

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0683245	<b>(X3) Date Survey Completed</b>  12/20/2023
<b>Name of Provider or Supplier</b>  Children's Specialized Hospital - Mtn Ltc	<b>Street Address, City, State</b>  150 New Providence Rd, Mountainside, NJ	
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>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), and interview with Technical Consultant (TC), the laboratory failed to follow the procedure for " External Electronic Simulator " from 8/17/21 to the date of survey. The findings include: 1. The PM states "Use the external Electronic Simulator to test i-Stats's thermal probes twice a year." 2. There was no documented evidence the procedure was performed. 3. The TC confirmed on 12/20/23 at 12:00 pm, the laboratory did not have documented evidence the above mentioned procedure was performed.</p>