

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0994658	<b>(X3) Date Survey Completed</b>  06/12/2018
<b>Name of Provider or Supplier</b>  Whites Pediatrics Of Chatsworth	<b>Street Address, City, State</b>  925 North 3rd Avenue, Chatsworth, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on June 12, 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:
<b>D5437</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on review of hematology calibration documents and an interview the laboratory coordinator, the laboratory failed to calibrate the Horiba ABX Micros 60 analyzer at least once every 6 months in 2016 and 2017. Findings include: 1. A review of hematology calibration records revealed calibrations were not performed in October 2016 and April 2017 as data dictated. 2. Calibrations were performed once in 2016 (4/12/16) and once in 2017 (11/2/2017). 3. An interview with the laboratory coordinator at approximately 1:25 PM on June 12, 2018 in the patient review room confirmed the calibrations were not performed at least every 6 months in 2016 and 2017.</p>
<b>D6049</b>	<b>TECHNICAL CONSULTANT RESPONSIBILITIES</b>

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's maintenance records and an interview with the laboratory coordinator, the Technical Consultant (TC) who is also the laboratory director failed to review maintenance records in 2016, 2017, 2018. Findings include: 1. Review of maintenance logs including refrigerators, Humidity, room temperature, eye wash and problem logs revealed logs were not reviewed and signed on a monthly basis by (TC). 2. An interview with the laboratory coordinator on June 12, 2018 at approximately 01:35 pm in the patient review room confirmed maintenance logs were not reviewed and signed by the (TC) who is also laboratory director.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(9)

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.

This STANDARD is not met as evidenced by:

Based on review of testing personnel (TP) documents and interview with the laboratory coordinator , the technical consultant failed to perform annual competency on all testing personnel in 2016 and 2017. Findings include: 1. Review of testing personnel documents revealed the technical consultant failed to perform annual competencies on TP #1 - #5 (CMS 209 form). 2. An interview with the laboratory coordinator at approximately 1:39 PM on June 12, 2018 in the patient review room confirmed no annual competencies was documented for the aforementioned testing personnel.