| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 37D0997316 | 10/31/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Oklahoma Center For Orthopedic And Multispecialty | 8100 S Walker Bldg C, Oklahoma City, 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 10/31/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director and outpatient director at the conclusion of the survey. |
| **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 the laboratory director and outpatient director, the laboratory failed to demonstrate the performance specifications for a replacement analyzer. Findings include: (1) During the survey, the laboratory director and outpatient director stated to the surveyor one Abbott iSTAT 1 analyzer (serial number 346699), was used to perform pH, pCO2, pO2, Sodium, Potassium, Hematocrit, and Hemoglobin testing using the E6+cartridge; (2) The laboratory director and outpatient director stated to the surveyor, the Abbott iSTAT 1 analyzer serial number 346699 was put into use on 09/24/19 (to replace serial number 329005); (3) The surveyor asked the laboratory director and outpatient director if the performance specifications had been demonstrated for the replacement analyzer. Both stated the performance specifications had not been demonstrated for the replacement analyzer. |
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| **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 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 and interview with the laboratory director and outpatient director, the laboratory failed to perform quality control as stated in the IQCP. Findings include: (1) During the survey, the laboratory director and outpatient director stated the following to the surveyor: (a) One Abbott iSTAT 1 analyzer (serial number 346699), was used to perform pH, pCO2, pO2, Sodium, Potassium, Hematocrit, and Hemoglobin testing using the E6+cartridge; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system and external QC (quality control) was performed monthly and with new lot numbers of cartridges. (2) The surveyor reviewed QC records from December 2017 through the day of the survey and identified that QC had not been tested monthly, as stated in the IQCP. QC had not been tested between: (a) 12/31/17 and 06/28/18 (b) 06/28/18 and 11/16/18 (c) 11/16 /18 and 01/21/19 (d) 01/21/19 and 07/09/19 (3) The surveyor reviewed the records with the laboratory director and outpatient director and asked if QC had been performed monthly. Both stated to the surveyor QC had not been performed monthly, but had only been performed with new lot numbers of cartridges; (4) The surveyor asked for dates that patient testing had been performed. The laboratory director and outpatient director stated a patient had been tested on 10/30/18; (5) The surveyor reviewed the records with the laboratory director and outpatient director. Both stated the laboratory had not performed QC as stated in the IQCP. |