

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1011572	<b>(X3) Date Survey Completed</b>  07/12/2021
<b>Name of Provider or Supplier</b>  Pedia-Care Physicians Llc	<b>Street Address, City, State</b>  290 Norwood, Deal, 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>D2000</b>	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to enroll in an approved PT program for Throat Culture testing from January 2019 to the date of survey. The TP #2 as listed on CMS form 209 confirmed on 7/12/21 at 9:45 am the laboratory was not enrolled in PT testing.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to ensure that an approved PM was available to all testing personnel from 8/22/18 to the date of the survey. The finding includes: 1.</p>

	<p>The laboratory could not provide a PM that was approved and signed by the current laboratory director. 2. The TP #2 as listed on CMS form 209 confirmed on 7/12/21 at 10:15 am that the PM was not approved and signed by the Laboratory Director.</p>
<p><b>D5803</b></p>	<p><b>TEST REPORT</b> CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Patient Charts (PC), Test Reports (TR) and interview with the Testing Personnel (TP), the laboratory failed to have TR in one out of six PC reviewed from August 2018 to the date of the survey. The TP # 2 as listed on CMS form 209 confirmed on 7/12/21 at 11:00 am there was no TR in the PC.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on an office review of the laboratory's performance in Proficiency Testing (PT) surveys, the Laboratory Director (LD) failed to provide appropriate direction to the laboratory personnel to ensure that the PT surveys are performed satisfactorily and compliance with the CLIA regulations are maintained. 1. The LD failed to ensure that the laboratory was enrolled in a PT program. Cross refer to D6015 2. The LD failed to ensure that PT samples were tested for Throat Culture tests. Cross refer to D6016 3. The LD failed to ensure that the established QC program was maintained. Cross Refer to D6020</p>
<p><b>D6015</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)</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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Proficiency Testing (PT) and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the laboratory was enrolled in an approved PT program from January 2019 to the date of the survey. The TP # 2 as listed on CMS form 209 confirmed on 7/12/21 at 9:45 am the laboratory was not enrolled in PT.</p>

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that PT samples were tested for Throat Culture (TC) tests from January 2019 to the date of the survey. The TP #2 listed on CMS form 209 confirmed on 7/12/21 at 9:45 am that the LD did not ensure PT TC samples were tested.

**D6020**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(5)

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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure that the QC program is maintained for laboratory services provided from 8/22/18 to the date of the survey. The findings include: 1. The LD did not review Throat Culture (TC) QC. 2. The TP # 2 as listed on CMS form 209 confirmed on 7/12/21 at 10:00 am the LD did not ensure the QC program is maintained.