

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2144247	(X3) Date Survey Completed 06/14/2019
Name of Provider or Supplier Ascension St John Clinic Urgent Care - Jenks	Street Address, City, State 220 S Elm, Suite 101, Jenks, 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 initial survey was performed on 06/14/19. The findings were reviewed with technical consultant #1 and the laboratory coordinator at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
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, written policy and interview with the laboratory coordinator and technical consultant #1, the laboratory failed to have a written technical consultant competency policy based on the job responsibilities as listed in Subpart M. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for competency assessments performed during 2017, 2018 and 2019. There was no evidence competencies had been performed for the technical consultant, based on their job responsibilities; (2) The surveyor asked the laboratory coordinator and technical consultant #1 if a written policy to evaluate the technical consultant based on job responsibilities was available. The laboratory coordinator and technical consultant #1 stated a policy to evaluate the technical consultant based on job responsibilities had not been written; and competencies had not been performed.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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</p>

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 laboratory coordinator, the laboratory failed to follow the manufacturer's instructions for Hematology. Findings include: (1) At the beginning of the survey, the laboratory coordinator stated CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's instructions for verifying morphology flags obtained on the analyzer: (a) "AG (Platelet Flag) (Platelet Aggregate Code)" (i). Action - "1. Check specimen for clots. If clotted, results are invalid. 2. If no clots are present, rerun specimen. 3. OK TO REPORT if AG flag remains and the platelet result is within normal range of 150-480." (ii). Reporting - "DO NOT REPORT if AG flag remains and value is not within normal range, send lavender and blue specimens to RML." (b) "WL (WBC error flag but will flag the Diff also)" (i) Action - "1. Do Autorinse and Assure Background Counts are within limits. 2. Check specimen for clots. If clotted, results are invalid. 3. If no clots are present, rerun the specimen. 4. If WL flag stil remains and /or specimen has clots then results are invalid-DO NOT REPORT." (ii) Reporting - "DO NOT REPORT at all if WL flag remains send lavender and blue specimens to RML." (3) The surveyor randomly reviewed 21 patient records containing flags from CBC testing performed during July 2018, October 2018, January 2019, March 2019, and May 2019. For 2 of 21 records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flag: (a) Patient #1 - AG flag reported on patient testing performed on 10/24/18 at 09:19 am, with a platelet result of 607; (b) Patient #2 - WL flag reported on patient testing performed on 05/23/19 at 09:06 am (4) The surveyor reviewed the records with laboratory coordinator who stated the flags obtained for the above patients had not been documented as verified.

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, procedure manual, and interview with the laboratory coordinator, the laboratory failed to ensure the verified reportable ranges were used by the laboratory. Findings include: (1) On the first day of the survey, the laboratory coordinator stated the laboratory began using the Sysmex XP-300 analyzer to perform routine CBC (Complete Blood Count) testing beginning 05/21/18; (2) The surveyor reviewed the validation records for the analyzer. The reportable range was verified as follows: (a) Hemoglobin 0.0 - 21.6 g/dL (b) Hematocrit 0 - 59 % (3) The surveyor then reviewed the laboratory computer system and identified the following reportable ranges used by the laboratory were wider than the verified reportable ranges: (a)

Hemoglobin 7 - 25 g/dL (b) Hematocrit 20 -70 % (4) The surveyor reviewed the results with the laboratory coordinator who stated the laboratory computer system's reportable range were wider than the verified reportable ranges.

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 laboratory coordinator, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Findings include: (1) At the beginning of the survey, the laboratory coordinator stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (2) Later during the survey, the surveyor reviewed the manufacturer's maintenance requirements as stated on the manufacturer's maintenance logs: (a) Weekly Maintenance (i) Clean SRV Tray (3) The surveyor then reviewed maintenance records from July 2018 through May 2019. There was no evidence the weekly maintenance had been performed: (a) Between 07/17/18 and 08/11/18 (b) Between 08/11/18 and 08/29/18 (c) Between 09/11/18 and 10/01/18 (d) Between 11/01/18 and 12/01/18 (e) Between 12/01/18 and 12/11/18 (f) Between 01/14/19 and 02/05/19 (g) Between 02/12/19 and 02/26/19 (h) Between 02/26/19 and 03/05/19 (i) Between 03/05/19 and 03/26/19 (j) Between 04/09/19 and 05/06/19 (4) The surveyor reviewed the records with the laboratory coordinator, who stated the weekly maintenance had not been documented as performed as indicated above.