

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1023907	(X3) Date Survey Completed 04/02/2019
Name of Provider or Supplier Laboratorio Clinico D Maes	Street Address, City, State 306 Carr Pr-123, Ponce, 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
D2067	<p>SYPHILIS SEROLOGY CFR(s): 493.835(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (years 2017-2019) and laboratory director interview on April 2, 2019 at 10: 00 A.M., it was determined that the laboratory failed to participate in the syphilis serology second testing event performed in August 2018. The findings include: 1. Proficiency testing records were reviewed from March 2017 to March 2019. 2. The laboratory did not participate in the second testing event of syphilis serology performed in August 2018. 3. The laboratory director confirmed on April 2, 2019 at 10:00 A.M., that the laboratory failed to participate in the second testing event of syphilis serology specialty in August 2018.</p>
D2077	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended</p>

during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program records reviewed (years 2017-2019) and laboratory director interview on April 2, 2019 at 10: 00 A.M., it was determined that the laboratory failed to participate in the general immunology (Rheumatoid Arthritis and Monotest) second testing event performed in August 2018. The findings include: 1. Proficiency testing records were reviewed from March 2017 to March 2019. 2. The laboratory did not participate in the second testing event of general immunology (RA and Monotest) performed in August 2018. 3. The laboratory director confirmed on April 2, 2019 at 10:00 A.M., that the laboratory failed to participate in the second testing event of general immunology specialty in August 2018.

D2100

ENDOCRINOLOGY
CFR(s): 493.843(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program records reviewed (years 2017-2019) and laboratory director interview on April 2, 2019 at 10: 00 A.M., it was determined that the laboratory failed to participate in the endocrinology (Human Chorionic gonadotropin qualitative) third testing event performed in October 2018. The findings include: 1. Proficiency testing records were reviewed from March 2017 to March 2019. 2. The laboratory did not participate in the third testing event of endocrinology (hCG qualitative) performed in October 2018. 3. The laboratory director confirmed on April 2, 2019 at 10:00 A.M., that the laboratory failed to participate in the third testing event of endrocrinology specialty in October 2018.

D6116

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(3)

The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program records reviewed (years 2017-2019) and laboratory director interview on April 2, 2019 at 10: 00 A.M., it was determined that the technical supervisor did not make sure to participate in all proficiency program testing events of year 2018. The finding includes: 1. The laboratory processed and reported patients specimens for syphilis serology (Rapid plasma reagin), general immunology (RA and Monotest) and endocrinology (hCG qualitative) during year 2018. 2. Review of proficiency testing results showed that the laboratory did not participated in the second testing event of year 2018 for syphilis serology, Monotest and Rheumatoid factor, not third testing event for serum qualitative hCG tests. 3. The laboratory director stated on April 2, 2019 at 10:00 AM that although the laboratory performed patients samples testing, they did not participate in the second proficiency testing event and third proficiency testing event of year 2018.