

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D0304310	<b>(X3) Date Survey Completed</b>  06/19/2019
<b>Name of Provider or Supplier</b>  Pediatric Healthcare	<b>Street Address, City, State</b>  4700 Woodmere Blvd, Montgomery, AL	
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>D6066</b>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(4)(ii)</p> <p>Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of personnel listed on Form CMS-209, a review of the personnel files, and an interview with the Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure two of two new testing personnel had documentation of training for moderate complexity testing completed before performing patient testing. The findings include: 1. A review of Form CMS-209 revealed two of the seven testing personnel listed had been hired since the previous survey on 3/28/2017. A review of the test menu for this laboratory revealed moderate-complexity testing personnel performed CBC's (Complete Blood Counts) and waived testing, and set up Bacteriology cultures for the Laboratory Director and other physicians to read and interpret. 2. A review of the personnel files revealed TP #2 was hired with an initial evaluation on 3/25/2019. TP #3 was hired 7/10/2017, with a semi-annual competency evaluation in February 2018, and an annual assessment on 7/10/2018. There was no documentation of training in the files for TP #2 or #3. 3. During an interview on 6/19/2019 at 10:55 to 11:00 AM, the surveyor asked TP #1 about the training for TP #2 and #3. TP #1 stated she had the new personnel with her for a week in the laboratory for training. The surveyor then asked if the training was documented, reviewed and approved by the Laboratory Director (also Technical Consultant #1); TP #1 stated she had not realized this was required, and had not documented training staff on the operation of the Horiba Micros 60 Hematology analyzer, or Bacteriology culturing procedures. Thus the above noted findings were confirmed. .</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p>

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on a review of Bacteriology Quality Control (QC) records, a review of the manufacturer's package insert for BD BBL Taxo A discs, and an interview with Testing Personnel (TP) #1, the Laboratory Director failed to ensure QC results were reported correctly and were acceptable from 2015 - 2018. Findings include: 1. A review of Bacteriology QC records revealed the reactivity of BD BBL Taxo A discs were checked when new lot numbers of discs were received once or twice each year. 2. A review of the QC logs revealed Group A Strep (*Streptococcus pyogenes*) with "Expected" results of "Growth", and "Actual" results documented as "Growth" on 3/17/2015, 9/10/15, 1/13/2016, September 2017, 5/8/2018 and 9/26/18. [Group B-*Streptococcus agalactia* was documented with "Expected" and "Actual" results of "Negative" on the same dates.] 3. During an interview on 6/19/2019 at 3:40 PM, page 2 of the package insert for BD BBL Taxo A discs was reviewed with TP #1, as follows: "... User Quality Control ... RESULTS: A zone of inhibition is formed around the BD BBL Taxo A disc if the organism is a group A streptococcus. ... No zone of inhibition (growth up to the edge of the disc) is reported as "beta-hemolytic *Streptococcus*, presumptively not group A by bacitracin". ..." 4. As the interview continued, the surveyor explained their records had documented "Growth" for the positive Group A Strep QC since 2015, and as per the manufacturer's instructions, these QC results were unacceptable. Also following the manufacturer's instructions, the laboratory should specify the "Expected" results as "Positive" for zone of inhibition for the Group A Strep (*Streptococcus pyogenes*). The surveyor then asked who performed the testing; TP #1 explained the Medical Assistants inoculate the media cultures and place the Taxo A disc on the plates for the QC and patient cultures. Only the Laboratory Director or other physicians read and interpret the cultures. TP #1 stated she believed she had misunderstood what the physicians had reported to her, and had documented the QC incorrectly 2015-2018. The surveyor then stated in the specialty of Microbiology in this lab, the physicians are technically the high-complexity "Testing Personnel", and thus should document their own interpretations for QC and patients to ensure the results are transcribed correctly. Thus the above noted findings were confirmed. SURVEYOR ID #32558 Licensure and Certification Surveyor