng/mL Barbiturates: 200 ng/mL Benzodiazepine: 200 ng/mL Cocaine: 150 ng/mL or 300 ng/mL Methadone: 300 n/mL Opiates: 300 ng/mL or 2000 ng/mL PCP: 25 ng/mL THC: 50 ng/mL 6. In further interview on June 23, 2021 at 11:50 am, the Technical Consultant stated the positive control utilized for urine drug screen testing was not relative to the drug's cut-off. 7. Review of the laboratory's test menu revealed the laboratory performs 420 amphetamine, 420 barbiturates, 420 benzodiazepines, 420 cocaine, 420 methadone, 420 opiates, 420 PCP, and 420 THC tests annually.
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's quality control (QC) records, policies, patient test logs, test menu, and interview with personnel, the laboratory failed to perform two (2) levels of controls every eight (8) hours of patient testing for Coagulation testing for two (2) of 151 days reviewed. Findings: 1. Observation by surveyor during the laboratory tour on June 22, 2021 at 10:33 am revealed the laboratory utilizes the Sysmex CA-600 series instrument for coagulation testing for the following tests: prothrombin time (PT), partial thromboplastin time (PTT), and D-dimer. 2. Review of the "Laboratory QC policy" revealed the following: "Coagulation: QC is to be performed every eight (8) hours prior to patient testing. Laboratories test two or three levels of external control material every 24 hours to monitor the accuracy and precision of the analytic test system components." 3. Review of the laboratory's QC records for PTT and D-dimer from December 2020 through April 2021 revealed the following two (2) dates, two (2) levels of controls were not tested prior to patient testing: PTT: March 13, 2021 QC level 3 not tested D-dimer: March 26, 2021 QC level 6 not tested 4. Review of patient test logs revealed the following patients were reported without two (2) levels of QC performed prior: PTT: March 13, 2021: Patient 10074630 D-dimer: March 26, 2021: Patient 10075305 5. In interview on June 24, 2021 at 10:03 am, the Technical Consultant stated he was unable to find the second level of QC for the identified dates. The Technical Consultant confirmed the laboratory did not perform two (2) levels of QC prior to patient testing for the identified dates. 6. Review of the laboratory's test menu revealed the laboratory performs 107 PTT and nienty four (94) D-dimer tests annually
D5553	IMMUNOHEMATOLOGY

	CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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 review of the laboratory's policies, emergency request forms, and interview with personnel, the laboratory failed to ensure the pathologist (Laboratory Director) reviewed blood products released for emergency release for one (1) of one (1) patients reviewed. Findings: 1. Review of the laboratory's "Emergency Release of Blood" policy revealed "A pathologist should be notified of the emergency situation." 2. Review of the laboratory's "Emergency Transfusion Request" form revealed a signature/date line for "Pathologist (Lab Director)." 3. Review of emergency transfusion request forms for 2020 revealed the Laboratory Director (pathologist) did not review the emergency release form for Patient 10071041 released on December 19, 2020. 4. In interview on June 24, 2021 at 1:44 pm, the laboratory's Compliance personnel confirmed the Laboratory Director (pathologist) did not review the identified emergency release of blood products.
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: I. Based on review of the laboratory's blood bank temperature charts, policies, and interview with personnel, the laboratory failed to perform quarterly blood bank refrigerator alarm checks for two (2) of nine (9) quarters reviewed. Findings: 1. Review of the laboratory's "Blood Bank Alarm Check" policy revealed "The alarms on the blood storage refrigerator are checked quarterly for the proper function of the alarm system. 2. Review of the laboratory's 2019, 2020, and 2021 quarterly alarm checks for the blood bank refrigerator revealed the laboratory did not perform alarm checks for the following quarters: January 2020: low alarm check was not performed /documented February 2020: low alarm check was not performed/documented No alarm check 2021: due January 2021 3. In interview on June 24, 2021 at 1:34 pm, the Technical Consultant confirmed the laboratory did not document quarterly alarm checks for the identified quarters. II. Based on review of the laboratory's policies, blood bank temperature charts, and interview with personnel, the laboratory failed to monitor the blood bank refrigerator's temperature for the storage of blood products for two (2) of four (4) weeks in January 2020. Findings: 1. Review of the laboratory's "Procurement and Storage of Blood Products" policy under "Storage of Blood" section revealed "The refrigerator must be equipped with a continuous temperature monitoring system that records temperatures at least once every four hours. The units

	of blood must be maintained at a temperature of 1-6 degrees C." 2. Review of the laboratory's blood bank refrigerator's circular temperature charts for January 2020 revealed the laboratory did not have documented temperatures for January 8, 2020 through January 22, 2021. 3. Further review of the laboratory's blood bank refrigerator's circular temperature charts revealed the following comment "Note 1/8-1 /15 chart & 1/15-1/22 chart in file for BB incident." 4. Review of the laboratory's "Blood Bank Patient Log Review 2020" revealed "Blood Bank Temperature Charts for January: missing Chart: 1/8-1/15 spike noted: however it was when they changed out the marker. Chart for 1/15-1/22 marker noted a fluctuation on Wednesday during time of change of chart." 5. Further review of the laboratory's blood bank records revealed the laboratory did not have documented temperatures at least every four (4) hours for the identified dates. 6. In interview on January 24, 2021 at 4:50 pm, Testing Personnel 1 confirmed the laboratory did not have documentation of continuous monitoring of the blood bank refrigerator for the identified dates in January 2020.
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: I. Based on observation by surveyor, review of policies, quality control (QC) records, patient test reports, and interview with personnel, the laboratory failed to take corrective action when QC values were unacceptable for Coagulation testing for two (2) of fourteen (14) days reviewed in February 2021. Findings: 1. Observation by surveyor during the laboratory tour on June 22, 2021 at 10:33 am revealed the laboratory utilizes the Sysmex CA-600 series instrument for coagulation testing for the following tests: prothrombin time (PT), partial thromboplastin time (PTT), and D-dimer. 2. Review of the "Laboratory QC policy" revealed the following: "Coagulation: QC is to be performed every eight (8) hours prior to patient testing. When a QC analysis is found to be outside established limits, a systematic effort should be made to resolve the problem. The following steps should be followed for this purpose (All failed QC is to be recorded on a QC Corrective Action Log):]a. Perform QC analysis again using the same control material. b. If QC falls in an 'out of range' situation again, repour fresh sample sup of QC material from the same QC bottle. c. If QC fails again, reconstitute the QC material or open a new vial of QC material. d. If QC fails again, open a 'new well' on the reagent pack or place a new reagent pack on the analyzer, if applicable, and then rerun QC. e. If QC fails again, calibrate the analyte if applicable. IF the test values are still unacceptable, call Manufacturer Technical Support." 3. Review of coagulation QC records for February 2021 revealed the laboratory did not perform corrective action for the following two (2) dates with unacceptable QC : PT: a) February 22, 2021 QC level 3 at 9:36 reported 46.8 sec with flag "*" PTT: a) February 24, 2021 QC level 3 at 18:43 reported 26.5 sec with flag "*" 4. Review of patient test reports revealed the following patients were reported without corrective action: PT: a) February 22, 2021: Patient 10073545, Patient 10073549 PTT: a) February 24, 2021: Patient 10073783 5. In interview on

	June 22, 2021 at 4:02 pm, the Technical Consultant confirmed the laboratory reported the identified patients without corrective action for the unacceptable QC for the identified dates in February 2021. II. Based on observation by surveyor, review of policies, quality control (QC) records, patient test reports, and interview with personnel, the laboratory failed to take corrective action when QC values were unacceptable for Chemistry testing for one (1) of twenty nine (29) days reviewed in February 2020. Findings: 1. Observation by surveyor during the laboratory tour on June 22, 2021 at 10:33 am revealed the laboratory utilizes the Siemens Dimension EXL instrument for chemistry testing for the following analytes: Hemoglobin A1C, acetaminophen, HDL, albumin, alkaline phosphatase, alanine aminotransferase, ammonia, amphetamine, amylase, aspartate aminotransferase, barbiturates, benzodiazepines, BUN, calcium, cholesterol, creatine kinase, cocaine, carbamazepine, direct bilirubin, digoxin, carbon dioxide, ethanol, FT4, glucose, lactate dehyrdogenase, lipase, HCG, creatine kinase MB, , BNP, potassium, chloride, sodium, methadone, magnesium, opiates, albumin, PCP, phosphorus, phenytoin, salicylate, T4, total bilirubin, triglycerides, THC, troponin, total protein, PSA, TSH, thyroid uptake, uric acid, valproic acid, and vancomycin. 2. Review of the "Laboratory QC policy" revealed the following: "Chemistry Dimension EXL: QC is to be performed each day (every 24 hours) prior to patient testing. Patient testing may be performed anytime within the 24 hours period. When a QC analysis is found to be outside established limits, a systematic effort should be made to resolve the problem. The following steps should be followed for this purpose (All failed QC is to be recorded on a QC Corrective Action Log):]a. Perform QC analyis again using the same control material. b. If QC falls in an 'out of range' situation again, repour fresh sample sup of QC material from the same QC bottle. c. If QC fails again, reconstitute the QC material or open a new vial of QC material. d. If QC fails again, open a 'new well' on the reagent pack or place a new reagent pack on the analyzer, if applicable, and then rerun QC. e. If QC fails again, calibrate the analyte if applicable. IF the test values are still unacceptable, call Manufacturer Technical Support." 3. Review of Chemistry QC records for February 2020 revealed the laboratory did not perform corrective action for the following one (1) date with unacceptable QC : Alkaline Phosphatase: February 18, 2020: QC level 1 reported 33. 6 , Flag "HI" (Acceptable QC range: 21.9-32.7) 4. Review of patient reports revealed the following patients were reported without corrective action: Alkaline Phosphatase: Patient 10023109 Patient 10060597 Patient 10060599 Patient 10060603 Patient 10060605 Patient 10060608 Patient 10060610 5. In interview on June 23, 2021 at 1:20 pm, the Technical Consultant confirmed the laboratory reported the identified patients without corrective action for unacceptable QC on February 18, 2020.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic 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 analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Laboratory QA" policy

	revealed "Retrospective review of all prior months' documentation in the laboratory for compliance. Revised Date 05/04/2017." 2. Observation by surveyor, review of records, and interview with personnel revealed the laboratory did not identify the following issues with the analytic system: a) The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 I. b) The laboratory failed to perform the platelet poor plasma studies annually per policy for one (1) of two (2) years reviewed. Refer to D5401 II. c) The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. d) The laboratory failed to ensure policies and procedures were updated to current instrumentation. Refer to D5407. e) The laboratory failed to document the appropriate expiration date of the saline utilized for blood bank testing as required. Refer to D5415. f) The laboratory failed to have complete reference range studies for D-dimer. Refer to D5421 I. g) The laboratory failed to have complete reference range studies for Hemoglobin A1C (HGB A1C). Refer to D5421 II. h) The laboratory failed to perform positive and negative controls for Acetone testing for one (1) of five (5) months reviewed. Refer to D5449. i) The laboratory failed to utilize control material relative to the specific drug of abuse cut-off values per manufacturer requirements for urine drug screen (UDS) testing. Refer to D5479. j) The laboratory failed to perform two (2) levels of controls every eight (8) hours of patient testing for Coagulation testing for two (2) of 151 days reviewed. . Refer to D5545. k) The laboratory failed to ensure the pathologist (Laboratory Director) reviewed blood products released for emergency release for one (1) of one (1) patients reviewed. Refer to D5553. l) The laboratory failed to perform quarterly blood bank refrigerator alarm checks for two (2) of nine (9) quarters reviewed. Refer to D5555 I. m) The laboratory failed to monitor the blood bank refrigerator's temperature for the storage of blood products for two (2) of four (4) weeks in January 2020. Refer to D5555 II. n) The laboratory failed to take corrective action when QC values were unacceptable for Coagulation testing for two (2) of fourteen (14) days reviewed in February 2021. Refer to D5783 I. o) The laboratory failed to take corrective action when QC values were unacceptable for Chemistry testing for one (1) of twenty nine (29) days reviewed in February 2020. Refer to D5783 II.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure that complete verification procedures were performed. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided and to identify failures as they occur. Refer to D6022. 5. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 6. The Laboratory Director failed to ensure

	policies and procedures for assessing personnel competency were established and maintained. Refer to D6030. 7. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
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. Findings: 1. The laboratory failed to have complete reference range studies for D-dimer. Refer to D5421 I. 2. The laboratory failed to have complete reference range studies for Hemoglobin A1C (HGB A1C). Refer to D5421 II.
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 record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5401 II.
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 observation, 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. Findings: 1. The laboratory failed to perform positive and negative controls for Acetone testing for one (1) of five (5) months reviewed. Refer to D5449. 2. The laboratory failed to utilize control material relative to the specific drug of abuse cut-off values per manufacturer requirements for urine drug screen (UDS) testing. Refer to D5479. 3. The laboratory failed to perform two (2) levels of controls every eight (8) hours of patient testing for Coagulation testing for two (2) of 151 days reviewed. Refer to D5545.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on observation by surveyor, 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 and to identify failures as they occur. Refer to D5793.
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 observation by surveyor, 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 D5783 I and D5783 II.
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 established and maintained. Findings: 1. The laboratory failed to ensure the personnel competency assessment policy included frequency of performance for the Technical Consultant and General Supervisor. Refer to D5209. 2. The Technical Consultant failed to evaluate competency annually in 2019 for seven (7) of twelve (12) Testing Personnel reviewed. Refer to D6054.
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 detailed written instructions for providers regarding specimen transport. Refer to D5317. 2. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401 I. 3. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 4. The laboratory failed to ensure policies and procedures were updated to current instrumentation. Refer to D5407.
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 observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D6040. 3. The Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D6042. 4. The Technical Consultant failed to ensure corrective actions were taken and

	documented when deviations from the laboratory's policies occurred. Refer to D6043. 5. The Technical Consultant failed to evaluate competency annually in 2019 for seven (7) of twelve (12) Testing Personnel reviewed. Refer to D6054.
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 record review and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5401 II.
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 by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure performance specification verification studies were complete. Refer to D5421 I and II.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to perform positive and negative controls for Acetone testing for one (1) of five (5) months reviewed. Refer to D5449. 2. The laboratory failed to utilize control material relative to the specific drug of abuse cut-off values per manufacturer requirements for urine drug screen (UDS) testing. Refer to D5479. 3. The laboratory failed to perform two (2) levels of controls every eight (8) hours of patient testing for Coagulation testing for two (2) of 151 days reviewed. Refer to D5545.
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 observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783 I and II.
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 review of policies, personnel records, and interview with personnel, the Technical Consultant failed to evaluate competency annually in 2019 for seven (7) of twelve (12) Testing Personnel reviewed. Findings: 1. Review of the laboratory's "Laboratory Competency" policy revealed "Documented training is initiated, upon hire. Upon completion, documenting the performance of individuals responsible for Non-waived testing is initiated for the new employee, 6 months after hire date, 12 months after hire date, and annually thereafter." 2. Review of personnel records revealed the laboratory did not have documentation of an annual competency assessment for 2019 for the following Testing Personnel: Three (3) current employees: Testing Personnel 1 Testing Personnel 2 Testing Personnel 4 Four (4) previous employees: Testing Personnel 7 (no longer employed as of May 17, 2021) Testing Personnel 8 (no longer employed July 21, 2020) Testing Personnel 11 (no longer employed March 19, 2021) 3. In interview on June 22, 2021 at 1:23 pm, the Technical Consultant confirmed the 2019 annual competency assessments for the identified employees were not completed. The Technical Consultant stated he was hired in May 2021.
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 observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel were performing test methods as required. Findings: 1. The laboratory failed to document the appropriate expiration date of the saline utilized for blood bank testing as required. Refer to D5415. 2. The laboratory failed to ensure the pathologist (Laboratory Director) reviewed blood products released for emergency release for one (1) of one (1) patients reviewed. Refer to D5553. 3. The laboratory failed to perform quarterly blood bank refrigerator alarm checks for two (2) of nine (9) quarters reviewed. Refer to D5555 I.

	4. The laboratory failed to monitor the blood bank refrigerator's temperature for the storage of blood products for two (2) of four (4) weeks in January 2020. Refer to D5555 II.
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 complete. Findings: 1. The laboratory failed to ensure the personnel competency assessment policy included frequency of performance for the Technical Consultant and General Supervisor. Refer to D5209. 2. The General Supervisor failed to evaluate competency annually in 2019 for seven (7) of twelve (12) Testing Personnel reviewed. Refer to D6151.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must 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. Refer to D3025.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on review of policies, personnel records, CMS-209 form, and interview with personnel, the General Supervisor failed to evaluate competency annually in 2019 for seven (7) of twelve (12) Testing Personnel reviewed. Findings: 1. Review of the laboratory's "Laboratory Competency" policy revealed "Documented training is initiated, upon hire. Upon completion, documenting the performance of individuals responsible for Non-waived testing is initiated for the new employee, 6 months after hire date, 12 months after hire date, and annually thereafter." 2. Review of personnel records revealed the laboratory did not have documentation of an annual competency

	assessment for 2019 for the following Testing Personnel: Three (3) current employees: Testing Personnel 1 Testing Personnel 2 Testing Personnel 4 Four (4) previous employees: Testing Personnel 7 (no longer employed as of May 17, 2021) Testing Personnel 8 (no longer employed July 21, 2020) Testing Personnel 11 (no longer employed March 19, 2021) 3. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the Technical Consultant also serves as the General Supervisor. 4. In interview on June 22, 2021 at 1:23 pm, the Technical Consultant confirmed the 2019 annual competency assessments for the identified employees were not completed. The Technical Consultant stated he was hired in May 2021.