Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0288106	08/24/2022
Name of Provider or Supplier	**Street Address, City, State**	
Seymour M Bigayer Dpm Pa	9770 Military Trl Ste B-12, Boynton Beach, 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	An announced recertification survey was conducted on 08/24/2022 at Seymour M Bigayer DPM PA, a clinical laboratory in West Palm Beach, Florida. Seymour M Bigayer DPM PA was not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to verify the accuracy of fungal cultures using dermatophyte test medium (DTM) at least twice annually in 2021. The finding included: Review of the "Quality Control Log" showed that the verification of the fungal cultures using dermatophyte test medium (DTM) was performed only once in 2021. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on 8/20/22, the laboratory had an estimated annual test volume of 286. On 8/24/22 at 1:52 p.m., the Laboratory Director confirmed the proficiency testing for the DTM testing was only done once in 2021
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to report the temperature of the refrigerator and the room temperature each day of testing from 6/14/20 to 8/24 /22. The findings included: Review of "Refrigerator Temperature Control Log" showed the refrigerator temperature was recorded only 85 times from 6/14/20 to08/24 /22. Review of the patient test results notebook showed the room temperature was recorded 72 times from 6/14/22 to 8/24/22. Review of the laboratory's procedure titled "Quality Assurance" noted "Refrigerator temperatures will be monitored on a bi-monthly basis" and "Room will be monitored on a bi-weekly basis." On 8/24/22 at 1: 55 p.m., the Laboratory Director stated the temperatures were not recorded daily and that he did not know they needed to record the temperatures of the refrigerator and the room temperature every date the facility was open.