

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0979133	(X3) Date Survey Completed 11/22/2021
Name of Provider or Supplier Florida Healthcare Associates Pl	Street Address, City, State 11195 Jog Rd Ste 3, Boynton Beach, 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 onsite special focused COVID-19 reporting survey was conducted on November 18, 2021 to November 22, 2021 at Florida Healthcare Associates PL, a clinical laboratory in Boynton Beach, Florida. Florida Healthcare Associates PL was not in compliance with Code of Federal Regulations (CFR), Part 493, requirements of clinical laboratories. The following Condition was cited: D3000 - 42 C.F.R. 493.1101: Facility Administration
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). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to report SARS-CoV-2 antibody results to the Department of Health (DOH) from January 26, 2021 through November 22, 2021 for a total of 10,146 Patient results. The findings included: Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS-116) signed by the Laboratory Director on November 17, 2021 revealed that the laboratory performed Anti-SARS-CoV-25 (COVID vaccine spike protein testing) on their Roche Cobas 501 Chemistry analyzer. On 11/22/2021 at 12:56 p.m., per electronic mail (email), Office Manager stated with our results export project manager from Labdaq on Friday as well as to</p>

DOH regarding our interface. In our communication, we discovered a problem with the results export interface where it is not transmitting to the DOH as it should.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on record review and interview with the technical supervisor, the laboratory failed to ensure corrective action was taken and documented for unacceptable samples for American Proficiency Institute (API) proficiency testing for 3 proficiency testing events (second testing event in 2019 for Chemistry Miscellaneous, the second testing event in 2021 for Chemistry Core and the third testing event in 2021 in Chemistry Core) out of 24 Events (2019 Chemistry Core 3rd Event, 2019 Hematology 3rd Event, 2019 Immunology 3rd Event, 2019 Chemistry Miscellaneous 2nd Event, 2020 1st, 2nd, and 3rd Events, 2020 Chemistry Core 1st, 2nd, and 3rd Events, 2020 Hematology 1st, 2nd, and 3rd Events, 2020 Immunology 1st, 2nd, and 3rd Events, 2020 Chemistry Miscellaneous 1st and 2nd Events, 2021 Chemistry Core 1st, 2nd, and 3rd Events, 2021 Hematology 1st, 2nd, and 3rd Events, and 2021 Immunology 1st and 2nd Events). The findings included: A review of the API proficiency testing documentation, revealed that for the second testing event in 2019 for Chemistry, sample IA-07 had an unacceptable result for Ferritin, which gave a score of 67%. The results were reviewed by the Technical Supervisor on 12/05/19 with no corrective action documented. A review of API proficiency testing documentation, revealed that for the second testing event in 2021 for Chemistry, sample CH - 06 had an unacceptable result for Low Density Lipoprotein (LDL), which gave a score of 80% . The results were reviewed by the Technical Supervisor on 08/08/2021 with no corrective actions documented for a clerical error. A review of API proficiency testing documentation , revealed that for the third testing event in 2021 for Chemistry, samples CH - 12 and CH - 15 had unacceptable results for Bilirubin, Total which gave a score of 60%. The results were reviewed by the Technical Supervisor on 10/21/2021 with no corrective action documented. On 11/18/21 at 12:00 PM, the Technical Supervisor stated he performed proficiency testing review but did not document corrective actions.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation, record review, and interview with Testing Personnel #B, the laboratory failed to label the quality control vials currently in use with the expiration date. Findings included: On 11/18/21 at 10:30 a.m. examination of the laboratory's quality controls revealed that the Roche Ammonia/Ethanol/Carbon Dioxide (AMM /ETOH/CO2) Normal Control (Lot# 51558001 - expiration date 2022-01-31) and

Abnormal (Lot #51558101 - expiration date 2022 - 01-31) and the Roche Rheumatoid Factor (RF) Level I (Lot #56941701 - expiration date 2022- 07 - 31) and Level II (Lot#56941701 - expiration date 2022 -07-31) for the Roche Cobas 501 instrument did not have the opened expiration date for the vials currently being used. Review of the Cobas product information sheets for the AMM/ETOH/CO2 Control revealed the following stability requirements for opened controls: "After opening: 8 weeks at 2-8 degrees Celsius provided that dispensing of the control occurs without microbial contamination, e.g. by pouring out", and the RF Control revealed the storage requirement: "After opening 24 hours at 15 - 25 degrees Celsius or 30 days at 2-8 degrees Celsius, provided that dispensing of the control occurs without microbial contamination, e.g., by pouring out." On 11/18/21 at 10:30 a.m., Testing Personnel #B stated that Testing Personnel #C did not label the control vials with the opened expiration dates but that the laboratory would use all of the control vial contents before the opened expiration dates.