

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D2139186	(X3) Date Survey Completed 07/23/2019
Name of Provider or Supplier Pediatric Diagnostic Associates - Georgia	Street Address, City, State 4700 Battlefield Parkway, Suite 230, Ringgold, GA	
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	An initial Clinical Laboratory Improvement Amendments (CLIA) survey was completed on July 23, 2018. The laboratory was not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on calibration document review and staff interview, the laboratory failed to</p>

perform instrument calibration with the frequency required by CLIA (Clinical Laboratory Improvement Amendments). Findings include: 1. Horiba Micros 60 hematology analyzer calibration document review revealed the March, 2019, calibration documents were unavailable at the time of survey. 3. An interview with Staff #2 (CMS 209) in the breakroom on 7/23/2019 at approximately 5:00 p.m. confirmed the aforementioned calibration documents were not available at the time of survey.

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on testing personnel (TP) document review and staff interview, the laboratory director (LD) failed to ensure all TP receive the appropriate training prior to testing patients' specimens. Findings include: 1. TP document review revealed the following TP did not have an initial competency performed onsite in 2018 (CMS 209 -- Staff #2, Staff #4, Staff #5, Staff #6). 2. An interview with Staff #2 (CMS 209) in the breakroom on 7/23/2019 at approximately 5 p.m. confirmed the aforementioned TP did not have initial competencies performed onsite in 2018.