

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D2069524	<b>(X3) Date Survey Completed</b> 07/26/2018
<b>Name of Provider or Supplier</b> Hamblen Pediatric Associates Of Sevierville	<b>Street Address, City, State</b> 629 Middle Creek Road, Sevierville, TN	
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>D6020</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.</p> <p>This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records for Complete Blood Counts (CBC) and throat culture QC with a lack of laboratory director proof of review by signature, and an interview with the office manager, the director failed to fulfill her responsibilities for assuring the quality of lab services provided during May and June of 2018. Findings include: 1. A review of QC, with parameters outside acceptability, for CBCs during May and June of 2018 showed a lack of director signature of review. 2. A review of throat culture QC for disc and media acceptability showed a lack of director signature of review for May and June 2018. 3. An interview with the office manager at 11:15 AM on July 26, 2018 confirmed a lack of director signature of reviews assuring the quality of lab services through acceptable QC.</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:  
Based on a review of testing personnel competency reports for 2017 and an interview with the office manager, the laboratory failed to show direct observations of performing testing; failed to assess problem solving skills and critical thinking of testing personnel; and failed to document testing personnel were following policies based on annual review of the work instructions during 2017. Findings include: 1. A review of testing personnel competency reports from 2017 failed to include direct observations of test performance by the technical consultant. 2. A review of testing personnel competency reports from 2017 did not include assessment of problem solving and critical thinking skills. 3. A review of the testing personnel competency reports from 2017 did not include annual reading of work instructions. 4. An interview with the office manager at 11:15 AM on July 26, 2018 confirmed the previous stated findings.

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:  
Based on a lack of educational verification for all testing personnel and an interview with the office manager, the laboratory failed to ensure the five testing personnel had at least proof of a high school education or equivalent prior to beginning testing on patients since 2017. Findings include: 1. A lack of testing personnel education verification for all testing personnel. 2. An interview with the office manager at 11:45 AM on July 26, 2018 confirmed the laboratory failed to ensure the five testing personnel had at least proof of a high school education or equivalent prior to beginning testing on patients since 2017.