

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0473397	(X3) Date Survey Completed 08/30/2018
Name of Provider or Supplier Ascension St John Sapulpa	Street Address, City, State Attn Laboratory, Sapulpa, 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	<p>The recertification survey was performed 08/27/18-08/30/18. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, the laboratory manager, the executive director, the director of community hospital laboratories, the accrediting and compliance officer, and the hospital president during an exit conference performed at the conclusion of the survey.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, interpretive guidelines, policies and procedures, and interview with technical consultant #2, the laboratory failed to establish a written policy/procedure for assessing the competency of the technical consultant as listed in Subpart M. Findings include: (1) On the first day of the survey, the surveyor reviewed the Laboratory Personnel Report (Form 209) completed by the laboratory prior to the survey. The form designated 4 individuals as technical consultants for the moderate complexity testing performed by the laboratory: (a) Technical consultant #1 /Laboratory Director (b) Technical consultant #2 (c) Technical consultant #3 (d) Technical consultant #4 (2) The surveyor then reviewed personnel records but could not find documentation competency assessments had been completed for the duties of the 4 technical consultants between 11/07/16 and the first day of the survey in 2018. The surveyor asked technical consultant #2 if a competency assessment had been completed for the duties of the technical consultants. Technical consultant #2 stated competency assessments had not been performed; (3) The surveyor asked technical consultant #2 if the laboratory had a written policy for performing an assessment of</p>

the duties performed by the technical consultants. Technical consultant #2 stated to the surveyor a policy/procedure for competency assessment of the technical consultants had not been written. NOTE: The interpretive guidelines at 493.1235, states "Competency Assessment Guidelines: Technical consultant, clinical consultant, technical supervisor, general supervisor - Documented competency assessment is required for the following named positions on the Form 209: technical consultant clinical consultant, technical supervisor, general supervisor. The laboratory must have policies and procedures to assess competency based on the position responsibilities listed in Subpart M and these assessments must performed at a frequency determined by the laboratory. If these people perform testing on patient specimens, they are required to have the six required procedures in their competency assessment in addition to a competency assessment based on their federal regulatory responsibilities (see 493.1413(b)(8)/493.1451(b)(8)).

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 #2, the laboratory failed to ensure the manufacturer's environmental requirements were met. Findings include: (1) On the first day of the survey, technical consultant #2 stated to the surveyor the laboratory used 2 Sysmex XS-1000i hematology analyzers to perform CBC's (Complete Blood Counts); (2) On the third day of the survey, the surveyor reviewed the operator's manual for the analyzers and identified the manufacturer required an operating humidity between 30% and 85%; (3) The surveyor then reviewed humidity logs from 12/01/16 through 07/31/18 and identified the humidity was documented as less than 30% on 199 days of the 546 days, reviewed, as follows: (a) December 2016 - 27 of 31 days: Days: 1,2, 3,5,6,7,8,9,10,11,12,13,14,15,16,18,19,20,21,22, 23,24,27,28,29,30,31 (b) January 2017 - 21 of 31 days: Days: 1,4, 5,6,7,8,9,11,13,15,17,18,21,23,24,25,27,28,29, 30,31 (c) February 2017 - 16 of 28 days: Days: 1,2,3, 4,5,8,9,10,13,14,15,16,17,25,26,27 (d) March 2017 - 12 of 31 days: Days: 2,3,4,7, 8,9,10,11,12,14,15,16 (e) April 2017 - 3 of 30 days: Days: 6,7,11 (f) May 2017 - 1 of 31 days: Day: 1 (g) October 2017 - 6 of 31 days: Days: 24,25, 27,28,29,31 (h) November 2017 - 15 of 30 days: Days: 1,8, 9,10,11,16,19,20,21,22,23,24,25,26,27 (i) December 2017 - 23 of 31 days: Days: 1,2,5, 6,7,8,9,10,11,12,13,14,15,16,23,24,25,26, 27,28, 29,30,31 (j) January 2018 - 25 of 31 days: Days: 1,2,3, 4,5,6,7,8,9,13,14,15,16,17,18,19,22,23,24,25,26,28, 29,30,31 (k) February 2018 - 19 of 28 days: Days: 1,2,3, 4,5,6,7,8,9,10,11,12,13,17,18,22,23,25,26 (l) March 2018 - 16 of 31 days: Days: 2,6,7, 8,9,12,13,14,15,17,18,19 21,22,25,31 (m) April 2018 - 15 of 30 days: Days: 1,2,4,5,6, 7,8,9,10,11,15,16,17,19,20 (4) The surveyor reviewed the findings with technical consultant #2 who agreed the laboratory failed to ensure the manufacturer's environmental specifications had been met for the Sysmex XS-1000i analyzers.

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, policies and procedures, and interview with technical consultant #2, the laboratory failed to follow its policy and procedure for storage of blood components. Findings include: (1) On the third day of the survey, technical consultant #2 verified the laboratory performed crossmatch testing (i.e. ABO/Rh typing, Antibody Screen Testing, and Compatibility Testing); (2) The surveyor observed the laboratory and identified the Helmer refrigerator located in the blood bank. Inside units of PRBC's (Packed Red Blood Cells) were stored. Technical consultant #2 stated to the surveyor the units of PRBC's were for patient transfusions; (3) The surveyor then reviewed the "Testing Blood Bank Component/Reagent Storage Equipment Alarms" policy and procedure, which stated for the manual High alarm activation: (a) Fill a container with 240 ml of cool water for component refrigerators; (b) Ensure documentation of the NIST (National Institute for Standards and Technology) serial number of the thermometer in the log sheet. Allow the thermometer to equilibrate to the temperature of the water; (c) Place the sensor into the cup. With continuous stirring, slowly add room temperature water to cause a rise in temperature of about 0.5 degrees C (Centigrade)/minute; (d) The alarm should sound at 5.5 degrees C; (e) Record the NIST thermometer temperature and the refrigerator LCD reading at which the alarm sound; (f) Evaluate acceptability of the results. Document any problems or corrective actions. (4) The surveyor reviewed the quarterly refrigerator alarm check records from 01/01/17 through 08/29/18. The records indicated 3 of the 6 quarterly Helmer refrigerator high alarm checks performed during 2018 were unacceptable, as follows: (a) Second Quarter 2018 - 04/26/18: The high temperature check activated the alarm at 5.6 degrees C instead of at 5.5 degrees C; (b) Third Quarter 2018 - 07/22/18: The high temperature check activated the alarm at 5.6 degrees C instead of at 5.5 degrees C. (5) The surveyor reviewed the findings with technical consultant #2, who stated to the surveyor, the laboratory failed to follow its policy for acceptable results of the high alarm checks, as listed above.