

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0111810	(X3) Date Survey Completed 05/16/2023
Name of Provider or Supplier Pediatricare Associates	Street Address, City, State 90 Prospect Ave, Hackensack, 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
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by:</p> <p>a) Based on surveyor review of the Final Report (FR) for SARS-CoV-2, Flu A, Flu B and Respiratory Syncytial Virus (RSV) and interview with the Testing Personnel (TP) the laboratory failed to ensure that the FR included the name and address of the laboratory where testing was performed on the date of survey. The finding includes: 1) Three out of three FR did not have the name and address of the laboratory where testing was performed 2) The TP confirmed on 5/16/23 at 11:00 am that the FR did not have name and address of the laboratory where testing was performed. b) Based on surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to report Covid 19 testing accurately on the date of survey. The finding includes: 1. The laboratory performed COVID 19 non Food and Drug Administration (FDA) cleared tests. 2. A review of three out of three Covid 19 TR revealed that the The FDA COVID EUA statement "This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories." did not appear on the TR when printed. 3. The GS confirmed on 10/6/22 at 3:00 pm that COVID 19 tests were not reported accurately. .</p>

D5807

TEST REPORT

CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:

Based on the surveyor review of the Final Reports (FR), and interview with the Testing Personnel (TP), the laboratory failed to have accurate Reference Interval (RI) for SARS-CoV-2, Flu A, Flu B and Respiratory Syncytial Virus (RSV) Analysis run on the Cepheid GeneXpert Xpress analyzer at the time of survey. The findings include: 1. A review of the FR revealed the FR did not have a RI for the above mentioned analytes. 2. The TP confirmed on 5/16/23 at 10:40 am that laboratory failed to have RI.