| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 37D2144247 | 05/10/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Ascension St John Clinic Urgent Care - Jenks | 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 recertification survey was performed on 05/10/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with technical consultant #2 and the laboratory coordinator at the conclusion of the survey. |
| **D2015** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(5)(6)<br><br>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #2, the laboratory failed to ensure a proficiency testing attestation statement had been maintained; and failed to ensure a proficiency testing attestation statement had been signed by the laboratory director or designee for two of ten events reviewed during 2021, 2022, and to date in 2023. Findings include: (1) A review of 2021, 2022, and 2023 proficiency testing records identified the following for two of ten events: (a) Third 2022 Hematology Event - The attestation statement had not been maintained. (b) Third 2022 Chemistry Core Event - The attestation statement had not been signed by the laboratory director or designee. (2) The findings were reviewed with technical consultant #2 who stated on 05/10/2023 at 03:20 pm, the attestation statements had not been signed or maintained as stated above. |

| | |
|---|---|
| **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, written policies and procedures, and interview with technical consultant #2, the laboratory failed to follow their policy to assess the competency of the technical consultant, based on the position responsibilities as listed in Subpart M, for one of three persons serving as technical consultant during the review period of July 2021 through the current date. Findings include: (1) A review of the laboratory policy titled, "Technical Consultant Competency" stated, "The Technical Consultant will be evaluated on their ability to perform the responsibilities established by the Urgent Care's accrediting agency. The technical consultant will be evaluated at least annually"; (2) A review of the Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of July 2021 through the current date identified competencies, based on job responsibilities, had not been documented as performed until 05/10/2023 for one of three persons listed as technical consultant on Form CMS-209; (3) The findings were reviewed with technical consultant #2 who stated on 05/10 /2023 at 11:10 am, the competency for the technical consultant had not been performed during the review period until 05/10/2023. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview with the laboratory coordinator, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the laboratory on 05/10/2023 at 01:15 pm identified the following expired collection tubes that appeared to be available for use: (a) Four Becton Dickinson Vacutainer Trace Element Serum tubes (lot #1350359) with an expiration date of 12/31/2022; (b) Six Becton Dickinson Vacutainer Serum tubes (lot #1236631) with an expiration date of 01/31/2023. (2) Interview with the laboratory coordinator on 05/10/2023 at 01:20 pm, confirmed the blood collection tubes would rarely be used to collect patient blood samples to send to the reference laboratory, however, the tubes were available for use. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with technical consultant #2 and the laboratory coordinator, the laboratory failed to demonstrate the performance specifications for one of one replacement analyzer. Findings include: (1) On 05/10 /2023 at 04:10 pm, technical consultant #2 stated the following: (a) The laboratory performed Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, and Creatinine testing using the iSTAT 1 analyzer and the Chem 8+ cartridge; (b) The laboratory began using iSTAT 1 (serial number 399431) to replace iSTAT 1 (serial number 399412) on 11/07/2022. (2) A review of records in 2022 identified no evidence the performance specifications (i.e., accuracy, precision, reportable range) had been demonstrated for the replacement iSTAT 1 analyzer; (3) The findings were reviewed with technical consultant #2 who stated on 05/10/2023 at 04:20 pm, the laboratory had not demonstrated the performance specifications for the replacement analyzer. |
| **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 #2 and the laboratory coordinator, the laboratory failed to perform calibration verification procedures at least once every six months for one of one test system during the review period of July 2021 through the current date. Findings include: (1) On 05/10/2023 at 10:35 am, the laboratory coordinator stated the laboratory performed Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, and Creatinine testing using the iSTAT 1 analyzer and the Chem 8+ cartridge; (2) A review of records from July 2021 through the current date identified no evidence calibration verification had |

| | |
|---|---|
| | been performed at least once every six months during the review period; (3) The records were reviewed with technical consultant #2 who stated on 05/10/2023 at 04:05 pm, calibration verification procedures had not been performed every six months. |
| **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 #2 and the laboratory coordinator, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP (Quality Control Plan) for one of one test system during the review period of July 2021 through the current date. Findings include: (1) On 05 /10/2023 at 10:35 am, the laboratory coordinator stated the following: (a) The laboratory performed Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, and Creatinine testing using the iSTAT 1 analyzer and the Chem 8+ cartridge; (b) An IQCP (Individualized Quality Control Plans) had been developed for the test system. (2) A review of the IQCP for the test system identified that QA (Quality Assessment) reviews of the QCP (Quality Control Plan) were to be performed on an annual basis; (3) A review of records for the test system from July 2021 through the current date identified no documentation that annual QA reviews had been performed during the review period; (4) The records were reviewed with technical consultant #2 and the laboratory coordinator. Both stated on 05/10/2023 at 04:35 pm, annual QA reviews had not been documented as performed for the above test system. |