

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1011572	(X3) Date Survey Completed 08/22/2018
Name of Provider or Supplier Pedia-Care Physicians Llc	Street Address, City, State 290 Norwood, Deal, 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 lack of the Competency Assessment (CA) records, reviewed via faxed copy in the office and interview with the Testing Personnel (TP), the laboratory failed to perform CA correctly on two out of two TP in 2017. The findings include: 1. The laboratory used Performance Review form to document CA but did not have the following: a. All six tools to be accessed. b. Name of the test. c. What records were reviewed and how TP were accessed. 2. This was confirmed with the TP # 1 via phone on 8/24/18 at 10:00 am.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p>

This STANDARD is not met as evidenced by:
Based on lack of the Procedure Manual on site and interview via phone with the Testing Personnel (TP), the Laboratory Director failed to establish a Competency Assessment (CA) procedure with the required elements from 8/16/16 to the date of the survey. The TP # 1 listed on the CMS form 209 confirmed via on 8/24/18 at 10:00 am that a CA procedure was not established.