

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0287446	(X3) Date Survey Completed 01/20/2023
Name of Provider or Supplier Mark S Block Dpm	Street Address, City, State 660 Glades Rd Ste 120, 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 01/20/2023 found the MARK S BLOCK DPM clinical laboratory 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 observation, record review and interview, the laboratory failed to follow manufacturer instructions for temperature storage of Dermatophyte Test Medium (DTM) Agar tube from 01/01/2021 to present. Findings include: During the laboratory tour on 01/20/2023 at 10:00 AM, the surveyor found two boxes of Remel DTM Agar with lot number 579797 and three boxes of lot number 583651 stored at room temperature in the facility storage room. -Observation of Remel DTM Agar box label revealed that displayed the sign for storage at "2 - 8 C". -Review of patient log from 01/01/2021 to 01/20/2023 revealed that during 2021 the laboratory tested 165 patients, during 2022 tested 127 patients and in January 2023 tested six patients. During an interview on 01/20/2023 at 10:00 AM, the testing person confirmed that the laboratory failed to store the DTM Agar as per manufacturer instructions for the period of reference.</p>