

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1093166	(X3) Date Survey Completed 09/25/2025
Name of Provider or Supplier Joseph E Mouhanna Md Pa	Street Address, City, State 7575 Sw 62 Ave Suite B, 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 announced CLIA recertification survey was conducted at JOSEPH E MOUHANNA MD PA from 09/18/2025 to 09/25/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
D5433	<p> MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) </p> <p> (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. </p> <p> This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document all maintenance activities for the Immunoanalysis IMMTOX as per the ImmTox Maintenance log from July 2024 to August 2025. Findings included: 1-The laboratory used ImmTox Maintenance Log to document the Daily Start Up (DU), Daily Shutdown (DS), and Weekly and Monthly maintenance. 2-Review of ImmTox Maintenance Log from July 2024 to August 2025, revealed the following: July 2024: 07/01/2024 and 07/02/2024 the laboratory failed to document the DS, no weekly, no monthly. August 2024: The laboratory missed weekly maintenance on 08/12/2025. No monthly maintenance. September 2024: Missed weekly maintenance on 09/04/2024 October 2024: No monthly maintenance documented. On 10/18/2024, The laboratory ran Quality Controls (QC) and 7 patients, the laboratory failed to document the DU, DS. On 10/31/2024 no DS documented November 2024: No DS on 11/01/2024, 11/05/2025, 11/08/2025, 11/11/2025, 11/13/2025 and 11/19/2025. No weekly maintenance, no monthly maintenance. January 2025: Documented on 01/08/2025 and 01/09/2025 DU and DS, no weekly maintenance no monthly. February 2025: No weekly maintenance on 02/27/2025. April 2025: Missed weekly maintenance on 04/01/2025 </p>

and 04/16/2025. May 2025: Missed weekly maintenance on 05/28/2025. June 2025: Missed weekly maintenance on 06/24/2025. July: Missed weekly maintenance on 06/09/2025. August: Missed weekly maintenance on 08/07/2025. 3- During an interview on 09/18/2025 at 12:30 PM, the Testing Personnel confirmed that the laboratory failed to have documentation of the maintenance activities listed above.