

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0192475	(X3) Date Survey Completed 01/14/2026
Name of Provider or Supplier Pediatrics Of Northeastern Pa	Street Address, City, State 920 Viewmont Drive, Dickson City, 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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Clinical Supervisor (CS), the laboratory failed to monitor and document room humidity to ensure operating conditions were met for 1 of 1 Magellan LeadCare II Analyzer used to perform whole blood lead (WBL) testing from 02/14/2024 to 1/14/2026. Findings include: 1. The manufacturers operating environment specifications stated: "Operate the analyzer only within the specified humidity range, 12 to 80% relative humidity." 2. On the day of the survey, 1/14/2026 at 12:15pm, the laboratory failed to provide documentation for the monitoring of room humidity to ensure operating conditions were met for the following instrument used to perform WBL testing from 02/14/2024 to 1/14/2026: - 1 of 1 Magellan LeadCare II Analyzer (S/N WLC10619). 3. The CS confirmed the above findings on 01/14/2026 at 1:35 pm.</p>
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) Proficiency Testing (PT) records, lack of documentation, and interview with the Clinical Supervisor (CS), the laboratory failed to document the evaluation and verification activities performed for 1 of 3 CAP PT Bacteriology testing events in</p>

2024. Findings include: 1. On the day of the survey, 01/14/2026 at 12:45 pm, review of the laboratory's CAP PT records revealed the laboratory failed to document the corrective action taken when the laboratory received a score of less than 100% for the following 1 of 3 CAP PT Throat culture testing events performed in 2024: - Score 80%: CAP Throat Culture D-1-B-2024:TC-07: unacceptable 2. The CS confirmed the above findings on 01/14/2026 at 1:20 pm.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, lack of documentation, and interview with the Clinical Supervisor (CS), the laboratory failed to perform and document the maintenance and function checks as defined by the manufacturer for 2 of 2 McKesson thermometers used for monitoring storage and incubation temperatures in the laboratory from 02/14/2024 to the day of the survey. Findings include: 1. On the day of the survey, 01/14/2026 at 1:55 pm, observation of the laboratory revealed the following thermometers used to monitor the storage and incubation temperatures for Group A Selective Strep Agar with 5% Sheep Blood were past due for calibration: - McKesson Thermometer S/N 51631, due 09/19/2025 - McKesson Thermometer S/N 51684, due 09/19/2025 2. The laboratory failed to provide maintenance/functions checks records for 2 of 2 McKesson thermometers from 09/19/2025 to 01/14/2026. 3. The laboratory performed 1792 throat cultures in 2025 (CMS 116, estimated annual volume, dated 1/14/2026). 4. The CS confirmed the above findings on 01/14/2026 at 2:10 pm.