

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2337124	(X3) Date Survey Completed 09/02/2026
Name of Provider or Supplier Saint Francis Bristow Lab	Street Address, City, State 700 W 7th Ave, Bristow, OK	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The initial survey was performed on 08/31/2026 through 09/02/2026. Standard-level deficiencies were cited.
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 a review of the policy and procedure manuals and interview with the laboratory director, the laboratory failed to have complete written policies and procedures for one of two test systems reviewed. Findings include: (1) On 08/31/2026 at 11:20 am, the laboratory director stated the following: (a) The laboratory performed

	hemogram (WBC (White Blood Cell), RBC (Red Blood Cell), Hgb (Hemoglobin), Hct (Hematocrit), MCV (Mean Corpuscular Volume), MCH (Mean Corpuscular Hemoglobin), MCHC (Mean Corpuscular Hemoglobin Concentration), and PLT (Platelet Count) testing using the Sysmex XN 450 analyzer; (b) Three levels of Sysmex XN-L Check Quality Control (QC) materials (Level 1, Level 2, and Level 3) were performed each day of patient testing; (c) Beyond Care Quality Monitor (BCQM) was used to set the target values and acceptability of quality control results. (2) On 08/31/2026, a review of the policy and procedure for the Sysmex XN-450 identified the procedure did not include the following: (i) Type and identity of controls (e.g., Manufacturer and levels (low, normal, or abnormal), etc.); (ii) Number and frequency of testing controls; (iii) the step-by-step instructions for changing new lot numbers of QC materials. (3) The findings were reviewed with the laboratory director who stated on 08/31/2026 at 02:35 pm, the procedure had not included all of the required information.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory director, the laboratory failed to utilize the demonstrated reportable ranges for five of five analytes reviewed on the Sysmex XN 450 test system; failed to utilize the demonstrated reportable ranges for four of four analytes reviewed on the i-STAT CG4+ test system; failed to utilize the demonstrated reportable ranges for three of three analytes reviewed on the i-STAT Chem8+ test system; failed to utilize the demonstrated reportable range for one of one analyte reviewed on the i-STAT hs-TnI test system, failed to utilize the demonstrated reportable range for one of one analyte reviewed on the i-STAT PT Plus test system; and failed to utilize the demonstrated reportable range for one of one analyte reviewed on the Quidel Triage MeterPro D-Dimer test system. Findings include: I. SYSMEX XN 450 (1) On 08/31/2026 at 11:20 am, the laboratory director stated the laboratory performed hemogram (White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin (Hgb), Hematocrit (Hct), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), and Platelet Count (Plt) testing using the Sysmex XN 450 analyzer; (2) A review of the performance specifications records identified the laboratory had demonstrated the following reportable ranges for five of five analytes reviewed: (a) Hct - 0.0 to 75.0 % (b) Hgb - 0.0 to 25.5 g/dL (c) RBC - 0.00 to 9.37 x 10⁶/uL (d) WBC - 0.0 to 566.61 x 10³/uL (e) Plt - 0.0 to 5920 x 10³/uL (3) Interview with the laboratory director on 08/31/2026 at 02:00 pm confirmed the laboratory was using the following reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) Hct - 0.0 to 89.13 % (b) Hgb - 0.0 to 31.88 g/dL (c) RBC - 0.0 to 11.4 x 10⁶/uL (d) WBC - 0.01 to 693.31 x 10³/uL (e) Plt - 0.0 to 7618.8 x 10³/uL II. ABBOTT ISTAT CG4+ (WHITE) (1) On 8/31/2026 at 11:40 am, the laboratory director stated the laboratory began performing Lactate

and Blood Gas (pCO₂, pH, and pO₂) using two i-STAT1 analyzers (serial number (SN) 436713 and SN 338763) and CG4+ cartridge (White) in May 2026; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) SN 338763: (i) Lactate -0.56 to 15.58 mmol/L (ii) pCO₂ - 12.6 to 85.6 mmHg (iii) pH - 6.535 to 7.885 (iv) pO₂ - 58 to 382 mmHg (b) SN 436713: (i) Lactate -0.54 to 15.58 mmol/L (ii) pCO₂ - 14.2 to 85.6 mmHg (iii) pH - 6.537 to 7.885 (iv) pO₂ - 57 to 385 mmHg (3) Interview with the laboratory director 08/31/2026 at 11:35 am confirmed the laboratory was using the following reportable ranges: (a) SN 338763: (i) Lactate -0.484 to 18.34 mmol/L (ii) pCO₂ - 11.47 to 100.28 mmol/L (iii) pH - 6.22 to 8.27 (iv) pO₂ - 44.0 to 390 mmHg (b) SN 436713: (i) Lactate -0.427 to 19.94 mmol/L (ii) pCO₂ - 12.83 to 100.28 mmHg (iii) pH - 6.22 to 8.27 (iv) pO₂ - 50.1 to 461.1 mmHg III. ABBOTT ISTAT CHEM8+ (1) On 8/31/2026 at 11:40 am, the laboratory director stated the laboratory began performing Sodium (Na), Pottasium (K), Chloride (Cl), TCO₂, ionized Calcium (iCa), Glucose, Blood Urea Nitrogen (BUN), Creatinine (Crea), Hematocrit using two i-STAT1 analyzers serial number (SN) 436713 and SN 338763 and Chem8+ cartridge in March 2026; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) SN 338763: (i) CO₂ - 12 to 44 mmol/L (ii) Glucose - 25 to 550 mmol/L (iii) chloride - 64 to 122 mmol/L (b) SN 436713: (i) CO₂ - 11 to 16 mmol/L (ii) Glucose - 23 to 554 mmol/L (iii) chloride - 62 to 123 mmol/L (3) Interview with the laboratory director 08/31/2026 at 11:35 am confirmed the laboratory was using the following reportable ranges: (a) SN 338763: (i) CO₂ - 10.8 to 49.5 mmol/L (ii) Glucose - 21.6 to 605 mmol/L (iii) chloride - 54 to 137.5 mmol/L (b) SN 436713: (i) CO₂ - 9.9 to 48.4 mmol/L (ii) Glucose - 22.5 to 605 mmol/L (iii) chloride - 54 to 143.0 mmol/L IV. ABBOTT ISTAT HIGH SENSITIVY TROPONIN I (HS-TNI) (1) On 8/31/2026 at 11:40 am, the laboratory director stated the laboratory began perfroming hs-TnI using two i-STAT1 analyzers serial number (SN) 436713 and SN 338763 and hs-TnI cartridge in March 2026; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) SN 338763: (i) hs-TnI - 3.2 to 1032.6 ng/L (b) SN 436713: (i) hs-TnI - 2.9 to 1217.6 ng/L (3) Interview with the laboratory director 08/31/2026 at 11:35 am confirmed the laboratory was using the following reportable ranges: (a) SN 338763: (i) hs-TnI - 2.48 to 1267.9 ng/L (b) SN 436713: (i) hs-TnI - 2.25 to 1494.5 ng/L V. ABBOTT ISTAT PTPLUS (1) On 8/31/2026 at 11:40 am, the laboratory director stated the laboratory began performing finger stick Prothrombin Time/International Normalized Ratio (PT/INR) testing using two i-STAT1 analyzers serial number (SN) 436713 and SN 338763 (denoted as MN300) and PTPlus cartridge in February 2026; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) SN 338763: (i) PT- 10.2 to 37.1 seconds (ii) INR - 1.0 to 3.7 seconds (b) SN 436713: (i) PT - 10.2 to 37.1 seconds (ii) INR - 1.0 to 3.7 seconds (3) Interview with the laboratory director 08/31/2026 at 11:35 am confirmed the laboratory was using the following reportable ranges: (a) SN 338763: (i) PT - 9.71 to 43.7 seconds (ii) INR - 0.96 to 4.34 seconds (b) SN 436713: (i) PT - 9.71 to 43.7 seconds (ii) INR - 0.96 to 4.4 seconds VI. QUIDEL TRIAGE METER PRO (1) On 8/31/2026 at 09:15 am, the laboratory director stated the laboratory began performing D-Dimer testing, using the Quidel Triage MeterPro analyzer and the D-Dimer cartridge in May 2026. (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable range: (a) D-Dimer - 196 to 3880 ng/mL (3) Interview with the laboratory director 09/01/2026 at 11:35 am confirmed the laboratory was using the following reportable ranges: (a) D-Dimer - 165 to 5000 ng/mL

D5807

TEST REPORT

CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the laboratory director, the laboratory failed to ensure reference intervals were determined as appropriate for the laboratory's patient population for two of two patient reports reviewed. Findings include: (1) On 08/31/2026 at 11:20 am, the laboratory director stated the laboratory performed hemogram (White Blood Cell (WBC), Red Blood Cell (RBC), Hemoglobin (HCH) Hematocrit (Hgb), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Hemoglobin Concentration (MCHC), and Platelet Count (PLC) testing using the Sysmex XN 450 analyzer; (2) A review of two patient reports (the first report was for an adult female patient with the testing performed on 09/01/2026 at 18:12 pm and the second report was for an adult male patient with the testing performed on 09/01/2026 at 23:19 pm) identified both reports included the same reference intervals for the following parameters: (a) RBC - 4.5 to 5.9 Kcmm; (b) Hct - 11.5 to 16.0 g/dL. (3) The reports were reviewed with the laboratory director who stated on 09/02/2026 at 10:15 am, the patient reports did not include gender specific reference ranges for RBC and Hct.