

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D2099470	(X3) Date Survey Completed 04/16/2025
Name of Provider or Supplier Green Clinics Laboratory	Street Address, City, State 1633 Sorghum Mill Road, Dover, DE	
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 was conducted on April 16, 2025, at approximately 10:00 AM. The laboratory was surveyed according to 42 CFR Part 493 Clinical Laboratory Improvement Amendments (CLIA) requirements. Deficiencies were identified as follows:
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 interview and document and policy review, the laboratory did not enroll in a CLIA-approved proficiency testing (PT) program in the areas of Mycology and Bacteriology. This was noted for 2 of 4 areas of molecular tests reviewed. Findings included: A laboratory standard policy and procedures titled, "Verification of Performance Specifications," dated 01/17/2018, revealed the following statement regarding proficiency testing enrollment: "If the test(s) are new to the laboratory test menu and are listed as regulated by CLIA, the laboratory must enroll in an approved proficiency testing program." A "Nail Fungal Validation Report" revealed the laboratory validated a molecular assay for the detection and identification of fungus in nail specimens under the area of Mycology on 10/26/2023. A "UTI [urinary tract infection] Validation Report" revealed the laboratory validated a molecular assay for the detection and identification of organisms in urine specimens causing UTI in the</p>

areas of Bacteriology and Mycology on 12/05/2023. A CMS-116 form and CMS-116 attachments, signed by the Laboratory Director (LD) on 04/16/2025, revealed Nail Fungus and UTI Panels were used for patient testing. During an interview on 04/16/2025 at 2:20 PM, Technical Supervisor #5 confirmed the laboratory was not enrolled in PT for nail fungus testing (Mycology) or UTI panel (Bacteriology) and she could not find an appropriate PT. During an interview on 04/16/2025 at 2:50 PM, the LD confirmed the laboratory was not enrolled in a CLIA-approved PT for the Nail Fungus or UTI Panel assays.