

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0192475	(X3) Date Survey Completed 02/14/2024
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologist (CAP) proficiency testing (PT) records and interview with testing personnel (TP) #1 (CMS 209 personnel #8), the laboratory failed to provide 5 of 6 CAP PT attestation statements for microbiology testing events performed in 2022 and 2023. Findings include: 1. On the day of the survey, 02/14/2024 at 01:47 pm, the laboratory could not provide attestation statements for the following 5 of 6 CAP Microbiology PT events: - 2022 Throat Culture 1st event (D1-A), 2nd event (D1-B) and 3rd event (D1-C) - 2023 Throat Culture 1st event (D1-A) and 3rd event (D1-C) 2. TP #1 confirmed the findings above on 2/14/2024 around 01:47 pm.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's competency assessment records, competency assessment policy, and interview with testing personnel TP #1 (CMS 209 personnel #8), the laboratory failed to establish and follow policies to assess the competency of 4 of 4 Clinical Consultants (CC) and 2 of 2 Technical Consultants (TC) for their supervisory responsibilities in 2022. Findings include: 1. On the day of the survey, 02/14/2024 at 01:19 pm, review of the laboratory provided policy "Clinical Consultant /Technical Consultant Responsibilities" stated that "the lab director must complete a competency assessment on all Clinical/Technical Consultants." 2. The laboratory failed to provide competency records on 02/14/2024 for 4 of 4 CC (CMS 209 personnel #2, #3, #4, #5) and 2 of 2 TC (CMS 209 personnel #6, #7) for their supervisory responsibilities in 2022. 3. TP #1 interviewed on 2/14/2024 at 01:19 pm confirmed the findings above.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologists (CAP) proficiency testing (PT) records and interview with testing personnel (TP) #1 (CMS 209 personnel #8), the laboratory director (LD) failed to ensure that 6 of 6 CAP PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action from 03/07/2022 through 02/14/2024. Findings include: 1. On the date of the survey, 02/14/2024 at 01:23 pm, the laboratory could not provide documentation that the LD ensured the following 6 of 6 CAP Microbiology PT results were reviewed and assessed by the appropriate staff: - 2022 Throat Culture 1st event (D1-A), 2nd event (D1-B) and 3rd event (D1-C) - 2023 Throat Culture 1st event (D1-A), 2nd event (D1-B) and 3rd event (D1-C) 2. TP # 1 confirmed the findings above on 02/14/2024 at 01:23 pm.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory personnel report (CMS-209), personnel credentials, competency assessment (CA) records, and interview with testing personnel (TP) #1

(CMS 209 personnel #8), the Technical Consultant (TC) failed to evaluate the competency of 10 of 10 testing personnel (TP) that performed Bacteriology testing in 2023. Findings include: 1. On the day of the survey, 02/14/2024 at 01:15 pm, record review revealed the TC failed to perform CA assessments on the following TP that performed Throat Cultures in 2023: - 10 of 10 TP (CMS 209 personnel #8, #9, #10, #11, #12, #13, #14, #15, #16, #17). 2. Further review of CA records and interview with TP #1 on 02/14/2024 at 01:15pm, revealed that TP #1 performed the competency assessments for 10 of 10 TP that performed Throat Cultures in 2023. 3. Review of personnel credentials provided on the date of the survey, revealed TP #1 has a high school diploma. 4. TP #1 confirmed the findings above on 02/14/2024 at 01:15 pm.