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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br>40D0861654     | <b>(X3) Date Survey Completed</b><br>10/29/2020 |
| <b>Name of Provider or Supplier</b><br>Laboratorio Clinico Pajuil  | <b>Street Address, City, State</b><br>Carretera 490 Km 4 Hm 5, Hatillo, 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>  |
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| <b>D2067</b>              | <p><b>SYPHILIS SEROLOGY</b><br/>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:<br/>Based on Puerto Rico Proficiency Testing Program records review ( 2019-2020) and laboratory general supervisor interview on October 29, 2020 at 9:10 A.M., it was determined that the laboratory failed to participate in the syphilis serology second testing event performed in December 2019. The findings include: 1. Puerto Rico Proficiency Testing Program records were review from year 2019 to 2020. 2. The records showed that the laboratory did not participate in the third testing event of syphilis serology ( December 2019) established by the Proficiency Testing Program. 3. The laboratory general supervisor confirmed on October 29, 2020 at 9:45 A.M., that the laboratory failed to participate in the third testing event of syphilis serology sub-specialty in November 2019.</p> |
| <b>D2123</b>              | <p><b>HEMATOLOGY</b><br/>CFR(s): 493.851(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</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 review ( 2019-2020) and laboratory general supervisor interview on October 29, 2020 at 9:10 A.M., it was determined that the laboratory failed to participate in the Hematology third testing event performed in November 2019. The findings include: 1. Puerto Rico Proficiency Testing Program records were review from year 2019 to 2020. 2. The records showed that the laboratory did not participate in the third testing event of hematology ( November 2019) established by the Proficiency Testing Program. 3. The laboratory general supervisor confirmed on October 29, 2020 at 9:45 A.M., that the laboratory failed to participate in the third testing event of hematology specialty in November 2019.

**D6089**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:  
Based on Puerto Rico Proficiency testing records review (2019-2020) and laboratory general supervisor interview on October 29, 2020 at 9:45A.M. it was determined that the laboratory failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. The findings include: 1. The laboratory failed to participate in the Hematology third testing event performed in November 2019. Refer to D2123. 2. The laboratory failed to participate in the Syphilis Serology third testing event performed in December 2019. Refer to D2067.