| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D1046214 | 01/26/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Olympic Plaza | Extension Centro Comercial, Caribbean Shopping, Las Piedras, 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 |
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| **D5451** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(iii)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on syphilis serology testing records(years 2020 and 2021) review and laboratory director interview on January 26, 2022 at 10:15 AM, it was determined that the laboratory failed to include at least once a day, a control material with tittered reactivity besides the non reactive control material when 20 out of 20 patients specimens were processed for syphilis serology quantitative tests by the rapid plasma reagin (RPR) method from January 25, 2021 to September 28, 2021. The findings include: 1. The laboratory processed and reported qualitative and quantitative syphilis serology test by the RPR method. 2. On January 26, 2022 at 10:15 AM, the syphilis serology testing records showed that the laboratory did not include at least once a day, the control material with tittered reactivity besides the non reactive control material when 20 out of 20 patients specimens were processed for syphilis serology quantitative test by the RPR method from January 25, 2021 to September 28, 2021. The laboratory include the following controls: non reactive, the weekly reactive and the reactive control 3. The laboratory director confirmed on January 26, 2022 at 10:15 AM, that the laboratory did not include each day of testing the control material with tittered reactivity when patients specimens were processed for syphilis serology quantitative test. She stated that the laboratory include the following controls without tittered: non reactive, the weekly reactive and the reactive. 4. The laboratory |

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| | processed and reported 20 out of 20 patients specimens for syphilis serology quantitative tests the RPR method from January 25, 2021 to September 28, 2021. |
| **D6020** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on syphilis serology testing records(years 2020 and 2021) review and laboratory director interview on January 26, 2022 at 10:15 AM, it was determined that the laboratory director failed to establish the quality control procedures for the syphilis serology quantitative tests by the RPR method. Refer to D 5451 ( The laboratory did not include each day of testing a control material with tittered reactivity besides the non reactive control material when 20 out of 20 patients specimens were processed for syphilis serology quantitative tests from January 25, 2021 to September 28, 2021). |