

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0990036	<b>(X3) Date Survey Completed</b>  12/02/2021
<b>Name of Provider or Supplier</b>  All Care Pediatrics, Pa	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 surveyor review of the Competency Assessment (CA) records and interview with the Office Manager (OM) the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel who perform Bacteriology testing in the calendar year 2020. The findings include: 1. The CA was not performed twelve out of twelve TP in 2020. 2. The TP #8 listed on CMS form 209 confirmed on 12/2/2021 at 1:30 pm that the CA was not performed.</p>
<b>D5477</b>	<p><b>CONTROL PROCEDURES</b> 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 Testing Personnel (TP), the laboratory failed to check each batch of Selective Strep</p>

Agar (SSA) used for Throat Culture (TC) tests for sterility, its ability to support growth and select or inhibit specific organisms from 10/6/21 to the date of the survey. The findings include: 1. Current lots of SSA in use #128026/1746 and 141097 did not have documented evidence QC was performed prior to putting into use. 2. The laboratory performed approximately 448 TC per month. 3. The TP #8 listed on CMS form 209 confirmed on 12/2/21 at 2:00 pm that the laboratory did not perform QC as stated above.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1407(e)(11)

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 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 Test Personnel (TP), the Laboratory Director (LD) failed to have appropriate education documentation for all Testing Personnel (TP) performing laboratory testing from 6/6 /19 to the date of survey. The findings include: 1. The laboratory did not have education records for three out of twelve TP listed on the CMS form 209. 2. The TP #8 on CMS form 209 confirmed on 12/2/21 at 1:40 pm the above records were not on file.