

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0656672	(X3) Date Survey Completed 10/31/2019
Name of Provider or Supplier Ascension St John Jane Phillips Nowata	Street Address, City, State 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 10/30/19 and 10/31/19. The findings were reviewed with the technical consultant, Pathology Laboratory Associates support services, nurse manager, out-patient manager, and hospital administrator during an exit conference performed at the conclusion of the survey. The laboratory was found out of compliance with the following CLIA regulations: 493.1409; D6033: Technical Consultant
D3025	<p>REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, nursing policy, and interview with the technical consultant the laboratory failed to ensure written policies were followed for preventing transfusion reactions for 2 of 9 patients. Findings include: (1) On the first day of the survey, 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 the second day of the survey, the surveyor reviewed the hospital policy regarding transfusion reactions. The policy "Transfusion and Transfusion Practices" defined the parameters of issuing blood products from the blood bank; (3) The surveyor further reviewed the policy which stated: (a) "ISSUING BLOOD PRODUCT(S) FROM BLOOD BANK" (i) "2. All blood and/or blood components signed out of the Blood Bank and NOT transfused or started within 20 minutes of being issued must be returned to the Blood Bank. If the blood is not used within 20 minutes of being issued, blood must be discarded, and lab notified of wastage." (4) The surveyor then reviewed transfusion records for 9 patients with the</p>

technical consultant. For 2 of the 9 units transfused the policy was not followed by nursing personnel. (a) Unit #W204919421595 - The unit was checked out from the blood bank on 09/20/19 at 11:11 am transfusion began at 11:34 pm on 09/20/19 (23 minutes after unit checked out from the blood bank). (b) Unit #W204919421595 - The unit was checked out from the blood bank on 09/27/19 at 11:00 pm transfusion began at 11:30 pm on 09/27/19 (30 minutes after unit checked out from the blood bank). (5) The surveyor explained to the technical consultant that in order to ensure a transfusion reaction is promptly identified, nursing personnel must follow their policy.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the technical consultant, the laboratory failed to review and evaluate proficiency testing results for 2 of 18 events. Findings include: (1) At the beginning of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records and identified the following biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) Third 2018 Chemistry Core Event (i) Total Bilirubin - 3 of 5 results exhibited a positive bias (aa) CH-12- SDI of 2.2 (bb) CH-13 - SDI of 2.6 (cc) CH-14 - SDI of 2.0 (b) Third 2018 Hematology Event (i) RDW (Red Blood Cell Distribution Width) - 4 of 5 results exhibited a negative bias (aa) XE-11- SDI of -2.3 (bb) XE-12- SDI of -2.2 (cc) XE-13- SDI of -2.4 (dd) XE-14- SDI of -2.3 (2) The surveyor further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) The surveyor then reviewed the records with the technical consultant and asked if the biases had been addressed. The technical consultant stated the biases had not been addressed. D5411 was cited on the recertification survey performed on 03/26,27,28/18.

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 the technical consultant, the laboratory failed to ensure analyzers were stored as required by the manufacturer. Findings include: HUMIDITY - HEMATOLOGY (1) On the first day of the survey, the technical consultant stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) On the second day of 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 January 2019 through September 2019 which verified the humidity readings were less than 30% for 4 of 9 months as follows: (a) January 2019 - 27 of 31 humidity readings were documented as less than 30% (days 1,2,3,4,5,6,8,9,10,11,13,14,15,16,19,20,21,22,23,24,25,26,27,28,29,30,31); (b) February 2019 - 24 of 28 humidity readings was documented as less than 30% (days 5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28); (c) March 2019 - 28 of 31 humidity readings were documented as less than 30% (days 1,2,3,4,5,6,7,8,10,11,12,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,30,31); (d) April 2019 - 9 of 30 humidity readings were documented as less than 30% (days 1,2,3,4,5,12,13,14,15,); (4) The surveyor reviewed the records with the technical consultant who stated the humidity of the laboratory had been maintained below 30% as indicated above. TEMPERATURE - URINALYSIS (1) On the first day of the survey, the technical consultant stated to the surveyor Urinalysis testing was performed on the Clinitek 500 analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's environmental requirement for the analyzer. The manufacturer required the operating temperature be maintained within the range of 64 - 86 degrees Fahrenheit; (3) The surveyor reviewed laboratory temperature records between January 2019 through September 2019, which verified the temperature readings were less than 64 degrees Fahrenheit for 6 of 9 months as follows: (a) February 2019 - 1 of 28 temperature readings was documented as less than 64 degrees Fahrenheit (day 13); (b) May 2019 - 1 of 31 temperature readings was documented as less than 64 degrees Fahrenheit (day 6); (c) June 2019 - 3 of 30 temperature readings were documented as less than 64 degrees Fahrenheit (days 5,19,29); (d) July 2019 - 6 of 31 temperature readings were documented as less than 64 degrees Fahrenheit (days 1,2,4,5,7,12); (e) August 2019 - 3 of 31 temperature readings were documented as less than 64 degrees Fahrenheit (days 17,18,29); (f) September 2019 - 1 of 30 temperature reading was documented as less than 64 degrees Fahrenheit (day 6); (4) The surveyor reviewed the records with the technical consultant who stated the temperature of the laboratory had been maintained below 64 degrees Fahrenheit as indicated above. D5413 was cited on the recertification survey performed on 03/26,27,28/18.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

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 performing maintenance procedures for 1 of 9 months. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex XS-1000i analyzer; (2) On the second day of the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs. The requirements for monthly maintenance were as follows: (a) Perform Monthly Rinse (3) The surveyor then reviewed maintenance records for 9 months (January 2019 through September 2019). There was no evidence the monthly maintenance had been performed: (a) Between 12/11/18 and 02/24/19 (4) The surveyor reviewed the records

with the technical consultant, who stated the maintenance had not been documented as performed as required. D5429 was cited on the recertification survey performed on 03/26,27,28/18.

D5545

HEMATOLOGY

CFR(s): 493.1269(b)(d)

(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) 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 perform two levels of quality control materials each eight hours of PT/INR (Prothrombin Time/International Normalized Ratio testing for 3 of 12 days. Findings include: (1) On the first day of the survey, the technical consultant stated to the surveyor PT/INR testing was performed on the Hemochron Jr. Signature+ analyzer; (2) On the second day of the survey, the technical consultant stated to the surveyor two levels of quality control (QC) materials were performed each eight hours of patient testing; (3) The surveyor reviewed QC and patient testing records for testing performed between 09/16/19 and 10/30/19 and identified that two levels of QC testing had not been performed each eight hours of patient testing for 3 of 12 days of patient testing: (a) QC testing had been performed on 10/01/19 at 06:49 am and patient testing had been performed on 10/05/19 at 08:14 am; (b) QC testing had been documented as performed on 10/07/19 at 09:00 am and patient testing had been performed on 10/12/19 at 02:48 pm; (c) QC testing had been performed on 10/07/19 at 09:00 am and patient testing had been performed on 10/16/19 at 07:27 pm. (4) The surveyor reviewed the records with the technical consultant, who stated two levels of QC materials had not been performed each eight hours of patient testing as indicated above.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the technical consultant, the laboratory director failed to attest that, at the time of testing, proficiency testing samples were tested in the same manner as patient specimens as required under Subpart H for 8 of 18 events. Findings include: (1) On the first day of the survey, the surveyor reviewed 2018 and 2019 proficiency testing records. It was identified for 8 of 18 events, the attestation statements had been signed approximately 2-3 months after the samples had been tested (not within a timeframe for the director to attest that, at the time of testing, the proficiency samples had been tested as required) as follows:

(a) Chemistry Core Second event of 2018 - The samples had been tested on 05/23/18 and the attestation statement had not been signed by the laboratory director until 07/19/18; (b) Chemistry Core Third event of 2018 - The samples had been tested on 08/29/18 and the attestation statement had not been signed by the laboratory director until 10/15/18; (c) Chemistry Miscellaneous Second event of 2018 - The samples had been tested on 10/18/18 and the attestation statement had not been signed by the laboratory director until 01/14/19; (d) Hematology Second event of 2018 - The samples had been tested on 07/16/18 and the attestation statement had not been signed by the laboratory director until 10/15/18; (e) Hematology Third event of 2018 - The samples had been tested on 11/16/18 and the attestation statement had not been signed by the laboratory director until 01/14/19; (f) Immunology Second event of 2018 - The samples had been tested on 08/08/18 and the attestation statement had not been signed by the laboratory director until 10/15/18; (g) Chemistry Miscellaneous First event of 2019 - The samples had been tested on 04/23/19 and the attestation statement had not been signed by the laboratory director until 07/22/19; (h) Microbiology First event of 2019 - The samples had been tested on 01/20/19 and the attestation statement had not been signed by the laboratory director until 04/01/19; (2) The surveyor reviewed the findings with the technical consultant and explained that attestation statements must be signed within a timeframe to definitively attest to the fact that proficiency samples were tested in the same manner as patient specimens.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
 CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
 Based on a review of records and interview with the technical consultant, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035.

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
 CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the

technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

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 the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for 3 of 13 testing persons. Findings include: (1) At the beginning of the survey, the surveyor reviewed records for 13 persons performing moderate complexity urinalysis testing in 2018 and 2019. The records indicated the evaluations for 3 of 12 persons had been performed by an individual who did not meet the regulatory qualification requirements of the technical consultant: (a) Testing Person #6 (i) The 2019 evaluation had been performed by the testing person #5 on 05/14/19 (this person had earned a bachelor of science degree with 5 months of experience in urinalysis). (b) Testing Person #7 (i) The 2019 evaluation had been performed by the testing person #5 on 05/15/19. (c) Testing Person #8 (i) The 2019 evaluation had been performed by the testing person #5 on 05/15/19. (2) The surveyor explained to the technical consultant that all components of the competency evaluations must be performed by a person who qualifies as a technical consultant (an individual with a minimum of a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution, and at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service).