

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0673199	(X3) Date Survey Completed 11/14/2023
Name of Provider or Supplier Ch Pc Med-Care Of Fairfield	Street Address, City, State 150 Fairfield Rd, Fairfield, 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: Based on surveyor review of the Test Report (TR) and interview with the Testing Personnel (TP), the laboratory failed to report SARS-CoV-2 IgG tests results accurately from May 2020 to the date of survey. The finding includes: 1. The laboratory performed non Food and Drug Administration (FDA) cleared tests and there was no statement stating "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; use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests. This product has been authorized only for detecting the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 360bbb-3 (b)(1), unless the declaration is terminated authorization is revoked sooner". 2. The TP confirmed on 11/14/23 at 11:45 am that tests SARS-CoV-2 IgG 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 surveyor review of the Test Reports (TR) for Virology and Chemistry tests and interview with the Testing Personnel (TP), the laboratory failed to have a Reference Interval (RI) on TR from 6/1/22 to the date of survey. The findings include:

1. The TR did not have a RI for estimated Glomerular Filtration Rate (eGFR) and Sars-Cov-2. 2. The TP confirmed on 11/14/23 at 12:00 pm the laboratory failed to include a RI for the aforementioned analytes.