

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1056486	(X3) Date Survey Completed 08/07/2019
Name of Provider or Supplier Ascension St John Owasso, Inc	Street Address, City, State 12451 E 100th St North 1st Floor, Owasso, 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 validation survey was performed on 08/05/19-08/07/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, laboratory manager, and pathology assistant for Pathology Laboratory Associates during an exit conference performed at the conclusion of the survey.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with the pathology assistant for Pathology Laboratory Associates, the laboratory failed to document all control activities for Gram stain testing. Findings include: (1) On the first day of the survey, the pathology assistant for Pathology Laboratory Associates stated to the surveyors the laboratory performed Gram stain testing. In addition, the pathology assistant for Pathology Laboratory Associates stated to the surveyors, QC (Quality Control) testing was performed using commercially prepared QC slides weekly, or with each new lot of Gram stain reagents. Each slide contained bacterial cell suspensions of a positive Gram stain control (Staphylococcus aureus) and a negative Gram stain control (Escherichia coli) to validate the stain and technique acceptability; (2) On the third day of the survey, surveyor #2 reviewed the weekly Gram stain QC records from 01/03/18 through 08/02/19, and could not find documentation of the lot number and expiration date of the Gram stain QC slides used during the review period; (3) Surveyor #2 asked the pathology assistant for Pathology Laboratory Associates for records with documentation of the lot numbers and expiration dates of the Gram stain QC slides used during the review period. The pathology assistant for Pathology</p>

Laboratory Associates stated to surveyor #2 documentation of the lot number and expiration date of the Gram stain QC slides was not maintained; (4) Surveyor #2 explained to the pathology assistant for Pathology Laboratory Associates that all quality control records, including lot numbers and expiration dates of quality control materials must be retained for at least 2 years.

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 laboratory manager, the laboratory failed to review and evaluate proficiency testing results. Findings include: (1) On the first day of the survey, surveyor #3 reviewed 2017, 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) Second 2018 General Chemistry (C-B) Event (i) HDL (High Density Lipoprotein) - 5 of 5 results exhibited a positive bias (aa) CHM-06 - SDI of 2.9 (bb) CHM-07 - SDI of 3.2 (cc) CHM-08 - SDI of 2.9 (dd) CHM-09 - SDI of 2.7 (ee) CHM-10 - SDI of 2.4 (2) Surveyor #3 further reviewed the records and could not locate documentation verifying the biases had been identified and addressed; (3) Surveyor #3 then reviewed the records with the laboratory manager, and asked if the biases had been addressed. The laboratory manager stated the biases had not been addressed.

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, observation, and interview with the laboratory manager, the laboratory failed to ensure materials were being stored as required. Findings include: (1) On the first day of the survey, the surveyors observed the outpatient draw stations. There were two rooms denoted by the laboratory as Room 1 and Room 2. The following examples of collection tubes, used by the laboratory to collect patient blood specimens, were observed in the rooms, with the manufacturer's storage requirements: (a) Room 1 (i) BD Vacutainer Buff Na Citrate 3.2% tubes - 63 tubes of lot #9036654; storage requirement of 4-25 degrees Centigrade (C); (ii) BD Vacutainer SST tubes - 48 tubes of lot #9059877; storage requirement of 4-25 degrees C; (iii) BD Vacutainer K2 EDTA tubes - 28 tubes of lot #9036763; storage requirement of 4-25 degrees C. (b) Room 2 (i) BD Vacutainer Buff Na Citrate 3.2% tubes - 25 tubes of lot #9036654 and 100 tubes of lot #9065703; storage requirement of 4-25 degrees

Centigrade (C); (ii) BD Vacutainer SST tubes - 173 tubes of lot #9059877; storage requirement of 4-25 degrees C; (iii) BD Vacutainer K2 EDTA tubes - 100 tubes of lot #9004595 and 100 tubes of lot #9036785; storage requirement of 4-25 degrees C. (2) The surveyors asked the laboratory manager if the temperature of the draw stations were being monitored. The laboratory manager stated the laboratory was not monitoring the temperatures of the outpatient draw stations.

D5449

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (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 testing person #6 and the laboratory manager, the laboratory failed to document appropriate control procedures each day of blood bank testing. Findings include: (1) On the first day of the survey, the laboratory manager stated to the surveyors the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)) using the Ortho Workstation; (2) Surveyor #3 reviewed records for blood bank testing performed from 12/2018 through 07/2019 and identified the expected reactions for Anti-A,B were not within the acceptable results of (2 - 4) for the following days: (a) 07/04/19 Anti-A,B documented as "0" (b) 07/05/19 Anti-A,B documented as "0" (c) 07/06/19 Anti-A,B documented as "0" (d) 07/07/19 Anti-A,B documented as "0" (3) Surveyor #3 reviewed the records with testing person #6 and the laboratory manager. Both stated the expected reaction for Anti-A,B were not within the acceptable results.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with the pathology assistant for Pathology Laboratory Associates, the laboratory failed to ensure that test reports included the address of the laboratory location. Findings include: (1) On the first day of the survey, the pathology assistant for Pathology Laboratory Associates stated to the surveyors the laboratory performed microscopic interpretations of frozen sections from histology specimens; (2) On the third day of the survey, surveyor #1 reviewed 5 patient reports containing frozen section interpretations. 1 of the 5 reports did not

include the address of the laboratory location where the testing had been performed (the test date on the report was 01/08/19); (3) Surveyor #1 reviewed the report with the pathology assistant for Pathology Laboratory Associates, who stated the report did not include the address of the laboratory location where the frozen section had been performed.