

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0280554	(X3) Date Survey Completed 09/24/2019
Name of Provider or Supplier Finlay Clinical Laboratory Inc	Street Address, City, State 330 Sw 27th Ave Ste 101, 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, 9/23-24/2019 found that Finlay Clinical Laboratory Inc., clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2075	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(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 record review of College of American Pathologists (CAP) proficiency testing records and interview with Technical Supervisor (TS), the laboratory failed to score at least 80 % on Immunoglobulin M (IgM) for one (3rd event of 2017) out of six (2017 3rd; 2018 1st, 2nd and 3rd; 2019 1st and 2nd) events for General Immunology specialty reviewed. Findings include: Review of CAP proficiency records revealed a score of 20 % for IgM in the 3rd event of 2017. During an interview on 09/23/2019 at 3:30 PM, the TS confirmed the failed proficiency testing score.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 record review of College of American Pathologists (CAP) proficiency testing records and interview with Technical Supervisor (TS), the laboratory failed to score at least 80 % on Calcium (Ca) and Creatine Kinase Isoenzymes (CK-Iso) for 1</p>

(2nd event of 2019) out of 6 (2017 3rd; 2018 1st, 2nd and 3rd; 2019 1st and 2nd) events for Routine Chemistry specialty reviewed. Findings include: Review of CAP proficiency records revealed a score of 40 % for Ca and 60 % for CK-Iso in the 2nd event of 2019. During an interview on 09/23/2019 at 3:30 PM, the TS confirmed the failed proficiency testing score.

D2098

ENDOCRINOLOGY
CFR(s): 493.843(a)

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.

This STANDARD is not met as evidenced by:

Based on record review of College of American Pathologists (CAP) proficiency testing records and interview with Technical Supervisor (TS), the laboratory failed to score at least 80 % on Thyroxine (Ty) for 1 (2nd event of 2019) out of 6 (2017 3rd; 2018 1st, 2nd and 3rd; 2019 1st and 2nd) events reviewed for Endocrinology specialty. Findings include: Review of CAP proficiency records revealed a score of 60 % for Ty in the 2nd event of 2019. During an interview on 09/23/2019 at 3:30 PM, the TS confirmed the failed proficiency testing score.