

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0109932	(X3) Date Survey Completed 07/19/2023
Name of Provider or Supplier Pediatricare Associates	Street Address, City, State 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
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: Based on surveyor review of Quality Control (QC) records and interview with the Teting Personnel (TP), the laboratory failed to check each batch of Selective Strep Agar (SSA) used for Throat Culture (TC) tests for sterility, its ability to support growth, select or inhibit specific organisms and document the physical characteristics of the media from 6/21/23 to the date of the survey. The findings include: 1. There was no documented evidence the above mentioned QC was performed on SSA lot # 601915. 2. The TC confirmed on 7/19/23 at 11:00 am that the laboratory did not perform QC as stated above.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</p> <p>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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the</p>

type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Personnel Files (PF) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to have appropriate education documentation on all Testing Personnel (TP) performing laboratory testing on the date of survey. The findings include: 1. The laboratory did not have education records for two out of ten TP listed on the CMS form 209. 2. The TP confirmed on 7/19/23 at 10:40 am the above records were not on file.