

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D2116085	<b>(X3) Date Survey Completed</b>  12/18/2018
<b>Name of Provider or Supplier</b>  Laboratorio Clinico Perla Del Plata	<b>Street Address, City, State</b>  Carr Num 156, Km 35 Hm 4, Barrio Dona Elena, Comerio, 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>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 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 ( 2017-2018) laboratory director, and laboratory general supervisor interview on December 18, 2018 at 9: 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 February 2017 to October 2018. 2. The laboratory did not participate in the second testing event of syphilis serology performed in August 2018 established by the Proficiency Testing Program. 3. The laboratory general supervisor confirmed on August 18, 2018 at 9:00 A.M., that the laboratory failed to participate in the second testing event of syphilis serology specialty in August 2018.</p>
<b>D5291</b>	<p><b>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:

Based on quality assessment records review (2017-2018) and laboratory director interview on December 18, 2018 at 10:10 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for general laboratory systems: confidentiality of patient information. The findings include: 1. Review of the quality assessment records showed that the evaluations to confidentiality of patient information must be performed each six months. 2. Review of the quality assessment records showed that the last evaluations to confidentiality of patient information was performed in June 2017. 3. The laboratory director confirmed on December 18, 2018 at 10:10 A.M. that the evaluations to confidentiality of patient information were not performed since June 2017.

**D5391**

**PREANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1249(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) records review (2017-2018) laboratory director and general supervisor interview on December 18, 2018 at 9:45 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for pre-analytic systems (test request). The findings include: 1. Review of the laboratory quality assessment records showed that the laboratory establishes a quarterly assessment for each pre-analytic process to keep track the laboratory performance. 2. Since June 2017, the quality assessment (QA) records showed that the laboratory did not perform the quarterly evaluation of the pre-analytic systems. 3. The laboratory confirmed on December 18, 2018 at 9:45 A.M., that failed to follow written polices for the pre analytic systems (test request).

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) records review, laboratory director and laboratory general supervisor interview on December 18, 2018 at 10:00 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1.

	<p>Review of the laboratory quality assessment records showed that the laboratory establishes a monthly assessment for each analytic process to keep track the laboratory performance. 2. Since June 2017, the quality assessment (QA) records showed that the laboratory did not perform the monthly evaluation of the analytic system. 3. The laboratory director confirmed on December 18, 2018 at 10:00 A.M., that the laboratory failed to perform the monthly evaluation of the analytic system.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment records review (2017-218) and laboratory director interview on December 18, 2018 at 10:30 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for post-analytic systems ( test results ). The findings include: 1. Review of the quality assessment records showed that evaluations to patient's final test reports must be evaluated each three months. 2. Review of the quality assessment records showed that the last evaluations to patient's final test reports was performed in June 2017. 3. The laboratory director confirmed on December 18, 2018 at 10:00 A. M., that evaluations to patient's final test reports and turn around time were not performed since June 2017.</p>
<p><b>D6089</b></p>	<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 Program testing records review ( 2017 to 2018 ) and laboratory director interview on December 18, 2018 at 11:00 AM, 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.</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review and laboratory director interview on December 18, 2018 at 10:30 A.M, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records showed that the laboratory did not evaluate the</p>

established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. 2. The laboratory director confirmed on December 18, 2018 at 10:30 A.M., that failed to evaluate the requirements for laboratory general systems, preanalytic, analytic and postanalytic systems. Refer to D5291 , D5391, D5791 and D5891.