

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2108215	(X3) Date Survey Completed 02/25/2020
Name of Provider or Supplier Biotrinetix Llc	Street Address, City, State 1020 Holland Dr Ste 115, Boca Raton, FL	
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
D0000	A recertification survey conducted on 02/25/2020 found Biotrinetix LLC clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on Spectrophotometer manual review and staff interview, the laboratory failed to document room humidity to ensure optimal operation for the Epoch Microplate Spectrophotometer during 2 out of 2 years reviewed. The findings include: A review of Epoch Microplate Spectrophotometer manual revealed a requirement humidity range for optimal operation between 10% and 85 %. A review of temperature logs for 2018 and 2019 revealed that there was no documentation recorded for room humidity. During an interview at 11:00 am on 02/25/20, the laboratory director confirmed that there was no documentation of the room humidity for the period of above reference.</p>