

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0990036	(X3) Date Survey Completed 06/06/2019
Name of Provider or Supplier All Care Pediatrics, Pa	Street Address, City, State 90 Millburn Avenue, Millburn, 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 the surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check each new lot number and shipment of culture media for sterility, ability to support growth and select or inhibit organisms from 5/15/19 to the date of the survey. The finding Includes: 1) Selective Strep Agar plates Lot # 1907707 was not checked for sterility, ability to support growth and ability to select or inhibit organisms. 2) Approximately 10 patients were runs and reported each day of testing. 3) The TP #1 list on CMS form 209 confirmed on 6/6/2019 the laboratory did not perform the above QC.</p>
D5801	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically</p>

transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on surveyor review of Patient Charts (PC), work records, and interview with the Testing Personnel (TP), the laboratory failed to ensure test results were transcribed for Urine Culture (UC) test from 11/10/18 to the date of survey. The finding includes:

1. One out of five patients test results was not entered in the PC.
2. The TP #1 listed on CMS form 209 confirmed on 6/6/19 at 10:00 am that the laboratory did not transcribe results in the PC.