

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0683245	(X3) Date Survey Completed 08/17/2021
Name of Provider or Supplier Children's Specialized Hospital - Mtn Ltc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to ensure that all Testing Personnel (TP) who performed Hematology and Chemistry tests participated in the College of American Pathologists (CAP) PT events in the calendar years 2020 and 2021. The finding includes: 1. A review of all PT events revealed that only two out of seventeen TP performed PT for all events in 2020 and 2021. 2. The TC confirmed on 8 /17/21 at 11:30 am that PT events were not rotated between TP.</p>
D5401	<p>PROCEDURE MANUAL 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 the Technical Consultant (TC), the laboratory failed to follow their PM policy for "Periodic Procedures for Cartridges" from 2/26/19 to the date of survey. The findings include: 1. The PM stated "From each lot of cartridges received, use representational</p>

number of cartridges to analyze i-stat level 1, 2, and 3 controls. Use the expected values published in the package insert to verify the integrity of the cartridges." 2. There was no documented evidence that the above procedure was performed. 3. The PM stated "i-STAT cartridges are shipped refrigerated with a four-window indicator to monitor temperature during transit. Action: Fill out the record of receipt and forward materials to refrigerator. If all windows are white or if only the A or B windows are blue or the 1 or 2 windows are red, then transit temperatures were satisfactory and the cartridges can be used. " 4. There was no documented evidence that the above procedure was performed. 5. The TC confirmed on 8/17/21 at 12:00 pm that the above mentioned procedures were not performed.

D5469

CONTROL PROCEDURES
CFR(s): 493.1256(d)(10)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on surveyor review of Quality Control records and interview with the Technical Consultant (TC), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment of Hematology and Chemistry QC used on the i-Stat analyzer from 2/26/19 to the date of survey. The finding includes: 1. All i-Stat tri-controls had one out of three levels verified with each new lot or shipment. 2. The TC confirmed on 8/17/21 at 11:00 am that all assayed QC material was not verified before putting in use.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:
Based on the lack of Performance Specification (PS) records and interview with the Laboratory Director (LD), the LD failed to ensure that PS procedures for Chemistry and Hematology tests performed on iStat analyzers were adequate from January 2020

to the date of survey. The LD confirmed on 8/17/21 at 11:20 am that PS records were not done.

D6072

TESTING PERSONNEL RESPONSIBILITIES

CFR(s): 493.1425(b)(3)

Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Calibration Verification (CV) Records and interview with the Technical Consultant (TC), the Testing Personnel failed to maintain quality control records. The finding includes. 1. The laboratory failed to retain the i-STAT Calibration Verification Set manufacturers package insert with the CV ranges. 2. Calibration ranges for all CV lots used previous were not documented. 3. The TC confirmed on 8/17/21 at 11:50 am that the laboratory did not maintain all CV records.