

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D1062273	(X3) Date Survey Completed 01/29/2019
Name of Provider or Supplier Ascension St John Urgent Care - Utica	Street Address, City, State 1717 A South Utica Ave, Tulsa, 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 01/29/19. The laboratory was found to be in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory services manager 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 laboratory services manager, the laboratory failed to ensure the manufacturer's environmental specifications were met. Findings include: HUMIDITY (1) At the beginning of the survey, the laboratory services manager stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (e.g. WBC (White Blood Count), RBC (Red Blood Count), Hematocrit, Hemoglobin, Platelet count, etc.) using the Sysmex KX-21N hematology analyzer; (2) The surveyor reviewed the manufacturer's environmental requirements. The manufacturer required a humidity between 30 and 80% for optimal performance; (3) The surveyor then reviewed the laboratory humidity/temperature records from 10 months (January, February, April, May, June, July, August, September, November and December 2018). The surveyor identified on 37 of the 272 days reviewed, the manufacturer's humidity requirement had not been met, or the humidity had not been documented. The specific findings follow: (a) January 2018: On 2 of 31 days, the humidity was unacceptable: (i) 28%:</p>

Day 1 (ii) 29%: Day 2 (b) February 2018: On 7 of 28 days, the humidity was unacceptable: (i) 20%: Day 28 (ii) 26%: Day 5 (iii) 27%: Day 7,12 (iv) 29%: Days 3,8,11 (c) April 2018: On 1 of 30 days, the humidity had not been documented: Day 8 (d) May 2018: On 2 of 31 days, the humidity had not been documented: Days 4,29 (e) June 2018: On 2 of 30 days, the humidity had not been documented: Days 1,16 (f) July 2018: On 1 of 31 days, the humidity had not been documented: Day 30 (g) August 2018: The humidity was unacceptable, or had not been documented on 8 of 31 days: (i) 82%: Days 17,25 (ii) 83%: Day 29 (iii) 85%: Days 27,28 (iv) 86%: Day 26 (v) The humidity had not been documented: Days 30,31 (h) September 2018: The humidity was unacceptable, or had not been documented on 13 of 30 days: (i) 72% and 86% after recheck: Day 1 (ii) 82%: Days 19,25 (iii) 83%: Day 13 (iv) 84%: Day 5 (v) 85%: Days 2,3,8,14 (vi) 86%: Day 4 (vii) The humidity had not been documented: Days 7,18,30 (i) December 2018: The humidity had not been documented on 1 of 30 days: Day 20 (4) The surveyor reviewed the findings with the laboratory services manager. The laboratory services manager stated to the surveyor the laboratory failed to ensure the manufacturer's humidity requirement for the Sysmex KX-21N analyzer had been met as listed above.

REFRIGERATOR TEMPERATURE (1) The surveyor reviewed temperature records of the Tempure Scientific refrigerator from 9 months (July, August, November, and December 2017; January, March, April, October, and November 2018). The laboratory's acceptable temperature range was 2 to 8 degrees C (Centigrade). The surveyor identified on 52 of the 269 days reviewed, the refrigerator temperature was unacceptable, or had not been documented. The specific findings follow: (a) July 2017: The refrigerator temperature was colder than acceptable on 5 of 31 days: (i) 1.3 C: Day 11 (ii) 1.6 C: Day 9 (iii) 1.8 C: Day 8 (iv) 1.9 C: Days 7,10 (b) August 2017: The refrigerator temperature was colder than acceptable on 6 of 31 days: (i) 0.7 C: Day 12 (ii) 0.8 C: Day 15 (iii) 1.3 C: Days 7,14 (iv) 1.5 C: Day 13 (v) 1.9 C: Day 10 (c) November 2017: The refrigerator temperature was colder than acceptable on 24 of 29 days: (i) 0.1 C: Day 19 (ii) 0.5 C: Day 1 (iii) 0.6 C: Day 2 (iv) 0.8 C: Day 8 (v) 0.9 C: Days 3,4 (vi) 1.0 C: Days 11,16 (vii) 1.1 C: Day 22 (viii) 1.2 C: Day 24 (ix) 1.3 C: Day 17 (x) 1.5 C: Days 13,25 (xi) 1.6 C: Days 9,14,20,21,29,30 (xii) 1.7 C: Days 15,26 (xiii) 1.8 C: Days 12,27 (xiv) 1.9 C: Day 10 (d) December 2017: The refrigerator temperature was colder than acceptable on 12 of 30 days: (i) 0.8 C: Day 20 (ii) 1.1 C: Day 6 (iii) 1.2 C: Day 15,19 (iv) 1.4 C: Days 21,27 (v) 1.5 C: Day 14,18 (vi) 1.6 C: Days 8,26 (vii) 1.7 C: Day 13 (viii) 1.8 C: Day 12 (e) January 2018: The refrigerator temperature was colder than acceptable on 3 of 30 days: (i) 0.9 C: Day 13 (ii) 1.4 C: Day 12 (iii) 1.6 C: Day 14 (f) April 2018: The temperature had not been documented on 1 of 29 days (i) Day 29 (g) October 2018: The temperature had not been documented on 1 of 31 days (i) Day 22 (2) The surveyor asked the laboratory services manager what was stored in the refrigerator. The laboratory services manager stated the EightCheck 3WPX-XTRA hematology control materials had been stored in the Tempure Scientific refrigerator until it was replaced on 12/10/18 with a new refrigerator; (3) The surveyor then reviewed the manufacturer's instructions for the EightCheck 3WPX-XTRA hematology control materials. The manufacturer required a storage temperature between 2-8 degrees C; (4) The surveyor reviewed the findings with the laboratory services manager who stated to the surveyor the laboratory failed to ensure the manufacturer's storage requirement for the hematology control materials had been met, as listed above.

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 services manager, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) At the beginning of the survey, the laboratory services manager stated to the surveyor the laboratory performed CBC's (WBC (White Blood Count), RBC (Red Blood Count), Hemoglobin, Hematocrit, Platelet Count, etc.) using the Sysmex KX-21N hematology analyzer; (2) The surveyor reviewed the manufacturer's maintenance requirement for the analyzer. The manufacturer required the following procedures be performed: (a) Weekly: Clean the SRV (b) Monthly: (i) Clean transducer (ii) Clean waste chamber (3) Maintenance records from 06/01/17 through 12/31/18 were reviewed by the surveyor. The surveyor identified the required maintenance procedures had not performed as follows: (a) Weekly maintenance: Had not been performed: (i) Between 06/01/17 and 06/13/17 (ii) Between 06/08/18 and 06/19/18 (b) Monthly maintenance: Had not been performed during 1 of the 18 months reviewed: (i) Between 05/01/18 and 05/31/18 (4) The findings were reviewed with the laboratory services manager who stated to the surveyor there was no documentation the manufacturer's required weekly and monthly maintenance procedures had been performed as listed above.

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on a review of records, manufacturer's instructions and interview with the laboratory services manager, the laboratory failed to take corrective action when the manufacturer's environmental specifications had not been met. Findings include: HUMIDITY (1) At the beginning of the survey, the laboratory services manager stated to the surveyor the laboratory performed CBC (Complete Blood Count) testing (e.g. WBC (White Blood Count), RBC (Red Blood Count), Hematocrit, Hemoglobin, Platelet count, etc.) using the Sysmex KX-21N hematology analyzer; (2) The surveyor reviewed the manufacturer's environmental requirements for the analyzer. The manufacturer required a humidity between 30 and 80% for optimal performance; (3) The surveyor then reviewed the laboratory humidity/temperature records from 10 months (January, February, April, May, June, July, August, September, November and December 2018). The surveyor identified on 37 of the 272 days reviewed, the manufacturer's humidity requirement had not been met, or had not been documented and there was no documentation corrective action (e.g. recheck humidity, use a humidifier or a dehumidifier, retrain testing personnel, etc.) had been taken. The specific findings follow: (a) The laboratory humidity was less than 30%: (i) January 2018: On 2 of 31 days: Days 1,2 (ii) February 2018: On 7 of 28 days: Days 3,5,7,8,11,12,28 (b) The laboratory humidity was higher than 80%: (i) August 2018: On 6 of 31 days: Days 17,25, 26,27,28,29 (ii) September 2018: On 10 of 30 days: Days 1,2,3,4,5,8,13,14,19,25 (c) The laboratory humidity had not been documented: (i) April 2018: On 1 of 30 days: Day 8 (ii) May 2018: On 2 of 30 days: Days 4,29 (iii) June 2018: On 2 of 30 days: Days 1,16 (iv) July 2018: On 1 of 31 days: Day 30 (v)

August 2018: On 2 of 31 days: Days 30,31 (vi) September 2018: On 3 of 30 days: Days 7,18,30 (vii) December 2018: On 1 of 30 days: Day 20 (4) The surveyor reviewed the findings with the laboratory services manager. The laboratory services manager stated to the surveyor the laboratory had not taken corrective action for the unacceptable humidity listed above, and failed to take corrective action when the humidity had not been documented. REFRIGERATOR TEMPERATURE (1) The surveyor reviewed temperature records of the Tempure Scientific refrigerator from 9 months (July, August, November, and December 2017; January, March, April, October, and November 2018). The laboratory's acceptable temperature range was 2 to 8 degrees C (Centigrade). The surveyor identified on 52 of the 269 days reviewed, the refrigerator temperature was less than 2 degrees C, or had not been documented and there was no documentation the laboratory took corrective action: (a) Less than 2 degrees C: (i) July 2017: On 5 of 31 days: Days 7,8,9,10,11 (ii) August 2017: On 6 of 31 days: Days 7,10, 12,13,14,15 (iii) November 2017: On 24 of 29 days: Days 1,2,3,4,8,9,10,11,12,13,14,15,16,17,19,20,21, 22,24,25,26,27,29,30 (iv) December 2017: On 12 of 30 days: Days 6,8,12,13,14,15,18,19,20,21,26,27 (v) January 2018: On 3 of 30 days: Days 12,13,14 (b) The temperature had not been documented: (i) April 2018: On 1 of 29 days: Day 29 (ii) October 2018: On 1 of 31 days: Day 22 (2) The surveyor asked the laboratory services manager what was stored in the refrigerator. The laboratory services manager stated the EightCheck 3WPX-XTRA hematology control materials had been stored in the Tempure Scientific refrigerator until it was replaced on 12/10/18 with a new refrigerator; (3) The surveyor reviewed the manufacturer's instructions for the EightCheck 3WPX-XTRA hematology control materials. The manufacturer required a storage temperature between 2-8 degrees C; (4) The surveyor reviewed the findings with the laboratory services manager who stated to the surveyor the laboratory failed to take corrective action when the manufacturer's storage requirement for the hematology control materials had not been met.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
 Based on a review of records, manufacturer's instructions, and interview with the laboratory services manager, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment due to the following issues identified during the survey: (a) The laboratory failed to ensure the manufacturer's environmental specifications were met. Refer to D5413; (b) The laboratory failed to perform maintenance procedures as required by the manufacturer. Refer to D5429; (c) The laboratory failed to take corrective action when the manufacturer's storage and operation requirements had not been met. Refer to D5785.

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 laboratory services manger, the laboratory director failed to ensure proficiency testing samples were tested as required under Subpart H. Findings include: (1) At the beginning of the survey, the surveyor reviewed the 2018 proficiency testing records. It was identified for 1 of the 3 events reviewed, the laboratory director signed the attestation statement approximately 3 months after the samples had been tested (not within a time frame for the director to attest that, at the time of testing, the proficiency samples had been tested as required): (a) Second Hematology/Coagulation Event: The samples were tested on 07/09/18 and the laboratory director signed the attestation statement on 10/03/18. (2) The surveyor reviewed the findings with the laboratory services manger, and explained the attestation statement must be signed to definitively attest to the fact proficiency samples were tested in the same manner as patient specimens.