

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1060757	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Dallas Arthritis Center, Pa	Street Address, City, State 221 W Colorado Blvd Pavilion Ii, Suite 740, Dallas, TX	
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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory personnel records and staff interview, it was revealed the laboratory failed to have documentation of competency assessments performed on the technical supervisor/consultant. The findings were: 1. A review of the laboratory's submitted Form CMS 209 revealed the laboratory identified 1 technical supervisor/consultant for overseeing high and moderate complexity testing respectively. 2. A review of the laboratory's personnel files revealed the laboratory failed to have documentation of performing competency assessments on the technical supervisor/consultant. 3. The</p>

laboratory was asked to provide documentation of competency assessments. No documentation was provided. 4. An interview with the technical supervisor/consultant on 01/15/2019 at 09:20 hours in the break room revealed competency assessments had not been performed. This confirmed the findings.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's calibration verification policy for the Piccolo Express analyzer, calibration verification records and confirmed in interview, the laboratory failed to ensure calibration verification was performed and documented at least every 6 months for the Piccolo Express Chemistry analyzer as required by the manufacturer in 2017 and 2018. The findings were: 1. Review of the laboratory's policy "Linearity Testing (reportable range) Calibration Verification" (page 3 of 4) policy for the Piccolo Express stated, "Calibration verification is performed every six months, as stated in current CLIA regulations." Manufacturer's instructions for Piccolo Express stated, "Run verification samples per direction from Lab Consultant or Lab Director every 6 months to establish accuracy and precision of the Piccolo per CLIA Guidelines." 2. Records for the Piccolo Express in 2017 and 2018 revealed calibration verifications were performed on the following days: 01/31/2017 08/22 /2017 (6 month 3 weeks later) 03/28/218 (7 months 6 days later) 12/11/18 (8 months 2 weeks later) Calibration verification was not performed at least every 6 months, as required by the manufacturer. The analytes tested on the Piccolo Express included: Glucose, Blood Urea Nitrogen, Creatinine, Uric Acid, Calcium, Albumin, Total Protein, Alanine Aminotransferase, Aspirate Aminotransferase, Alkaline Phosphatase, Gamma-Glutamyl Transferase, Amylase and C-Reactive Protein. 4. During an interview on 01/15/2019 at 11:00 am in the break room, the Technical Consultant confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 12/28/2016