| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 40D2059841 | 05/29/2024 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Laboratorio Clinico Garnier Guaynabo | Carr Pr-834, Km 2 Hm 8 Bo Hato Nuevo, Guaynabo, 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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| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Mycoplasma pneumoniae IgM test performance verification and laboratory supervisor interview on May 29, 2024 at 12:45 P.M., it was determined that the laboratory failed to evaluate the performance verification of the Mycoplasma pneumoniae IgM test. The laboratory processed and reported 144 patient samples from January 1, 2023 to May 29, 2024. The findings include: 1. On May 29, 2024 at 12:45 P.M., the Mycoplasma pneumoniae IgM test performance verification was requested, and the laboratory supervisor stated that the laboratory did not evaluate the performance verification of the system prior to begin to test patient samples. 2. The laboratory supervisor stated on May 29, 2024 at 12:49 P.M., that the laboratory acquired the Mycoplasma pneumoniae IgM test system since January 1, 2023. 3. The laboratory supervisor confirmed on May 29, 2024 at 12:53 P.M., that the laboratory did not have the performance verification of the Mycoplasma pneumoniae IgM test. 4. The laboratory processed and reported 144 Mycoplasma pneumoniae IgM patient samples from January 1, 2023 to May 29, 2024. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g) |

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| | 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 Mycoplasma pneumoniae IgM test quality control and patient test worksheet records review and laboratory supervisor interview on May 29, 2024 at 12:16 P.M., it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae IgM patient testing, neither documented the internal control with each external control. The laboratory processed and reported a total of 144 Mycoplasma pneumoniae IgM test patients. The findings include: 1. The laboratory used the GenBio ImmunoWELL Mycoplasma pneumoniae IgM kit to perform patient Mycoplasma pneumoniae IgM tests. 2. Review of Mycoplasma pneumoniae IgM quality control and patient test worksheet records on May 29, 2024 at 12:16 P.M., showed that the laboratory did not include an external positive and negative control material each day of patient testing, neither documented the internal control with each external control.from January 1, 2023 to May 29, 2024, when the laboratory processed and reported a total of 144 patients. 3. The laboratory supervisor confirmed on May 29, 2024 at 12:21 P.M., that the laboratory failed to include a negative and positive control material each day of patient testing, and failed to document the internal control results with each external control. |
| **D6086** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(ii)<br><br>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.<br><br>This STANDARD is not met as evidenced by:<br>Based on lack of Mycoplasma pneumoniae IgM test performance verification and laboratory supervisor interview on May 29, 2024 at 12:45 P.M., it was determined that the laboratory director failed to fulfill her responsibility to perform, evaluate and sign the performance verification of the new Mycoplasma pneumoniae IgM test. Refer to D5421. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>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 Mycoplasma pneumoniae IgM test quality control and patient test worksheet records review and laboratory supervisor interview on May 29, 2024 at 12:16 P.M., it was determined that the laboratory director did not make sure to include a positive and |

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| | a negative control material each day of patient testing for Mycoplasma pneumonia tests, neither documented the internal control of each external control. Refer to D5449. |