| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 37D1077103 | 02/16/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ascension St John Clinic Urgent Care-Sand Springs | 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 |
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| **D0000** | The recertification survey was performed on 02/16/2022. The findings were reviewed with technical consultant #1 at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #1, the laboratory failed to follow the written technical consultant competency policy based on the job responsibilities as listed in Subpart M for three of three technical consultants. Findings include: (1) The surveyor reviewed personnel records for competency assessments performed during 2020 and 2021. There was no evidence competencies had been performed for technical consultant #1, technical consultant #2, and technical consultant #3 based on job responsibilities in 2020 and 2021; (2) The surveyor asked technical consultant #1 if a written policy to evaluate the technical consultants, based on job responsibilities, was available and if competencies had been performed during the review period. Technical consultant #1 stated to the surveyor on 02/16/2022 at 12:05 pm, a policy to evaluate the technical consultants annually based on job responsibilities was written but had not been documented as performed in 2020 and 2021. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the |

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| | 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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, written procedure, and interview with technical consultant #1, the laboratory failed to follow the laboratory humidifier procedure for seven of 24 months. Findings include: (1) On 02/16/2022 at 12:00 pm, technical consultant #1 stated the following to the surveyor: (a) Routine CBC (Complete Blood Count) was performed on the Sysmex XP-300 analyzer; (b) The acceptable humidity range was 30% to 85% (2) On 02/16/2022, the surveyor reviewed the laboratory's humidifier procedure titled, "URGENT CARE HUMIDITY LOG" which stated: (a) "Record Humidity in AM" (b) "If Humidity is below 35% Turn on Humidifier" (c) "Only Recheck if Humidity was out of Range" (d) "If Humidifier Turned On record Humidity in Recheck Box" (3) The surveyor reviewed humidity records between 01 /01/2020 through 12/31/2021 and identified the following: (a) The humidifier had not been turned on when the humidity was below 35% for seven of 24 months as follows: (i) 10/16/2020 - The humidity reading was documented at 32%; (ii) 10/17/2020 - The humidity reading was documented at 31%; (iii) 11/13/2020 - The humidity reading was documented at 31%; (iv) 11/15/2020 - The humidity reading was documented at 31%; (v) 11/17/2020 - The humidity reading was documented at 31%; (vi) 11/18/2020 - The humidity reading was documented at 31%; (vii) 11/19/2020 - The humidity reading was documented at 32%; (viii) 11/23/2020 - The humidity reading was documented at 34%; (ix) 11/29/2020 - The humidity reading was documented at 31%; (x) 01/21/2021 - The humidity reading was documented at 31%; (xi) 01/29/2021 - The humidity reading was documented at 30%; (xii) 03/28/2021 - The humidity reading was documented at 34%; (ix) 03/31/2021 - The humidity reading was documented at 16%. (b) Recheck not documented when humidity was out of range (i) 01/16/2021 - The humidity reading was documented at 21% and not documented as rechecked; (ii) 12/07/2021- The humidity reading was documented at 21% and not documented as rechecked; (iii) 12/08/2021 - The humidity reading was documented at 24% and not documented as rechecked. (4) The surveyor reviewed the findings with technical consultant #1. Technical consultant #1 stated on 02/16/2022 at 12:08 pm, the laboratory humidity procedure had not been followed as indicated above. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with technical consultant #1, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for four of 24 months. Findings include: (1) On 02/16/2022 at 12:00 pm, technical consultant #1 stated to the surveyor that CBC (Complete Blood Count) testing was performed on the Sysmex XP-300 analyzer; (2) On 02/16/2022, 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 reviewed maintenance records for 24 months (January |

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| | 2020 through December 2021) and identified the following: (a) There was no evidence the weekly maintenance had been performed (i) Between 01/21/2020 and 02 /04/2020 (ii) Between 02/18/2020 and 03/03/2020 (iii) Between 11/09/2021 and 11/23 /2021 (iv) Between 12/17/2021 and 12/28/2021 (4) The surveyor reviewed the records with technical consultant #1, who stated on 02/16/2022 at 12:15 pm, the weekly maintenance had not been documented as performed as required. |
| **D5439** | CALIBRATION AND CALIBRATION VERIFICATION<br>CFR(s): 493.1255(b)<br><br>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #1, the laboratory failed to perform calibration verification procedures at least once every six months for one of two calibration verification procedures. Findings include: (1) On 02 /16/2022 at 12:00 pm, technical consultant #1 stated to the surveyor: (a) BUN, Chloride, Creatinine, Ionized Calcium, Potassium, Sodium, and TO2 (Chem 8+ cartridge) was performed using the iSTAT analyzer. (2) The surveyor reviewed 2021 calibration records and identified that calibration verification procedures had not been performed since 01/06/2021 through the day of the survey (02/16/2022); (3) The surveyor asked technical consultant #1 if calibration verification procedures had been performed since 01/06/2021. Technical consultant #1 stated calibration verification procedures had not been performed since 01/06/2021 as indicated above. |
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(g)<br><br>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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when |

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| | they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, written policies, and interview with technical consultant #1, the laboratory failed to follow written quality control policies for one of 17 months. Findings include: (1) On 02/16/2022 at 12:00 pm, technical consultant #1 stated the following to the surveyor: (a) BUN, Chloride, Creatinine, Ionized Calcium, Potassium, Sodium, and TO2 (Chem 8+ cartridge) was performed using the iSTAT analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as effective on 07/01/2020 for the Chem 8+ cartridge) and identified the QCP required three levels of external QC materials be performed once each month (i.e., approximately each 30 days), new lot number, and shipment; (3) The surveyor then reviewed quality control records from August 2020 through December 2021 and identified the laboratory failed to follow the written QCP of performing quality control testing once a month. Three levels of quality control testing had not been performed between: (a) 09/16/2021 and 11/01/2021 (i) Two levels (Level 1- Lot# 101135 and Level 3- Lot# 121135) of external control had been performed on 10/10/2021 instead of three levels as required. (4) The findings were reviewed with technical consultant #1 who stated on 02/16 /2022 at 12:10 pm the laboratory had not performed quality control testing as required by the QCP. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #1, the laboratory failed to follow their policy for monitoring the effectiveness of their IQCP. Findings include: (1) On 02/16/2022 at 12:00 pm, technical consultant #1 stated the following to the surveyor: (a) BUN, Chloride, Creatinine, Ionized Calcium, Potassium, Sodium, and TO2 (Chem 8+ cartridge) was performed using the iSTAT analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP (dated as approved on 07/01 /2020). The section titled, "Quality Assessment Monitoring" stated, "a. Monitoring of this plan will occur annually at minimum, and reevaluation will be considered whey any changes occur with the following: Testing personnel, environment, specimens, reagents, test system"; (3) The surveyor reviewed records for 2020 and 2021 and could not locate annual QA reviews since the IQCP had been approved on 07/01 /2020; (4) The surveyor reviewed the records with technical consultant #1 and asked if there was documentation of a QA review to evaluate the QCP annually. Technical consultant #1 stated to the surveyor on 02/16/2022 at 12:09 pm a QA review had not been documented as performed annually as stated in the policy. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9) |

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| | The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #1, the technical consultant failed to ensure an evaluation included complete documentation of all moderate complexity testing performed for one of 22 persons. Findings include: (1) On 02/16/2022 at 12:00 pm, technical consultant #1 stated to the surveyor the following testing were performed in the laboratory: (a) Chemistry testing (BUN, Chloride, Creatinine, Ionized Calcium, Glucose, Potassium, Sodium, TCO2) was performed on the iSTAT and Chem 8+ cartridge. (2) The surveyor then reviewed personnel records for 22 persons requiring annual competencies for the above testing, with the following identified for one of 22 persons: (a) Testing Person #1 - Annual competency dated as 12/22/2021 (i) Although the annual competency form had been signed and dated by technical consultant #3 on 12/22/2021, there was no documentation to prove the evaluation included an assessment of the testing listed above (this portion of the form was blank). (3) The surveyor reviewed the findings with technical consultant #1 who stated on 02/16/2022 at 12:05 pm that, although the assessments included all areas of testing, the form had not been completed. |