

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1077103	(X3) Date Survey Completed 11/06/2019
Name of Provider or Supplier Ascension St John Clinic Urgent Care-Sand Springs	Street Address, City, State 402 W Morrow Road, Sand Springs, 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 11/06/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #1 and technical consultant #4 at the conclusion of the survey.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #1 and technical consultant #4, the laboratory failed to thoroughly review and evaluate hematology proficiency testing results from 2 of 5 events. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to the surveyor that on 01/21/19 the laboratory put the Sysmex XP-300 analyzer into use to perform CBC testing (Complete Blood Count) (WBC-White Blood Count, RBC-Red Blood Count, Platelet count, etc.); (2) The surveyor reviewed hematology proficiency testing from the First, Second, and Third events of 2018, and the First and Second events of 2019. The surveyor identified in 2 of the 5 events, the laboratory's Platelet count results obtained Positive biases (the biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency testing program): (a) 2019 First Event: (i) 3 of 5 results exhibited a Positive bias: (aa) HSY-02: SDI 4.0 (bb) HSY-03: SDI 2.4 (cc) HSY-04: SDI 5.3 (b) 2019 Second Event: (i) 2 of 5 results exhibited a Positive bias: (aa) HSY-07: SDI 2.0 (bb) HSY-09: SDI 2.0 (3) There was no documentation located in the records, the laboratory identified the biases and took corrective action (i.e. review maintenance records, quality control results, reagent stability, patient results performed during the same time frame, etc.) to determine the cause of the biased</p>

proficiency results listed above; (4) The surveyor reviewed the findings with technical consultant #1 and technical consultant #4, who stated to the surveyor the biases listed above had not been identified and had not been thoroughly addressed.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
Based on a review of policies and procedures, and interview with technical consultant #1 and technical consultant #4, the laboratory failed to follow its written policies and procedures for the testing performed in the laboratory for 2 of 25 analyzer printouts reviewed. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to the surveyor the laboratory performed CBC testing (Complete Blood Count) (e.g., WBC (White Blood Count), Platelet Count, Automated WBC differential (lymphocytes, mixed, neutrophils) in percent and absolute values) using the Sysmex KX-21N analyzer until 01/21/19, when it was replaced with the Sysmex XP-300 hematology analyzer; (2) The surveyor reviewed the laboratory's policy and procedure for CBC testing titled, "Urgent Care Flag Reference Guide," which included instructions for CBC samples that obtained flagged results (technical consultant #1 verified the policy was used for both hematology analyzers). Examples of the flags included: (a) For Platelet Flag "AG" (Platelet Aggregate Code), the procedure stated: (i) Check specimen for clots; (ii) If no clot is present, rerun the original sample. If AG remains, it is OK to report the CBC and Diff if the Platelet count is between 150-480; (iii) Stamp the CBC result printout with the "AG" stamp. Make sure to get provider's signature. (b) For the Diff Flag "T2," the procedure stated: (i) Rerun specimen; (ii) If flag remains, you may report the other analytes but not the Diff portion of the CBC even if there are results in those fields; (iii) Stamp the CBC result printout with the "T2 Result flag on Diff. DIFF NOT VALID. Submit specimen to RML" (reference laboratory); (iv) Have provider sign CBC result. (3) The surveyor then reviewed analyzer printouts of patient CBC's from 6 months (March, April, and June 2018; and January, March, and October 2019). There was no documentation the laboratory followed its written procedure for 2 of the 25 flagged CBC results reviewed: (a) 04/03/18 at 04:19 PM - Patient #0024432667: The platelet count obtained an AG flag. The sample was not repeated and the results were reported to the provider; (b) 03/04/19 at 01:04 PM - Patient #29211710: The differential obtained the Diff flag "T2" on the percent and absolute values of Mixed and Neutrophils cell differentials. The sample was repeated 3 times and the flagged remained. The specimen was not sent to the reference laboratory and the results were reported to the provider. (4) The surveyor reviewed the findings with technical consultant #1 and technical consultant #4 who stated to the surveyor, the laboratory failed to follow its written policy and procedure for CBC's which obtained flags.

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 technical consultant #1 and technical consultant #4, 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 2 of 5 events. Findings include: (1) At the beginning of the survey, technical consultant #1 stated to the surveyor the laboratory performed CBC testing (Complete Blood Count) (e.g., WBC (White Blood Count), Platelet Count, Automated WBC differential (lymphocytes, mixed, neutrophils) in percent and absolute values) using the Sysmex KX-21N analyzer until 01/21/19, when it was replaced with the Sysmex XP-300 hematology analyzer; (2) The surveyor reviewed hematology proficiency testing from the First, Second, and Third events of 2018, and the First and Second events of 2019. It was identified for 2 of 5 events reviewed, 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) First event of 2018: The samples had been tested on 03/23/18 and the attestation statement had not been signed by the laboratory director until 06/12/18; (b) Second event of 2018: The samples had been tested on 07/24/18 and the attestation statement had not been signed by the laboratory director until 09/11/18. (3) The surveyor reviewed the findings with technical consultant #1 and technical consultant #4 and explained attestation statements must be signed within a timeframe to definitively attest to the fact proficiency samples were tested in the same manner as patient specimens.