| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D0658306 | 01/20/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Flores | Calle Marginal 12 Ave 65 Infanteria, San Juan, 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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| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(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-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on General Immunology (COVID-19 IgM/IgG) quality control records, manufacturer instructions for use (IFU) review and interview the laboratory director on January 20, 2022 at 8:36 AM, it was determined that the laboratory did not include an external positive and negative control materials each day of testing when nine out of nine patient's specimens were tested for COVID-19 rapid test from October 1, 2021 to October 15, 2021. The findings include: 1. The laboratory use the Healgen COVID-19 IgG/IgM Rapid Test Cassette to perform rapid immunology IgM/IgG patient test. 2. The quality control section of the IFU stated that: additional controls may be required according to guidelines or local, state and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations. 3. Review of COVID-19 IgM/IgG quality control records showed that the laboratory performs patient testing from October 1, 2021 to October 15, 2021, the laboratory did not include every day of testing the positive and the negative control materials. Instead the laboratory run the external controls when a new reagent kit lot or shipment were received. 4. From October 1, 2021 to October 15, 2021 the laboratory processed and reported 9 patient samples. 5. The laboratory director confirmed on January 20, 2022 at 8:36 AM, , that the laboratory failed to include a negative and positive external control materials each day of testing. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES |

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| | CFR(s): 493.1445(e)(5)<br><br>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.<br><br>This STANDARD is not met as evidenced by:<br>Based on General Immunology (COVID-19 IgM/IgG) quality control records, manufacturer instructions for use (IFU) review and interview the laboratory director on January 20, 2022 at 8:36 AM, it was determined that the laboratory director failed to establish the quality control procedures for the COVID-19 IgM/IgG test. Refer to D 5449 (The laboratory did not include each day of testing an external positive and negative control material when nine out of nine patient's specimens were tested for COVID-19 rapid test from October 1, 2021 to October 15, 2021). |