

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0189268	<b>(X3) Date Survey Completed</b>  01/10/2018
<b>Name of Provider or Supplier</b>  Geisinger Pediatrics - Lewisburg	<b>Street Address, City, State</b>  55 Medical Park Drive, Lewisburg, PA	
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>D5431</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(2)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the Laboratory incubator, review of the Laboratory Temperature records, and interview of the Head Nurse, the Laboratory did not ensure that equipment function checks were within manufacturer's established limit's for throat culture incubation, before patient testing is conducted. Findings include: 1. The manufacturer's package insert for BBL Taxo A discs specifies an incubation range of 35C- 37C for use of BBL Taxo A discs, with throat cultures. 2. At the time of (15:30 01/06/2018), the Laboratory was using a throat culture incubation range of 98F - 100F. 3. The farenheight equivalent of 35C - 37C = 95F - 98.6F. 4. 24 of 62 temperature readings reviewed from 12/02/2017 through 01/09/2018 were above 98.6 F. 5. During the survey, the Head Nurse confirmed the above findings.</p>