

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1077103	(X3) Date Survey Completed 02/08/2018
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 findings were reviewed with the radiology team lead at the conclusion of the survey.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the radiology team lead, the laboratory failed to ensure an analyzer was stored as required by the manufacturer. Findings include: (1) At the beginning of the survey, the radiology team lead stated to surveyor #2 CBC (Complete Blood Count) testing was performed on the Sysmex KX-21N analyzer; (2) Later during the survey, surveyor #1 reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required the relative humidity be maintained within the range of 30-85%; (3) Surveyor #1 reviewed laboratory humidity records from February 2016 through December 2017 which verified the humidity readings were less than 30% for 7 of 23 months as follows: (a) February 2016 - 7 of 29 humidity readings were documented as less than 30% (days 04,08,09,10,12,13,14); (b) March 2016 - 1 of 31 humidity readings was documented as less than 30% (day 20); (c) December 2016 - 13 of 31 humidity readings were documented as less than 30% (days 08,09,10,12,14,15,18,19,20,21,22,30,31); (d) January 2017 - 13 of 31 humidity readings were documented as less than 30% (days</p>

01,04,05,06,07,08,09,13,14,15,27,28,29); (e) February 2017 - 7 of 28 humidity readings were documented as less than 30% (days 02,03,04,05,09,25,26); (f) November 2017 - 1 of 30 humidity readings was documented as less than 30% (day 22); (g) December 2017 - 15 of 31 humidity readings were documented as less than 30% (days 07,08,09,10,11,12,13,14,16,26,27,28,29,30,31). (4) The surveyors reviewed the records with the radiology team lead who stated the humidity of the laboratory had been maintained below 30% 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 radiology team lead, 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. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. It was identified for 4 of 6 events, the attestation statements had been signed approximately 2 - 9 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 2016 Hematology Event - The samples had been tested on 03/22/16 and the attestation statement had not been signed by the laboratory director until 12/20/16; (b) Second 2016 Hematology Event - The samples had been tested on 07/26/16 and the attestation statement had not been signed by the laboratory director until 12/20/16; (c) First 2017 Hematology Event - The samples had been tested on 03/20/17 and the attestation statement had not been signed by the laboratory director until 06/20/17; (d) Second 2017 Hematology Event - The samples had been tested on 07/13/17 and the attestation statement had not been signed by the laboratory director until 09/12/17. (2) The surveyors reviewed the findings with the radiology team lead 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.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the radiology team lead, the laboratory director failed to ensure proficiency testing reports were reviewed. Findings include: (1) At the beginning of the survey, surveyor #2 reviewed 2016 and 2017 proficiency testing records. The Performance Evaluation for 1 of 6 events not been signed and dated as reviewed by the laboratory director: (a) Third 2017 Hematology Event (2) The surveyors reviewed the records with the radiology team lead, who stated the Performance Evaluation, as indicated above had not been signed and dated as reviewed by the laboratory director.