

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0961807	(X3) Date Survey Completed 04/30/2025
Name of Provider or Supplier Manuel J Sone Dpm Pa	Street Address, City, State 9831 Nw 58 St Unit 127, Doral, 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 CLIA recertification survey was conducted at MANUEL J SONE DPM PA on April 30, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D2000 CFR 493.801 Enrollment and Testing of Samples.
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of records and interview with Laboratory Director (LD), the laboratory failed to enroll in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for Mycology since January 2025. Findings included: 1. Review of test menu listed on Form CMS-116 signed by Laboratory Director on 04/30/2025, revealed that the laboratory performed the Fungal Detection Test using the Remel Dermatube Dermatophyte Test (DTM). 2. Review of Patient tests results revealed that the Laboratory tested 116 patients from 01/01/2025 to 04/15/2025. 3. No PT records found for 2025. 4. During an interview on 04/30/2025 at 12:30 PM, the LD confirmed that the facility failed to enroll in PT since January 2025, the LD explained he was not aware of the change of the DTM test to a Regulated test and that he had to enroll the laboratory in PT.</p>