

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0898403	<b>(X3) Date Survey Completed</b>  08/08/2018
<b>Name of Provider or Supplier</b>  Lab Clin Asociacion Maestros De Pr	<b>Street Address, City, State</b>  Calle Ramos Antonini 158 Este, Mayaguez, PR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on lack of Puerto Rico Proficiency testing records review ( 2017) and interview with the laboratory general supervisor on August 8, 2018 at 11:00 A.M., it was determined that the laboratory failed to enroll in an approved proficiency program for cell identification, sed rate, hCG, urinalysis, urine sediment and syphilis serology in year 2017. The findings includes: 1. The proficiency testing records ( 2017 ) showed that the laboratory failed to enroll and participate in proficiency testing samples for cell identification, sed rate, hCG, urinalysis, urine sediment and syphilis serology in year 2017 ( June, July , August and December ). 2. The laboratory general supervisor confirmed on August 8, 2018, that the laboratory failed to enroll and participate in proficiency testing samples for cell identification, sed rate, hCG, urinalysis, urine sediment and syphilis serology in year 2017 ( June, July , August and December ).</p>
<b>D2067</b>	<p><b>SYPHILIS SEROLOGY</b> 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</p>

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 ( 2017-2018) and laboratory general supervisor interview on August 8, 2018 at 11:00 A.M., it was determined that the laboratory failed to participate in the syphilis serology second and third testing event performed in August and December 2017. The findings include: 1. Proficiency testing records were reviewed from February 2017 to July 2018. 2. The laboratory did not participate in the second and third testing event of syphilis serology performed in August and December 2017. 3. The laboratory general supervisor confirmed on August 8, 2018 at 11: 00 A.M., that the laboratory failed to participate in the second and third testing event of syphilis serology performed in August and December 2017. 4. This deficiency was cited on the last survey performed on June 1, 2016.

**D2089**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(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 ( 2017-2018) and laboratory general supervisor interview on August 8, 2018 at 11:00 A.M., it was determined that the laboratory failed to participate in the routine chemistry second testing event performed in June 2017. The findings include: 1. Proficiency testing records were reviewed from February 2017 to July 2018. 2. The laboratory did not participate in the second testing event of routine chemistry ( urinalysis and urine sediment) performed in June 2017. 3. The laboratory general supervisor confirmed on August 8, 2018 at 11: 00 A.M., that the laboratory failed to participate in the second testing event of routine chemistry ( urinalysis and urine sediment) performed in June 2017.

**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 ( 2017-2018) and laboratory general supervisor interview on August 8, 2018 at 11:00 A.M., it was determined that the laboratory failed to participate in the endocrinology ( human chorionic hormone) second testing event performed in June 2017. The findings include: 1. Proficiency testing records were reviewed from February 2017 to July 2018. 2. The laboratory did not participate in the second testing event of endocrinology ( human chorionic hormone) performed in June 2017. 3. The laboratory general supervisor confirmed on August 8, 2018 at 11: 00 A.M., that the laboratory failed to participate in the second testing event of endocrinology sub-specialty in June 2017. 4. This deficiency was cited on the last survey performed on June 1, 2016.

**D2123**

**HEMATOLOGY**

CFR(s): 493.851(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:

1. Based on Puerto Rico Proficiency Testing Program records reviewed ( 2017-2018) and laboratory general supervisor interview on August 8, 2018 at 11:00 A.M., it was determined that the laboratory failed to participate in the hematology second testing event performed in July 2017. The findings include: a. Proficiency testing records were reviewed from February 2017 to July 2018. b. The laboratory did not participate in the second testing event of hematology ( cell identification and sed rate) performed in July 2017. c. The laboratory general supervisor confirmed on August 8, 2018 at 11: 00 A.M., that the laboratory failed to participate in the second testing event of hematology in July 2017. 2. Based on Medical Laboratory Evaluation ( MLE) Proficiency Testing Program records reviewed ( 2017-2018) and laboratory general supervisor interview on August 8, 2018 at 11:00 A.M., it was determined that the laboratory failed to participate in the hematology first testing event performed in March 2017. The findings include: a. Proficiency testing records were reviewed from February 2017 to July 2018. b. The laboratory did not participate in the second testing event of hematology (complete blood count) performed in March 2017. c. The laboratory general supervisor confirmed on August 8, 2018 at 11: 00 A.M., that the

	<p>laboratory failed to participate in the second testing event of hematology in March 2017.</p>
<b>D6076</b>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on Puerto Rico Proficiency testing records review ( 2017-2018 ) and laboratory general supervisor interview on August 8, 2017 at 11:00 AM. , it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the proficiency testing requirements. Refer to D 6089.</p>
<b>D6089</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency testing records review ( 2017-2018 ) and laboratory general supervisor interview on August 8, 2018 at 11:00 A.M., it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2067, D2089, D2100 and D2123.</p>
<b>D6144</b>	<p><b>GENERAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1463</p> <p>The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico proficiency testing records review ( 2017-2018 ) and laboratory general supervisor interview on August 8, 2018 at 11:00 A.M., it was determined that the general supervisor failed to ensure that the proficiency testing were tested as required under Subpart H requirements. Refer to D2067, D2089, D2100 and D2123.</p>