

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2053614	(X3) Date Survey Completed 04/26/2021
Name of Provider or Supplier Synergy Medical Laboratories Inc	Street Address, City, State 152 State Route 35, Keyport, 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
D5807	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of the Final Reports (FR) and interview with the General Supervisor (GS), the laboratory failed to have accurate Reference Ranges (RR) for Prothrombin Time (PT), International Normalized Ratio (INR) from 9/18/19 to the date of the survey. The findings include: 1. A review of the FR revealed the RR for PT was 12-15 seconds, but the laboratory did not establish a normal patient mean.. 2. A review of the FR revealed the RR for INR was 2-3 ratio, but the FR has interpretation of normal as 0.9-1.1. 3. The GS confirmed on 4/26/21 at 11:00 am that these tests did not have accurate Reference Ranges on the FR.</p>