

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2164726	(X3) Date Survey Completed 06/28/2022
Name of Provider or Supplier Mobil Lab For All Inc	Street Address, City, State 1053 Sw 12th St, 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 06/28/2022 found the MOBIL LAB FOR ALL INC clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. Cited the following Conditions: -D2000. Enrollment and Testing of Samples. -D6000. Moderate Complexity Laboratory Director.
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 record review and owner interview, 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 2021 and 2022 for the hematology specialty. Findings include: -Review of laboratory records showed there was no documentation of PT performed. -The laboratory was performing the following hematology tests: white blood cell count (WBC), red blood cell count, hematocrit, hemoglobin, platelet count, and a WBC differential. According to the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the owner on 06/21/2022, the laboratory had an estimated annual test volume of 200. During an interview on 06/28/2022 at 10:30 AM the owner confirmed that the facility failed to enroll in PT for 2021 and 2022 for the analytes of reference.</p>

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and owner interview, the laboratory director failed to effectively oversee the laboratory from 01/01/2021 to 06/28/2022 in proficiency testing. Findings include: -Failed to ensure the laboratory enrollment in a Proficiency Testing (PT) program. Refer to D6015

D6015

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on lack of records and interview, the Laboratory Director failed to ensure that the laboratory enrolled in proficiency testing in 2021 and 2022. Refer to D2000.