| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D0672860 | 11/06/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Villa Ana Gurabo | Calle Santiago # 55 Norte, Gurabo, 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 |
|---|---|
| **D5445** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of Individualized Quality Control Pan (IQCP) in General Immunology and interview with the laboratory manager at 12:05 PM on November 6, 2019, the laboratory failed to develop complete IQCP for the Mycoplasma IgM Test by the Immuno Card Mycoplasma method since January, 2019. The findings included: 1. The IQCP for the Mycoplasma IgM Test Immuno Card Mycoplasma method did not include the Quality Control Plan (QCP) section with the approval signature of the laboratory director. 2. At 12:05 PM on November 6, 2019, the laboratory manager confirmed that the IQCP for the Mycoplasma IgM Test Immuno Card Mycoplasma method did not include the QCP section. 3. The laboratory processed and reported 107 patients specimens for the Mycoplasma IgM Test from January 1, 2019 to November 5, 2019. |
| **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 review of Individualized Quality Control Pan (IQCP) in General Immunology and interview with the laboratory manager at 12:05 PM on November 6, 2019, the laboratory director failed to develop complete IQCP for the Mycoplasma IgM Test by the Immuno Card Mycoplasma method since January, 2019. Refer to D 5445. |
| **D6029** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(11)<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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of testing personnel records and interview with the laboratory manager\owner at 11:00 AM on November 6, 2019. it was determined that the laboratory director did not assure that the new testing personnel for the Saturday shift was trained before perform patient testing. The findings include: 1. The testing personnel records of the new testing personnel (the Saturday shift ) did not include any training given before patient testing. 2. At 11:00 AM on November 6, 2019, the laboratory manager\owner stated that the new testing personnel works on Saturday a month ago and the training was given but is not available in the laboratory. |