

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0685825	<b>(X3) Date Survey Completed</b>  06/21/2023
<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 onsite recertification survey was conducted at Julio J Valdes MD PA on 06/21/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
<b>D3009</b>	<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 report positive and negative Corona Virus Disease (COVID) test results as required by the Florida Department of Health (FDOH) from 01/02/2022 to 06/21/2023. Findings include: The mandatory reporting requirements outlined by FDOH Executive Order 20-013, section 381.0031, Florida Statutes, and Florida Administrative Code Chapter 64D-3, noted laboratories must report both negative and positive COVID-19 test results. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, signed and dated by the Owner of the Laboratory on 06/21/2023, revealed the lab performed waived COVID-19 testing using the QuickVue SARS Antigen Test. Review of the QuickVue SARS Antigen test instructions for use revealed "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." Review of the list of patients that had COVID testing revealed 1,843 patients were tested from 01/02/2022 to 06/21/2023 without reporting results to the FDOH. On 06/21/2023 at 10:55 AM, the Laboratory Director stated he did not know the laboratory was performing COVID testing and confirmed no records for reporting results to FDOH were present.</p>