

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2016366	(X3) Date Survey Completed 06/06/2023
Name of Provider or Supplier Somerset Pediatric Group Llc	Street Address, City, State 1390 Route 22 West, Lebanon, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Test Report (TR) and interview with the General Supervisor (GS), the laboratory failed to report Covid 19 testing accurately. The findings state: 1. The laboratory performed non Food and Drug Administration (FDA) cleared tests and there was no statement "This test has not been FDA cleared or approved; The test has been authorized by the FDA under an Emergency Use Authorization (EUA)". 2. The GS confirmed on 6/6/23 at 11:00 am that Covid 19 tests were not reported accurately.</p>