Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0109932	06/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Pediatricare Associates	20-20 Fairlawn Ave, Fair Lawn, NJ	

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 surveyor review of the Competency Assessment (CA) records and interview with the Nurse Manager (NM), the laboratory failed to perform the CA for Testing Personnel (TP) in 2019 and 2020. The finding includes: 1. Eleven out of eleven TP did not have a CA performed in the calendar year 2019 or 2020. 2. The NM confirmed on 6/10/2021 at 10:00 am that CA was not performed
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM), Bacitracin Disk Quality Control Log (QC) and interview with the Nurse Manager (NM), the laboratory failed to follow the PM for Control Procedures from 11/19/18 to the date of the survey. The findings include: 1. The QC log shows "QZ Organism used Lot # Health line". 2.

	There was no documented evidence showing that lot numbers and expiration dates were recorded. 3. The NM confirmed on 6/10/21 at 10:45 am that the laboratory did not follow the PM.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (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. This STANDARD is not met as evidenced by: Based on the surveyor review of the Quality Control (QC) records and interview with the Nurse Manager (NM), the laboratory failed to check each new lot number and shipment of Throat Culture media for sterility from 11/19/18 to the date of the survey. The NM confirmed on 6/10/21 at 10:30 am the laboratory did not perform the above QC.