Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0707957	06/18/2026
Name of Provider or Supplier	**Street Address, City, State**	
St Helena Parish Hospital	16874 Highway 43 North, Greensburg, 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 at St. Helena Parish Hospital, CLIA ID # 19D0707957, on June 15, 2026 through June 18, 2026. St. Helena Parish Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803 CONDITION: Successful participation 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing, Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of the CASPER 155D proficiency testing results, American Proficiency Institute (API) proficiency testing records, and interview with personnel,

	the laboratory failed to achieve a score of at least 80% for hemoglobin (HGB) in two out of three consecutive events, resulting in an initial unsuccessful performance. Refer to D2130.
D2130	HEMATOLOGY CFR(s): 493.851(f) (f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing results from CASPER 155 D reports, the laboratory's proficiency testing (PT)records, and interview with personnel, the laboratory failed to achieve a score of at least 80% for hemoglobin (HGB) in two out of three consecutive events in 2025 and 2026, resulting in an initial unsuccessful performance. Findings: 1. Review of the CASPER 155D report for PT results and the laboratory's American Proficiency Institute (API) PT records revealed the laboratory received the following unsatisfactory HGB scores resulting in an initial unsuccessful performance: a) 2025 Hematology/Coagulation 2nd event HGB score received 60% b) 2026 Hematology/Coagulation 1st event HGB score received 60% 2. In interview on June 16, 2026 at 9:30 am, the Technical Consultant confirmed the laboratory received unsuccessful PT scores for HGB testing for the 2025 2nd event and 2026 1st event.
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and interview with personnel, the laboratory failed to have written policies related to the state of Louisiana's fentanyl testing and reporting of minors requirement. Findings: 1. Review of the laboratory's policies revealed the laboratory did not have a written policy for the state of Louisiana's requirement of hospital fentanyl testing of minors with suspected opioid overdose and reporting of positive results, SB 487/Act 769. 2. In interview on June 18, 2026 at 10:10 am, the Technical Consultant stated there is a standing order for fentanyl testing for all persons suspected of drug overdoses. The Technical Consultant stated the person in charge of reporting was out sick. The Technical Consultant stated she could not find a written policy and procedure for fentanyl testing of minors and reporting per the state of Louisiana requirement.
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:
I. Based on review of the laboratory's policies, emergency department policies, nursing services policies, hospital forms, and interview with personnel, the laboratory failed to establish complete procedures for suspected transfusion reactions. Findings: 1. Review of the laboratory's "Transfusion Reaction Recognition, Investigation & Reporting" policy revealed "In general, one should consider any adverse manifestation occurring at the time of the transfusion to be a transfusion reaction until proven otherwise: Fever (2 degrees F increase) with or without chills associated with transfusion. Shaking chills with or without fever. Pain at the infusion site or in the chest, abdomen, or flanks. Blood pressure changes, usually acute, either hypertension or hypotension. Respiratory distress, including, dyspnea, tachypnea, wheezing, or hypoxemia. Skin changes, including urticaria, pruritis (itching), flushing, or localized edema (angioedema). Nausea with or without vomiting. Darkened urine or jaundice. Bleeding or other manifestations of a consumptive coagulopathy." The change in blood pressure was not defined. 2. Review of the emergency department's "Administration of Blood" policy revealed "Obtain and document vital signs 15 minutes after transfusion begins, then 30 minutes, 1 hour and 1 hour post transfusion. Check IV site for pain, warmth, redness, swelling and position of extremity every 30 minutes. Watch for signs of blood reaction: urticaria, hives, pharyngeal edema, wheezing, higher temperature, lower blood pressure, hematuria, chills, pain in lower back and legs, headache, elevated pulse." The increase in temperature and change in blood pressure were not defined. 3. Review of the nursing services "Blood and Blood Components-Transfusion" policy, effective "11/14/2022," revealed "Monitor vital signs before beginning transfusion, 15 minutes after infusion is initiated, thirty minutes after infusion initiated, hourly while infusion is administered, upon completion of each unit and one hour after completion." 4. Review of the nursing services "Blood and Blood Components-Transfusion Whole Blood and Packed Cells (PRBC) policy, effective "08/23/2024," revealed "Remain with the patient during the first 20 minutes, or first 50 mL of blood, and watch for signs of transfusion reaction. See Blood/Blood Components-Transfusion Reaction policy and procedures for types of reactions." Surveyor was not provided the referenced "Blood/Blood Components-Transfusion Reaction" policy. 5. Review of the hospital's "Informed Consent: Transfusion of Blood/Blood Products" form revealed the following symptoms of transfusion reactions: fever, lower back pain, headache, nausea/vomiting, blood in the urine/dark urine, flushing of the face, feeling of uneasiness, weakness or fainting, other abnormalities or discomfort, hives, rash, or itching, chest pain, and decreased urine output." 6. Further review of the nursing services and emergency department policies revealed the signs and symptoms for suspected transfusion reactions did not align with the laboratory's transfusion reaction policy. 7. In interview on June 18, 2026 at 12:00 pm, nursing personnel confirmed the identified transfusion reaction policies for nursing services, emergency department, and laboratory did not match each other. II. Based on review of the emergency department policies, nursing services policies, patient transfusion records, and interview with personnel, the facility transfusion services failed to complete transfusion documentation for blood products for three (3) of four (4) patients reviewed. Findings: 1. Review of the emergency department's "Administration of Blood" policy revealed "Obtain and document vital signs 15 minutes after transfusion begins, then 30 minutes, 1 hour, and 1 hour post transfusion. Check IV site for pain, warmth, redness, swelling and position of extremity every 30 minutes. 2. Review of the nursing services "Blood and Blood Components-Transfusion" policy, effective "11/14/2022," revealed "Monitor vital signs before beginning transfusion, 15 minutes after infusion is initiated, thirty minutes after infusion initiated, hourly while infusion is administered, upon completion of each unit and one hour after completion." The frequency of

	documentation of vital signs differed from that of the emergency department's policy. 3. In interview on June 18, 2026 at 12:00 pm, nursing personnel stated vital signs are to be checked and documented prior to transfusion, 15 minutes after transfusion begins, 30 minutes after infusion initiated, hourly during transfusions until completion and 1 hour after completion. 4. Review of random selection of patient transfusion records revealed the vital signs documented differed from the policies identified: a) July 17, 2025: Patient 40065: transfusion started 10:30 with vitals taken prior, vital signs documented at 10:45, 11:45 (1 hours after previous check), 13:00 (1 hour 15 minutes after previous check), 13:45 (end of transfusion) b) April 16, 2026: Patient 30441: transfusion started at 21:50 with vitals taken prior, vital signs documented at 22:10 (20 minutes after start time), 22:40 (30 minutes after the previous check), and hourly thereafter until end of transfusion 1:10 April 17, 2026 (new unit of blood): Patient 30441: transfusion started 1:36 with vitals taken prior, vitals documented at 1: 55 (19 minutes after start time), 2:25 (30 minutes after the previous check) , 3:25, 4:25 and 5:35 (1 hour 10 minutes after previous check, transfusion complete at 5:55 c) May 17, 2026: Patient 13238: transfusion started 3:26 with vitals taken prior, vital signs documented at 3:41, 4:11 (30 minutes after the previous check), and hourly thereafter until end of transfusion. 5. In interview on June 18, 2026 at 12:00 pm, nursing personnel confirmed the vital sign documentation after thirty (30) minutes in nursing services policy differed from the emergency department policy. Nursing personnel confirmed the frequency of documentation of vital signs for the identified patient transfusion records did not follow the nursing services policy.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 interview with personnel, the laboratory failed to establish complete quality control (QC) procedures. Findings: 1. Review of the laboratory's "Quality Control Program" policy revealed "All out of control situations and corrective action are to be documented on Error/Variance log sheets. Patient results are NOT to be reported if an out of control situation is not clarified. Unresolved, out of control situations, and any unusual patient results, should

	be investigated see ('Handling out of control situations')." 2. Review of the laboratory's "QC Program Vitros 7600" policy revealed "All out of control situations and corrective actions are to be documented on Error/Variance log sheets. Patient results are NOT to be reported if an out of control situation is not clarified. Unresolved, out of control situations and any unusual patient results should be investigated. (See 'Handling Out of Control Situations'). Handling Out-of Control Situation: Random errors may be related to poor reproducibility, pipette error, instrument problems, handling of reagents. Systematic errors are those that cause changes in the curve slopes and affect the final results: 1. Document the reason for the out-of-control situation. This will help to indicate whether a problem is due to random of systematic error. Document on Error or Variance Log. 2. Review the function of equipment, and maintenance, and correct any problems if noted. Then repeat the controls. 3. Verify that all controls and reagents have been prepared properly and are being used within stated stability ranges. If there is a question, use fresh reagents and /or controls and repeat the controls. 4. Recalibrate assay if necessary and retest the controls. 5. If after an investigation and corrective measures are attempted but results are still out-of-control, report the problem to the supervisor and/or technical support before releasing test results. Thoroughly document the problem and all actions that have been undertaken. The supervisor will append a final document of correction after making an assessment of the problem. " 3. Review of the laboratory's "DxH 560 Quality Control" revealed "Remedial Action to Take When a Control is Outside its Expected Range: 1. Ensure the control: Material was mixed properly. If not, mix it according to the package insert. Identification information was entered correctly. If using a bar-code reader, ensure the bar-code labels are clean and positioned correctly. If using the Numeric Keypad, ensure you typed the correct information. Ensure that the control values (assigned values and expected ranges) are being compared to the correct control package insert. If they do not, change the control's information to match the package insert. 2. If any of these problems existed, rerun the control; otherwise, proceed to the next step. 3. Rerun the control to ensure the problem was not a statistical outlier. 4. Ensure the control material was not contaminated by another vial or level of control. 5. Watch for normal sample flow as part of troubleshooting the instrument. If necessary, call your Beckman Coulter Representative." 4. Further review of the laboratory's identified quality control policies revealed the laboratory did not include detailed written instructions for corrective action steps to take for QC outside of their expected limits. 5. In interview on June 16, 2026 at 1:22 pm, the Technical Consultant confirmed the laboratory's policies did not include detailed written instructions for QC mean and range adjustments and corrective actions for unacceptable QC.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview with personnel, the laboratory failed to label in-use Free Thyroxine (FT4) calibrators with open and expiration dates. Findings: 1. Observation during the laboratory tour on June 15, 2026 at 9:45 am revealed the

	following FT4 calibrators open for use in a rack on the top shelf of the American BioTech Supply refrigerator without labeled open and expiration dates: FT4 1, lot 6095, Quantity: one (1) FT4 2, lot 6095, Quantity: one (1) FT4 3, lot 6095, Quantity: one (1) 2. In interview on June 15, 2026 at 10:18 am, Testing Personnel 1 confirmed the identified open FT4 calibrators were not labeled with the open and expiration dates.
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: I. Based on review of the laboratory's policies, quality control (QC) records, and interview with personnel, the laboratory failed to document complete corrective actions performed for unacceptable Chemistry QC for a total of five (5) random dates in February 2025 and April 2026. Findings: 1. Review of the laboratory's "Quality Control Program" policy revealed "All out of control situations and corrective action are to be documented on Error/Variance log sheets. Patient results are NOT to be reported if an out of control situation is not clarified. Unresolved, out of control situations, and any unusual patient results, should be investigated see ('Handling out of control situations')." 2. Review of the laboratory's "QC Program Vitros 7600" policy revealed "All out of control situations and corrective action are to be documented on Error/Variance log sheets. Patient results are NOT to be reported if an out of control situation is not clarified. Unresolved, out of control situations and any unusual patient results should be investigated. (See 'Handling Out of Control Situations'). Handling Out-of Control Situation: Random errors may be related to poor reproducibility, pipette error, instrument problems, handling of reagents. Systematic errors are those that cause changes in the curve slopes and affect the final results: 1. Document the reason for the out-of-control situation. This will help to indicate whether a problem is due to random of systematic error. Document on Error or Variance Log. 2. Review the function of equipment, and maintenance, and correct any problems if noted. Then repeat the controls. 3. Verify that all controls and reagents have been prepared properly and are being used within stated stability ranges. If there is a question, use fresh reagents and/or controls and repeat the controls. 4. Recalibrate assay if necessary and retest the controls. 5. If after an investigation and corrective measures are attempted but results are still out-of-control, report the problem to the supervisor and/or technical support before releasing test results. Thoroughly document the problem and all actions that have been undertaken. The supervisor will append a final document of correction after making an assessment of the problem. " 3. Further review of the laboratory's identified quality control policies revealed the laboratory did not include detailed written instructions for corrective action steps to take for QC outside of their expected limits. 4. Review of random months of the laboratory's Chemistry QC records and "Error or Variance Log" revealed the laboratory did not

document the specific corrective actions steps for the following dates: a) February 9, 2026: Phenytoin: The "Error or Variance Log" had no documentation of unacceptable QC. The instrument printouts for QC level 3 (IA3) revealed QC failed at 13:50 with an initial value of 28.36 ug/mL (acceptable range 18.76-23.56 ug/mL) flag +3s with written comment "RR same qc." QC failed at 14:02 with a value of 24.25 ug/mL flag +2s with written comment "RR fresh qc." QC failed at 14:15 with a value of 23.59 ug /mL flag +2s with written comment "RR new qc." Acceptable QC value of 23.40 ug /mL at 14:33. b) February 25, 2026: Acetaminophen: The "Error or Variance Log" stated "Aceta L2 low rgt replaced RPT." The error log did not document all corrective actions taken. The instrument printouts for QC level 2 (IA2) revealed QC failed at 11: 28 with an initial value of 39.8 ug/mL (acceptable range 40.12-41.88 ug/mL) flag -2s with written comment "RR same QC." QC failed at 11:36 with a value of 39.3 ug/mL flag -3s with written comment "RR fresh QC." QC failed at 11:45 with a value of 39.7 ug/mL flag -2s with written comment "RR fresh QC." QC failed at 11:53 with a value of 38.8 ug/mL flag -3s with written comment "Thawing New Reag/QC." QC failed at 12:42 with a value of 39.9 ug/mL flag -2s with written comment "RR new QC." QC failed at 12:51 with a value of 39.6 ug/mL flag -3s with written comment "RR same QC." QC failed at 13:00 with a value of 39.6 ug/mL flag -3s with no written comment. Acceptable QC value of 39.7 ug/mL (new acceptable range 38.62-40.38 ug /mL) at 13:20 with no written comment. QC level 3 (IA3): The instrument printouts revealed QC failed at 11:28 with an initial value of 121.4 ug/mL (acceptable range 122.2-128.1) flag -2s with written comment "RR same QC RR-OK." Acceptable QC value of 122.7 ug/mL at 11:37. There was no documentation of the QC failure on the error log. c) February 26, 2026:Acetaminophen: The "Error or Variance Log" had no documentation of unacceptable QC. The instrument printouts for QC level 1 (IA1) revealed QC failed at 00:45 with an initial value of 10.4 ug/mL (acceptable range 10.60-12.60 ug/mL) flag -2s with written comment "RR." Acceptable QC value of 11.2 ug/mL at 1:33. QC level 3 (IA3): The instrument printouts revealed QC failed at 00:47 with an initial value of 122.2 ug/mL (acceptable range 122.2-128.1 ug/mL) flag -2s with written comment "RR." Acceptable QC value of 124.6 ug/mL at 1:33. d) April 12, 2026: Calcium: The "Error or Variance Log" stated "MC1 Ca RR x 3 range adjusted ok" The instrument printouts revealed QC level 1(MC1) failed at 2:21 with an initial value of 6.078 mg/dL (acceptable value 5.580-5.980 mg/dL) flag +2s with written comment "RR." QC failed at 2:44 with value of 5.996 mg/dL flag +2s with written comment "RR Ran w/same QC." QC failed at 2:47 QC failed at 3:24 with value of 6.086 mg/dL and no written comment. QC failed at 3:47 with value of 6.054 mg/dL flag +2s with no written comments. QC failed at 4:16 with value of 6.071 mg /dL flag +2s and no written comment e) April 18, 2026: Alkaline phosphatase, cholesterol, and direct high-density lipoprotein (dHDL) The "Error or Variance Log" had no documentation of unacceptable QC The instrument printouts for QC level 3 (MC3) revealed the following unacceptable QC: -Alkaline phosphatase initial value of 242.61 U/L (acceptable range: 245.0-266.8 U/L) flag -2s with written comment "RR." Acceptable QC value of 245.88 U/L at 2:20. -Cholesterol initial value of 265.67 mg /dL (acceptable range: 267.3-281.3 mg/dL) flag -2s with written comment "RR." Acceptable QC value of 269.99 mg/dL at 2:20. -dHDL initial value of 65.90 mg/dL (acceptable range: 58.35-65.71) flag +2s with written comment "RR." QC failed at 2: 20 with a value of 68.63 mg/dL flag +3s with written comment "RR fresh new thawed QC." QC failed at 3:02 with a value of 67.89 mg/dL flag +3s with written comment "RR." QC failed at 6:09 with a value of 67.19 mg/dL flag +2s with written comment "RR This was the last test on the reagent that was on-board. Put on another and RR." QC failed at 7:24 with a value of 67.42 mg/dL flag +2s with written comment "RR." QC failed at 8:17 with a value of 68.40 mg/dL flag +3s with written comment "RR." QC failed at 8:33 with a value of 70.39 mg/dL flag +3s with written comment "RR."

Acceptable QC value of 63.47 mg/dL at 8:55. 5. In interview on June 16, 2026 at 1:22 pm, the Technical Consultant confirmed the laboratory did not document all corrective action steps taken for unacceptable QC. II. Based on review of the laboratory's policies, quality control (QC) records, and interview with personnel, the laboratory failed to document complete corrective actions performed for unacceptable Complete Blood Count (CBC) QC for two (2) random dates in April 2026. Findings: 1. Review of the laboratory's "Quality Control Program" policy revealed "All out of control situations and corrective action are to be documented on Error/Variance log sheets. Patient results are NOT to be reported if an out of control situation is not clarified. Unresolved, out of control situations, and any unusual patient results, should be investigated see ('Handling out of control situations')." 2. Review of the laboratory's "DxH 560 Quality Control" policy revealed "Remedial Action to Take When a Control is Outside its Expected Range" revealed "1. Ensure the control: Material was mixed properly. If not, mix it according to package insert. Identification information was entered correctly. If using a bar-code reader, ensure the bar-code labels are clean and positioned correctly. If using the Numeric Keypad, ensure you typed the correct information. Ensure that the control values (assigned values and expected ranges) are being compared to the correct control package insert. If they do not, change the control's information to match the package insert. 2. If any of these problems existed, rerun the control; otherwise, proceed to the next step. 3. Rerun the control to ensure the problem was not a statistical outlier. 4. Ensure the control material was not contaminated by another vial or level of control. 5. Watch for normal sample flow as part of troubleshooting the instrument. If necessary, call your Beckman Coulter Representative." 3. Review of the laboratory's CBC QC instrument printouts and "Hematology-Control/Corrective Action Log" revealed the laboratory did not document the specific corrective actions steps for the following dates: a) April 19, 2026: Abnormal High Controls: The "Hematology-Control/Corrective Action Log" revealed "4-19-26 14:04 Ab High, RBC & Hct increased, Plt decreased/ RR x2 /OK." The corrective log actions did not correspond with the frequency of the control repeats and specific steps taken. The instrument printouts revealed the following unacceptable QC values: Red Blood Count (RBC) with an initial value of 5.56 x 10 ^6 /uL High (H) flag (acceptable range 5.03-5.53 x10 ^6/uL) at 2:04 pm with written comment "RR." Acceptable QC value of 5.40 x10 ^6 /uL at 2:07 pm. QC failed at 2: 09 pm with a value of 5.55 x10^6/uL H f'lag with written comment "RR." Acceptable QC value of 5.44 x10 ^6 /uL at 2:14 pm. Hematocrit (HCT) with an initial value of 53.6% with H flag (acceptable range 46.6-52.6 %) reported at 2:04 pm with written comment "RR." Acceptable QC value of 52.1 % at 2:07 pm. QC failed at 2:09 pm with a value of 53.7 % H f'lag with written comment "RR." Acceptable QC value of 52.4% at 2:14 pm. Platelet (PLT) with an initial value of 439.9 x10^3/uL with Low (L) flag (acceptable range 450.0-570.0 x10 ^3/uL) reported at 2:04 pm with written comment "RR." QC failed at 2:07 pm with a value of 445 x10^3/uL flag L with written comment "RR." QC failed at 2:09 pm with a value of 449.0 x10^3/uL L flag with written comment "RR." Acceptable QC value of 518.9 x10 ^3 /uL at 2:14 pm b) April 28, 2026: Abnormal High Control: The "Hematology-Control/Corrective Action Log" revealed "4-28-26 14:04 Ab High RBC & Hct increased Plt decreased-RR same QC x 5-OK." The instrument printouts revealed the following unacceptable QC values: Red Blood Count (RBC) QC failed at 2:08 pm with a value of 5.58 x 10^6 /uL (acceptable value 5.03-5.53 x 10^6/uL), flag H and written comment "RR." Acceptable QC value of 5.52 x 10^6/uL at 2:10 pm. QC failed at 2:36 pm with a value of 5.56 x 10^6/uL flag H with written comment "RR."Acceptable QC value of 5.47 x10 ^6 /uL at 2:38 pm. Hematocrit (HCT) with an initial value of 52.7% H flag (acceptable range 46.6-52.6 %) reported at 2:04 pm with written comment "RR." Acceptable QC value of 52.2% at 2:06 pm. QC failed at 2:08 pm with a value of 53.3

	% H flag with written comment "RR." QC failed at 2:36 pm H flag with written comment "RR." Acceptable QC value of 52.1 % at 2:38 pm. Platelet (PLT) with an initial value of 446.4 x10^3/uL Low (L) flag (acceptable range 450.0-570.0 x10 ^3 /uL) reported at 2:04 pm with written comment "RR." QC failed at 2:06 pm with a value of 439.3 x10^3/uL flag L with written comment "RR." QC failed at 2:10 pm with a value of 447.6% L flag with written comment "RR."QC failed at 2:36 pm with a value of 445.4 x10^3/uL L flag with written comment "RR." Acceptable QC value of 450.0 x10 ^3 /uL at 2:38 pm. 4. In interview on June 16, 2026 at 1:22 pm, the Technical Consultant confirmed the laboratory did not document all corrective action steps taken for unacceptable QC.
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 review of proficiency test records and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Refer to D6016.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on proficiency testing record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to 2130.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5415.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4)

	(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 that a complete quality control program was established to assure the quality of laboratory testing. Refer to D5403.
D6043	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(5) (b)(5) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratorys 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 documented when deviations from the laboratory's policies occurred. Findings: 1. The laboratory failed to document complete corrective actions performed for unacceptable Chemistry QC for a total of five (5) random dates in February 2025 and April 2026. Refer to D5781 I. 2. The laboratory failed to document complete corrective actions performed for unacceptable Complete Blood Count (CBC) QC for two (2) random dates in April 2026. Refer to D5781 II.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) 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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Findings: 1. The laboratory failed to have written policies related to the state of Louisiana's fentanyl testing and reporting of minors requirement. Refer to D3009. 2. The laboratory failed to establish complete procedures for suspected transfusion reactions. Refer to D3025 I. 3. The laboratory failed to establish and maintain a complete policy for transfusion services for blood products for three (3) of four (4) patients reviewed. Refer to D3025 II.

D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (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 surveyor and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 complete quality control programs were established and maintained to assure the quality of laboratory testing results. Refer to D5403.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and 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 the laboratory's policies occurred. Findings: 1. The laboratory failed to document complete corrective actions performed for unacceptable Chemistry QC for a total of five (5) random dates in February 2025 and April 2026. Refer to D5781 I. 2. The laboratory failed to document complete corrective actions performed for unacceptable Complete Blood Count (CBC) QC for two (2) random dates in April 2026. Refer to D5781 II.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisor(s)

	failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to establish complete procedures for suspected transfusion reactions. Refer to D3025 I. 2. The laboratory failed to establish and maintain a complete policy for transfusion services for blood products for three (3) of four (4) patients reviewed. Refer to D3025 II.