

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0685825	<b>(X3) Date Survey Completed</b>  08/14/2025
<b>Name of Provider or Supplier</b>  Julio J Valdes Md Pa	<b>Street Address, City, State</b>  4506 N Armenia Ave, Tampa, FL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Julio J Valdes MD PA on 08/14/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to maintain analytic records verifying the performance of new controls for the Hematology analyzer prior to using the new controls from 08/2023 through 12/2024 for data reviewed 08/2023 through 07/2025. Findings included: 1. The lab policy and procedure manual was reviewed. The manual included a policy, with a revision date of 04/20/2018, signed by the Lab Director, that required validating new controls against controls that were currently in use. 2. New control validation records for the months 08/2023 through 07/2025 were reviewed. No documentation was present for 08/2023 through 12/2024. 3. Testing Personnel #C was interviewed during a tour of the lab beginning at 10:15 a.m. on 08/14/2025. They stated new controls were validated prior to use which occurred approximately every three months. 4. The Lab Director was interviewed on 08/14/2025 at 12:50 p.m. They confirmed the lab failed to maintain the supporting documentation for new control validations from 08/2023 through 12/2024.</p>