

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2262021	(X3) Date Survey Completed 04/28/2023
Name of Provider or Supplier Medlab Diagnostics 2 Llc DbA Fastlabs Llc	Street Address, City, State 6193 Sunset Dr, South Miami, 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 initial survey conducted from 04/19/2023 to 04/28/2023 found the MEDLAB DIAGNOSTICS 2 D/B/A FAST LABS clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was cited - D6063 -Testing Personnel.
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to be in compliance with State requirement that testing personnel (TP) is required to have a Florida License. The laboratory started testing since 01/03/2023 and the laboratory failed to have TP with Florida License since 01/03/2023 to present. Findings included: -Review of FORM CMS-209 signed by the Laboratory Director (LD) on 04/19/2023 revealed the following: Laboratory Director (LD) and Technical Consultant was the same person, one clinical consultant and three TP: TP#A, TP#B and TP#C. -Personnel records review revealed that since the laboratory started testing on 01/03/2023 the three TP failed to have the Florida Department of Health Clinical Laboratory Personnel License. During an interview on 04/20/2021 at 02:45 PM, the laboratory manager revealed that she was unaware of the personnel requirement for Florida and she confirmed that the three TP failed to have the license.</p>
D5447	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--</p>

At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory failed to perform at least two levels of quality control (QC) each day of patient testing on the Complete Blood Cell Counter (CBC) DXH 560 for 13 out of 61 testing days. Findings include: -Review of procedure manual signed by the laboratory director on 01/06/2023 revealed that the Policy Quality Control Program (GEN-018) noted on page 3 in Section Procedure "Controls must be run on days patients samples are run prior to patient samples run." - Review of QC records and patients log, revealed that the following dates of patients testing no QC were run for the DXH 560 analyzer: -01/09/2023: three patients tested -02/14/2023: one patient tested -02/15/2023: one patient tested -02/21/2023: two patients tested -02/24/2023: two patients tested -02/27/2023: one patient tested -03/06/2023: five patients tested -03/07/2023: three patients tested -03/09/2023: two patients tested -03/10/2023: one patient tested -03/11/2023: one patient tested -03/14/2023: two patients tested -03/15/2023: one patient tested. During an interview on 04/20/2023 at 2:30 PM, testing personnel # A confirmed that the laboratory failed to run QC on the days of above reference.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on record review and interview, the laboratory failed to ensure that Testing Personnel (TP) who performed pre-analytic and analytic portions of testing in an Independent Laboratory possess current license issued by the State of Florida to be in compliance with the State law. Refer to D6064.

D6064

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(a)

Each individual performing moderate complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required.

This STANDARD is not met as evidenced by:

Based on record review and interview it was determined that the staff members who performed the testing on the Beckman Coulter Complete Blood Counter (CBC) DX 560 and the Sysmex CA- 600 series Coagulation analyzers does not possess a current license issued by the State of Florida to be in compliance with the State law. Findings included: -Review of DX 560 and Sysmex CA-600 analyzer records revealed that the staff members who performed testing for the Complete Blood Count and for the Prothrombin Time were not licensed in the State of Florida as a Clinical Laboratory Technologist or Clinical Laboratory Technician. Refer to D3009. -Since patient testing began on January 3rd, 2023; 79 patients were tested on the DX 560 CBC and

37 patients were tested on the Sysmex CA-600 Coagulation analyzers. During an interview on 04/20/2023 at 02:30 PM, the laboratory manager confirmed that the staff members that performed the testing were not licensed in the State of Florida as Clinical Laboratory Technologist or Clinical Laboratory Technician.