

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0192475	(X3) Date Survey Completed 03/07/2022
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
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, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory competency assessment records and interview with the Laboratory Manager (LM), the laboratory failed to assess the competency assessment of 4 of 5 Clinical Consultants (CC) and 6 of 7 Technical Consultants (TC) for their supervisory responsibilities from 03/07/2020 to 03/07/2022. Findings Include: 1. On the day of survey 03/07/2022 at 10:45 a.m, The LM could not provide competency assessment records for 4 of 5 CC and 6 of 7 TC for their supervisory responsibilities in 2020 and 2021. 2. The LM confirmed the finding above on 03/07/2022 at 01:15 p. m. * Repeated deficiency.</p>
D5477	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on review of quality control (QC) records and interview with the Laboratory Manager (LM), the laboratory failed to check and document each batch or shipment of Streptococcus Selective Agar (SSA) media for its ability to select or inhibit specific organisms from 03/07/2020 to the date of survey. Findings include: 1. On the day of survey, 03/07/2022 at 11:30 a.m, review of the media QC log revealed, the laboratory failed to document on new lots/shipments of SSA agar media for its ability to select or inhibit specific organisms from 03/07/2020 to the day of survey. 2. Reviewed of CMS 116 revealed that the laboratory analyzed 545 throat cultures annually. 3. The LM confirmed the finding above on 03/07/2022 at 01:15 p.m.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of incubators temperature logs and interview with the Laboratory Manager (LD), the laboratory failed to document all corrective actions taken for 2 of 2 incubators acceptable temperature (11 of 11 months reviewed) were exceeded from 03/07/2020 to 03/07/2022. Findings Include: 1. On the day of survey 03/07/2022 at 11:30 a.m. Review of the incubator temperature records revealed that the acceptable temperatures stated by the laboratory were, 35- 37 degree Celsius (C). 2. The follow temperatures were exceeded, and no corrective actions were documented for 2 of 2 incubators: - 18 of 31 days in March, 2021 - Temperature above 37 degrees C . - 14 of 30 days in April, 2021 - Temperature above 37 degrees C. - 21 of 31 days in May, 2021 - Temperature above 37 degrees C. - 23 of 30 days in June, 2021 - Temperature above 37 degrees C. - 15 of 31 days in July, 2021 - Temperature above 37 degrees C. - 21 of 31 days in August, 2021 - Temperature above 37 degrees C. - 16 of 30 days in September, 2021 - Temperature above 37 degrees C. - 23 of 31 days in October, 2021 - Temperature above 37 degrees C. - 20 of 30 days in November, 2021 - Temperature above 37 degrees C. - 20 of 31 days in December, 2021 - Temperature above 37 degrees C. - 24 of 31 days in January, 2022 - Temperature above 37 degrees C. 3. Reviewed of CMS 116 revealed that the laboratory analyzed 545 throat cultures annually. 4. The LM confirmed the findings above on 03/07/2022 around 01:20 p.m.