

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0688834	<b>(X3) Date Survey Completed</b>  10/21/2022
<b>Name of Provider or Supplier</b>  Alvaro J Dangond Md Pa	<b>Street Address, City, State</b>  7001 Sw 97th Ave Ste 201, Miami, 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>	A recertification survey conducted on 10/21/2022 found the ALVARO J DANGOND MD PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to document daily instrument cleaning for 350 out of 363 days for the Medonic M-Series Complete Blood Counter (CBC) analyzer. Findings include: -Review of Medonic M-Series CBC instrument procedure manual in the Maintenance Section stated: "Daily cleaning should be performed according to the Medonic M-Series User's Manual." -Review of the Validation study revealed that the instrument validation completion was 07/22 /20221. -Review of the Medonic M-Series Maintenance Log revealed that the laboratory failed to document the daily cleaning actions in 22 days in August 2021, 23 days in September 2021, 24 days in October 2021, 23 days in November 2021, 24 days in December 2021, 23 days in January 2022, 23 days in February 2022, 26 days in march 2022, 23 days in April 2022, 22 days in May 2022, 25 days in June 2022, 24 days in July 2022, 26 days in August 2022, 24 days in September 2022 and 18 days in October 2022. During an interview on 10/21/2022 at 11:00 AM, TP # A confirmed that the laboratory failed to document all daily cleaning actions for the period of reference.</p>