Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2117092	03/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Ascension St John Bartlesville	3550 Se Frank Phillips Blvd, Bartlesville, 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 findings were reviewed with technical consultant #4 and the laboratory coordinator at the conclusion of the survey.
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: Based on a review of records, manufacturer's instructions, and interview with technical consultant #4 and the laboratory coordinator, the laboratory failed to follow the manufacturer's instructions for waived testing. Findings include: (1) At the beginning of the survey, technical consultant #4 and the laboratory coordinator stated to the surveyor the laboratory performed Chemistry testing (e.g. Sodium, Potassium, Chloride, CO2, BUN (Blood Urea Nitrogen), and Creatinine) on patient venous whole blood samples using the i-STAT analyzer and Chem 8+ test cartridges; (2) The surveyor reviewed the manufacturer's instructions for the i-STAT (page 16), which stated: (a) "For acceptance of newly received cartridge lots, check the Temperature Monitor and perform integrity testing."; (b) "Check Temperature Monitor: i-STAT cartridges are shipped with a four-window indicator to monitor temperature during transit." (i) "Action:" (aa) "Fill out the record of receipt and forward materials to refrigerator." (bb) "If all windows are white, or the 1 or 2 windows are red, the transit temperatures were satisfactory and the cartridges can be used." (ii) "Remedial Action:" (aa) "If the C or D windows are blue, or the 3 or 4 windows are red": (i) "Quarantine the suspect cartons" (ii) "Notify the i-STAT system coordinator immediately" (iii) "DO NOT USE cartridges from suspect cartons." (3) The surveyor reviewed i-STAT QC (Quality Control) records from 01/01/17 through 03/01/18, which included records of newly received shipments of Chem 8+ test cartridges. The

	surveyor could not find documentation of the condition of the Temperature Monitor strip for each new shipment; (4) The surveyor asked the laboratory coordinator if the laboratory checked and documented the condition of the Temperature Monitor strip included in each shipment. The laboratory coordinator stated to the surveyor the condition of the temperature strip was observed, but had not been documented. The surveyor determined there was no evidence the transit temperature of newly received shipments of i-STAT test cartridges had been acceptable; (5) The surveyor reviewed the findings with technical consultant #4 and the laboratory coordinator, who agreed the laboratory failed to document the condition of the Temperature Monitor strip included in new shipments of i-STAT test cartridges as required by the manufacturer to ensure transit temperatures were acceptable.
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 instructions, and interview with technical consultant #4 and the laboratory coordinator, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, technical consultant #4 and the laboratory coordinator stated to the surveyor the laboratory began patient CBC (Complete Blood Count) (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) testing on 09/06/16 using the Sysmex XP 300 analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) The surveyor reviewed laboratory humidity records from October 2016 through February 2018 which verified the humidity readings were less than 30% for 7 of 17 months as follows: (a) December 2016 - 16 of 30 humidity readings were documented as less than 30%: Days: 13,15, 16,18,19,20,21,22,23,24,26,27,28,29,30,31 (b) January 2017- 20 of 31 humidity readings were documented as less than 30%: Days: 1,4, 5,6,7,8,9,12,13,14,15,23,24,25,26,27,28,29,30, 31 (c) February 2017 - 15 of 28 humidity readings were documented as less than 30%: Days: 1,2,3, 4,5,8,9,10,13,15,16,17,25,26,27 (d) March 2017 - 11 of 31 humidity readings were documented as less than 30%: Days: 2,4, 7,8,10,11,12,13,14,15,16 (e) October 2017 - 3 of 31 humidity readings were documented as less than 30%: Days: 28, 29,31 (f) November 2017 - 1 of 30 humidity readings was documented as less than 30%: Day: 23 (g) December 2017 - 19 of 30 humidity readings were documented as less than 30%: Days: 6,7, 8,9,10,11,12,13,14,15,16,23,24,26,27,28,29,30, 31 (4) The surveyor reviewed the findings with technical consultant #4 and the laboratory coordinator who stated the laboratory failed to ensure the manufacturer's required humidity requirements had been met, 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 technical consultant #4 and the laboratory coordinator, the laboratory failed to ensure reference intervals used with a new analyzer, had been determined as acceptable for the patient population it serviced. Findings include: (1) At the beginning of the survey, technical consultant #4 and the laboratory coordinator stated to the surveyor the laboratory began patient CBC (Complete Blood Count) (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, etc.) testing on 09/06/16 using the Sysmex XP 300 analyzer. In addition, technical consultant #4 stated to the surveyor the laboratory erformed CBC testing on pediatric patients (less than 18 years of age); (2) Later during the survey, the surveyor reviewed the laboratory's implementation records for the analyzer performed from 08/15/16 through 09/05/16. There was no evidence in the records the laboratory had established or verified reference intervals (normal ranges) for pediatric patients; (3) The surveyor asked technical consultant #4 and the laboratory coordinator if the laboratory had established or verified pediatric reference intervals for the pediatric patient population it serviced. Technical consultant #4 and the laboratory coordinator explained the laboratory used published reference intervals for pediatric patient CBC's but the laboratory had not verified the ranges were appropriate for the patient population it serviced; (4) The surveyor then reviewed 6 CBC (2 adult patients and 4 pediatric patients) test reports of testing performed between September 2017 and the day of the survey in 2018. For 4 of the 4 pediatric CBC test reports reviewed, the laboratory failed to have reference intervals specific for pediatric patients. Examples follow: (a) Patient #1 - 16 year old female with testing performed on 09/06/17: Normal reference ranges for Adult Females were included on the test report: (i) WBC: 3.1-10.3 (ii) RBC: 3.2-4.6 (iii) Hemoglobin: 9.9-13.6 (iv) Hematocrit: 30.2-42.3 (v) Platelet: 128-434 (vi) Lymphocyte %: 15.0-45.8 (vii) Neutrophil %: 43.7-77.1 (b) Patient #2 - 12 year old male with testing performed on 10/25/17: Normal reference ranges for Adult Males were included on the test report: (i) WBC: 2.6-8.8 (ii) RBC: 3.6-5.3 (iii) Hemoglobin: 11.3-15.7 (iv) Hematocrit: 32.6-47.5 (v) Platelet: 134-377 (vi) Lymphocyte %: 17.5-47.9 (vii) Neutrophil %: 38.3-69.0 (c) Patient #3 - 11 year old female with testing performed on 03/13/18: Normal reference ranges for Adult Females were included on the test report: (i) WBC: 2.6-8.8 (ii) RBC: 3.6-5.3 (iii) Hemoglobin: 11.3-15.7 (iv) Hematocrit: 32.6-47.5 (v) Platelet: 134-377 (vi) Lymphocyte %: 17.5-47.9 (vii) Neutrophil %: 38.3-69.0 (d) Patient #4 - 17 year old male with testing performed on 03/13/18: Normal reference ranges for Adult Males were included on the test report: (i) WBC: 2.6-8.8 (ii) RBC: 3.6-5.3 (iii) Hemoglobin: 11.3-15.7 (iv) Hematocrit: 32.6-47.5 (v) Platelet: 134-377 (vi) Lymphocyte %: 17.5-47.9 (vii) Neutrophil %: 38.3-69.0 NOTE: The Interpretive Guidelines for 493.1253(b)(1) state, "The laboratory may use the manufacturer's reference range provided it is appropriate for the laboratory's patient population (i.e., a normal range that reflects the type of specimen and demographic variables such as age and sex, as applicable). If the manufacturer has not provided

	reference ranges appropriate for the laboratory's patient population, the laboratory may use published reference range(s). The laboratory must evaluate an appropriate number of specimens to verify the manufacturer's claims for normal values or, as applicable, the published reference ranges."
D5807	TEST REPORT CFR(s): 493.1291(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 technical consultant #4 and the laboratory coordinator, the laboratory failed to ensure pediatric reference intervals were made available to the provider for interpretation. Findings include: (1) At the beginning of the survey, technical consultant #4 and the laboratory coordinator stated to the surveyor the laboratory began patient CBC (Complete Blood Count) (i.e. WBC-White Blood Count, RBC-Red Blood Count, Hemoglobin, Hematocrit, Platelet Count, Lymphocyte%, Neutrophil %, etc.) testing on 09/06/16 using the Sysmex XP 300 analyzer. In addition, technical consultant #4 stated to the surveyor the laboratory performed CBC testing on pediatric patients (less than 18 years of age); (2) Later in the survey, the surveyor reviewed 6 CBC test reports of patient testing performed between September 2017 and the day of the survey in March 2018 (2 adult patients and 4 pediatric patients). The reports included reference intervals for adult male and adult female patients, but did not include reference intervals for pediatric patients on 4 of the 4 pediatric patient CBC reports reviewed, as follows: (a) Patient #1 - 16 year old female: Testing performed on 09/06/17 (b) Patient #2 - 12 year old male: Testing performed on 10/25/17 (c) Patient #4 - 11 year old female: Testing performed on 03/13 /18 (d) Patient #5 - 17 year old male: Testing performed on 03/13/18 (3) The test reports of pediatric patient CBC testing included the same reference intervals as for adults, for the CBC parameters of WBC, RBC, Hemoglobin, Hematocrit, Platelet, Lymphocyte % and Neutrophil %, which were: (a) WBC: (i) Male: 2.6-8.8 (ii) Female: 3.1-10.3 (b) RBC: (i) Male: 3.6-5.3 (ii) Female: 3.2-4.6 (c) Hemoglobin: (i) Male: 11.3-15.7 (ii) Female: 9.9-13.6 (d) Hematocrit: (i) Male: 32.6-47.5 (ii) Female: 30.2-42.3 (e) Platelet: (i) Male: 134-377 (ii) Female: 128-434 (f) Lymphocyte %: (i) Male: 17.5-47.9 (ii) Female: 15.0-45.8 (g) Neutrophil%: (i) Male: 38.3-69.0 (ii) Female: 43.7-77.1 (4) The surveyor reviewed the findings with technical consultant #4 and the laboratory coordinator, who stated to the surveyor the laboratory failed to include CBC reference intervals specific for pediatric patients on the test reports, as listed above.