

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0688834	(X3) Date Survey Completed 12/29/2020
Name of Provider or Supplier Alvaro J Dangond Md Pa	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey conducted on 12/29/2020 found that the Alvaro J Dangond MD PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Condition was cited: -D3000- Facility Administration.
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of Accutest proficiency testing (PT) records and staff interview, the laboratory failed to score at least 80 % on Hematocrit (HCT) for 2 events (1st event 2019 and 3rd event of 2020) out of 6 events for Hematology reviewed. Findings include: Review of Accutest PT records revealed a score of 60 % for HCT for the 1st event 2019 and 40 % for 3rd event of 2020. During an interview on 12/29/2020 at 11: 30 am, the laboratory director confirmed the proficiency testing failure.</p>
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7).</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to follow the Florida</p>

Emergency Rule 64DER20-18 (64D-3.029) to report all COVID 19 tests results immediately to the Florida Department of Health (DOH). See 3009

D3009

FACILITIES
CFR(s): 493.1101(c)

The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

This STANDARD is not met as evidenced by:
Based on record review and staff interview, the laboratory failed to ensure that the testing laboratory reported negative COVID-19 Immunoglobulin G (IgG) and immunoglobulin M (IgM) results to the Florida Health Department from October 2020 to December 2020. Findings Included: No records available for documentation of reports to the Florida Health Department of COVID-19 for negative results for Hangzhou Right Sign COVID-19 IgG /IgM Rapid Test Cassette. The laboratory tested 49 cases in this period Review of FDOH Emergency Rule 64DER20-26 (64D-3.029) of April 10th 2020, revealed for COVID-19; the timeframe is immediately and had special reporting requirements. Results should be reported and accompanied by any testing conducted (positive and negative). For laboratories performing electronic laboratory reporting as described in subsection 64D-3.031 (5). F.A.C., all test results (positive and negative) are to be submitted, including screening test results (positive and negative). During an interview on 12/29/2020 at 11:56 am with the laboratory director, he confirmed that the laboratory does not have records of the notification to the Florida Health Department of negative results for COVID-19 IgG/IgM.