Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0192475	11/14/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pediatrics Of Northeastern Pa	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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records, review of procedure manuals and interview with testing personnel (TP) #1, the laboratory failed to follow their own laboratory procedure to assess the competency assessment of 10 of 11 TP analyzing throat cultures and failed to establish a complete procedure to assess the competency assessment 4 of 5 clinical consultants and 6 of 7 technical competency in 2018. Findings Include: 1. The laboratory's testing personnel procedure states, "newly hired employees trained upon the start of work, reviewed six months thereafter, yearly reviews monitored with current employees yearly record kept in the logbook. 2. On the day of survey, 11/14/2019, review of personnel records and the competency assessment procedure revealed: - Yearly competency assessment on 8 of 8 TP who analyzed throat cultures in 2018 were not performed. - 6 month competency assessment on 2 of 2 TP (TP#8 and TP#9) hired June of 2018 who analyzed throat cultures were not performed. 3. The laboratory could not provide a complete procedure to assess the competency assessment 4 of 5 clinical consultants and 6 of 7 technical competency in 2018. 4. 1,528 Throat cultures were analyzed in 2018. 5. TP #1 confirmed the findings above on 11/14/2019 around 9:17 am.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of the throat culture procedure manual and interview with testing personnel (TP) #1, the laboratory failed to include media quality control (QC) procedures in the throat culture procedure manual in 2018. Findings Include: 1. On the date of survey, 11/14/2019, review of the throat culture procedure manual revealed, the laboratory did not include media QC procedures in the manual for analyzing throat cultures in 2018. 2. Review of quality control records revealed, the laboratory did not perform QC on each batch of Becton Dickinson Group A Selective Strep Agar with 5% Sheep Blood, for its ability to support growth, select or inhibit specific organisms or produce a biochemical response. 3. 1,528 Throat cultures were analyzed in 2018. 4. The TP confirmed the finding above on 11/14/2019 around 10:25 am.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document 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 laboratory's refrigerator thermometer and interview with the testing personnel (TP) #1, the laboratory failed perform maintenance/ calibration on 1 of 1 fisher scientific traceable thermometer (refrigerator) from 2017 to the date of survey. Findings Include: 1. On the date of survey, 11/14/2019, while on tour of the laboratory, the surveyor observed 1 of 1 fisher scientific traceable thermometer was due for maintenance / calibration on February 12, 2018. 2. The laboratory could not provide documentation of the last calibrations/ maintenance performed on the above thermometer that houses becton dickinson Group A Selective Strep Agar with 5% Sheep Blood. 3. TP #1 confirmed the findings above on 11/14/2019 around 11:00 am.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not

	limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of testing personnel (TP) records, the college of american pathologist (CAP) 2018 proficiency testing (PT) scores and interview with TP #1, the technical consultant failed to assess the competency of 8 of 11 TP through internal blind testing samples or external PT samples in 2018. Findings Include: 1. On the day of survey, 11 /14/2019, review of TP records and CAP PT scores revealed, the laboratory did not assess the test performance of 8 of 11 TP (TP#2,3,4,5, 7, 8, 10, 11) thorough Thoat culture PT samples or internal blind testing samples in 2018. 2. TP#1 confirmed the finding above on 11/14/2019 around 9:45 am.