

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D2308737	(X3) Date Survey Completed 11/04/2025
Name of Provider or Supplier Upmc Children's North Surgery Ctr	Street Address, City, State 2599 Wexford Bayne Rd, Suite 1401, Sewickley, PA	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's verification of performance specifications records, lack of documentation, and interview with the Director of Operations, the laboratory failed to verify the required performance specifications for Chemistry testing performed on 1 of 1 i-STAT system analyzer before reporting patient test results from 06/09/2025 to the day of initial survey. Findings Include: 1. On the day of initial survey, 11/4/2025 at 10:47 am, review of the laboratory's verification of performance specification records for the 1 of 1 i-STAT system analyzer (s/n 314950) performed on 04/30/2025 revealed the laboratory failed to perform a reference range/normal value study appropriate for the laboratory's patient population for the following analytes from 06/09/2025 to 11/04/2025: - pH - Carbon Dioxide Partial Pressure (PCO2) - Oxygen Partial Pressure (PO2) - Sodium (Na) - Ionized calcium (iCa) - Potassium (K) - Glucose (Glu) - Hematocrit (HcT) 2. The laboratory could not provide a policy that included the laboratory's criteria to ensure a reference range /normal value study was appropriate for the laboratory's patient population. 3. The laboratory performed 1000 chemistry tests in 2025 (CMS 116, estimated annual volume, dated 11/04/2025). 4. The Director of Operations confirmed the above findings on 11/4/2025 at 1:04 pm.</p>

D6032

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(14)

(e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, lack of documentation and interview with the Director of Operations, the Laboratory Director failed to specify in writing the responsibilities and duties of 6 of 6 testing personnel (TP) involved in the pre-analytic, analytic, and post-analytic phases of moderate complexity chemistry testing from 6/09/2025 to 11/04/2025. Findings include: 1. The Laboratory Director Responsibilities and Delegation policy stated, "With respect to laboratory personnel, the LD or designee: Specifies in writing the responsibilities of each person engaged in the performance of the pre-analytic, analytic and post-analytic phases of testing. Identifies which examinations and procedures each individual is authorized to perform and whether supervision is required for such tasks." 2. On the day of initial survey, 11/04/2025 at 10:57 am, the laboratory failed to provide the written list of responsibilities for 6 of 6 TP (TP # 1 through TP# 6, CMS-209 dated 11/03/2025) involved in the pre-analytic, analytic, and post-analytic phases of moderate complexity chemistry testing from 06/09/2025 to 11/04/2025. 3. The laboratory could not provide documentation that identified which examinations each TP was approved to perform, and whether supervision is required for such tasks. 4. The Director of Operations confirmed the above findings on 11/04/2025 at 1:04 pm.