

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2003637	(X3) Date Survey Completed 03/04/2020
Name of Provider or Supplier Laboratorio Clinico Ocean Front	Street Address, City, State Road Pr 686 Km 9 Hm 5 Bo Yeguada, Vega Baja, PR	
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
D2071	<p>SYPHILIS SEROLOGY CFR(s): 493.835(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records review (2018-2019) and laboratory director interview on March 4, 2020 at 9:20 A.M., it was determined that the laboratory failed to report the syphilis serology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2018 to January 2019. 2. The deadline of the third testing event report of syphilis serology tests was December 21, 2018. 3. The laboratory did not report the third testing event of syphilis serology within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event 4. The laboratory director confirmed on March 4, 2020 at 9:20 A.M. that the laboratory did not report the syphilis serology proficiency testing results of the third testing event within the time frame established by the Proficiency Testing Program.</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p>

This STANDARD is not met as evidenced by:
Based on American Association of Bioanalyst (AAB) Proficiency Testing Program records review (2018-2019) and laboratory director interview on March 4, 2020 at 9: 20 A.M., it was determined that the laboratory failed to report the hematology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2018 to January 2019. 2. The deadline of the third testing event report of hematology tests was September 23, 2019. 3. The laboratory did not report the third testing event of hematology within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event 4. The laboratory director confirmed on March 4, 2020 at 9:20 A.M. that the laboratory did not report the hematology proficiency testing results of the third testing event within the time frame established by the Proficiency Testing Program.

D6017

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(ii)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:
Based on observation , AAB and Puerto Rico Proficiency Testing Program records review (year 2018-2019) and laboratory director interview on March 4, 2020 at 10:00 A.M., it was determined that the laboratory failed to ensure that report proficiency testing test results are returned within the time frame established by the proficiency testing program. The findings include: 1. Proficiency testing records were reviewed since February 2018. 2. The deadline of the PRPTP (December 2018 - third testing event) report of Syphilis Serology tests was December 21, 2018. 3. The deadline of the AAB Proficiency Testing (third testing event) report of hematology tests was September 23, 2019. 4. The laboratory did not report the third testing event of Syphilis Serology and hematology within the time frame established by the PR Proficiency Testing Program and AAB Proficiency Testing Program. 5. The laboratory director confirmed on March 4, 2020 at 10:00 A.M., that the laboratory failed to report the proficiency testing results within the time frame established by the PR Proficiency Testing Program and AAB Proficiency Testing Program.