Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0656672	01/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Jane Phillips Nowata	237 S Locust Street, Nowata, 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 recertification survey was performed on 01/14/2022. The findings were reviewed with the technical consultant, testing person #2, and outpatient laboratory manager during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for test timing for a blood gas cartridge for one of three test reports. Findings include: (1) On 01/14/2021 at 09:40 am, technical consultant stated the following to the surveyor: (a) The laboratory performed Chemistry (Sodium, Potassium, Ionized Calcium, and Glucose) and Blood Gas (pH, pCO2, pO2) testing using the iSTAT 1 analyzer (serial number: 373078) and the CG8 cartridge. (2) The surveyor reviewed the manufacturer's instructions under the section titled, "Mixing and Test Timing (time from collection to cartridge fill) for Chemistry and Blood Gas Cartridge". For test timing, the instructions stated, "Samples for pH, PCO2, PO2, TCO3 and ionized calcium should be tested within 10 minutes."; (3) The surveyor then reviewed patient testing records on 12/04/2021, 12/15/2021, and 12/29/2021 and identified the following for one of three patient test reports: (a) Patient specimen# 21-349-001461- The collection date and time was on 12/15/2021 at 07:14 am and the result date and

	time was on 12/15/2021 at 07:41 am (36 minutes later). (4) The surveyor reviewed the findings with the technical consultant. The technical consultant stated on 01/14/2021 at 02:26 pm, the laboratory could not prove the specimen was collected and tested within 10 minutes as required by the manufacturer.
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: Based on a review of records, written coagulation procedures, and interview with the technical consultant, the laboratory failed to follow coagulation procedures for two of two patients. Findings include: (1) On 01/14/2022 at 09:50 am, the technical consultant stated to the surveyor: (a) The laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) testing using the Hemochron Signature+ analyzer. (2) The surveyor reviewed the laboratory's written coagulation procedure log which stated, "INR>5, check for clots and repeat"; (3) The surveyor reviewed two patient records and identified the following: (a) Patient sample# 21-239-001215C - Test performed on 08/27/2021 with a INR result of 5.5; (b) Patient sample# 21-304-001807A 0 Test performed on 10/31/2021 with an INR result of 5.6. (4) The surveyor reviewed the findings with the technical consultant and asked the technical consultant if the patient sample had been checked for a clot and repeated. On 01/14/2021 at 03: 15 pm, the technical consultant stated there was no documentation to prove the laboratory had followed the laboratory procedure as indicated above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant, the laboratory failed to follow the manufacturer's instructions for implementing coagulation reagents for nine of nine lot numbers. Findings include: (1) On 01/14/2022 at 09:50 am, the technical consultant stated to the surveyor: (a) The laboratory performed PT/INR (Prothrombin Time/International Normalized Ratio) testing using the Hemochron Signature+ analyzer; (b) Two levels of Accriva direct Check whole blood quality control materials were performed each eight hours of patient testing. (2) The surveyor reviewed the manufacturer's instructions contained in the manufacturer's "Package Insert" for implementing new quality control material, which stated, "Accriva recommends that each institution establish its own expected range of response based on the mean 2 standard deviations of at least 20 repeated test results. The local mean values established should fall within the manufacturer's acceptable performance range. Studies show that intra-laboratory variation in test

	results should produce a coefficient of variation of approximately 14% or less for coagulation control tests."; (3) The surveyor reviewed the implementation records for nine quality control lot numbers and identified the coefficient of variation had not been calculated for the following quality control lot numbers: (a) Normal Control (i) Lot# E9DA003 put into use 08/16/2019 (ii) Lot# G9DNC013 put into use 03/31/2020 (iii) Lot# HODNC005 put into use 01/25/2021 (iv) Lot# E1DNC003 put into use 07/25 /2021 (v) Lot# A1DNC004 put into use 08/01/2021 (b) Abnormal Control (i) Lot# C9DNC004 put into use 08/16/2019 (ii) Lot# J9OAC008 put into use on 03/31/2020 (iii) Lot# DODAC002 put into use 01/25/2021 (iv) Lot# D1DAC001 put into use 07 /25/2021 (4) The findings were reviewed with the technical consultant. The technical consultant stated on 01/14/2022 at 02:10 pm the manufacturer's instructions had not been followed for the reagent lot changes as indicated above;
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's storage instructions, observation of the laboratory chemistry freezer, and interview with the technical consultant, the laboratory failed to ensure materials were being stored as required for three of three months. Findings include: (1) On 01/14/2022 at 09:45 am, the technical consultant stated to the surveyor: (a) The laboratory performed chemistry testing using the Abbott Architect analyzer beginning 10/11/2021. (2) On 01/14/2022 at 01:35 pm, the surveyor observed the following in the laboratory freezer: (a) 12 boxes (25 bottles each box) of Bio-Rad LiquiChek Unassayed Chemistry Control materials (level one: lot# 92901 and level two: 92902) with a manufacturer's storage requirement of -20 to -70 degrees Centigrade (C). (3) The surveyor asked the technical consultant to explain what the materials were used for. The technical consultant stated on 01/14/2022 at 01: 40 pm the following: (a) The Bio-Rad LiquiChek Unassayed Chemistry Control materials were used to perform daily quality control on the Abbott Architect analyzer. (4) The surveyor then reviewed temperature records for three months (October 2021 through December 2021). It was identified that documented temperatures were warmer than -20 degrees C (the warmest temperature allowed for the materials) for three of three months reviewed as follows: (a) October 2021 - 31 of 31 temperatures were documented warmer than -20 degrees C; (b) November 2021 - 30 of 30 temperatures were documented warmer than -20 degrees C; (c) December 2021 - 31 of 31 temperatures were documented warmer than -20 degrees C. (5) The surveyor reviewed the records with the technical consultant. The technical consultant stated 01 /14/2022 at 02:10 pm, the materials had not been stored according to manufacturer's requirements as indicated above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to verify normal patient reference ranges for one of one new test method. Findings include: (1) On 01/14/2021 at 10:20 am, the technical consultant stated the following to the surveyor: (a) Lactate testing was performed in the laboratory using the Nova Stat Strip analyzer beginning 06/10/2020; (2) On 01/14/2021, the surveyor reviewed the performance specification records for the new test systems and could not locate documentation to prove the laboratory had verified the normal patient reference range; (3) The surveyor reviewed the finding with the technical consultant. The technical consultant stated on 01/14/2022 at 04:00 pm, the laboratory did not verify the normal patient reference range as indicated above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant, the laboratory failed to ensure data supported the QC frequency as defined in the QCP portion of the IQCP. Findings include: (1) On 01/14/2021 at 09:40 am, technical consultant stated the following to the surveyor: (a) The laboratory performed Chemistry (Sodium, Potassium, Ionized Calcium, and Glucose) and Blood Gas (pH, pCO2, pO2) testing using the iSTAT 1 analyzer (serial number: 373078) and the CG8 cartridge beginning 09/06/2020; (b) An IQCP had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as effective on 09/06/2020 for the CG8 cartridge) and identified the QCP required two levels of external QC materials be performed once each month (i.e., approximately each 30 days); (3) The surveyor then reviewed the supporting documentation for the QCP and identified the following: (a) The laboratory had not tested external QC materials to support the QC frequency of monthly, as defined in the QCP; (b) Two levels of QC had been tested for three days (not at least 30 days). (4) The surveyor reviewed the records with technical consultant and asked if additional documentation was available to support the reduced external QC frequency of monthly. The technical consultant stated on 01/14/2022 at 02:40 pm QC had not been tested for at least 30 days.

D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of records and interview with the technical consultant, the laboratory failed to ensure units of blood were stored under appropriate conditions that included an adequate temperature alarm system that is regularly inspected for one of eight alarm checks. Findings include: (1) On 01/14/2022 at 10:00 am, the technical consultant stated the laboratory stored units of O negative packed red blood cells in the blood bank refrigerator, to be used for emergency transfusions; (2) On 01/14/2022, the surveyor reviewed the quarterly refrigerator alarm records for 2020 and 2021. The records indicated the alarm checks had not been performed quarterly. They had not been performed between 01/04/2021 and 07/26/2021; (3) The surveyor reviewed the records with the technical consultant. The technical consultant stated on 01/14/2022 at 01:10 pm, the alarm checks had not been performed quarterly as required.