

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2059841	(X3) Date Survey Completed 05/28/2026
Name of Provider or Supplier Laboratorio Clinico Garnier Guaynabo	Street Address, City, State 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
D0000	The Centers for Medicare & Medicaid Services (CMS) conducted an unannounced CLIA recertification survey at Laboratorio Clinico Garnier Guaynabo on May 28, 2026. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the recertification CLIA survey ending on May 28, 2026.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on hematology calibration verification records review (years 2024 - 2026), and laboratory director interview on May 28, 2026 at 10:44 AM, the laboratory did not</p>

perform, at least every 6 months, the calibration verification procedures for the hematology tests processed by the Sysmex KX-21N Analyzer, when the laboratory processed and reported 4,154 out of 4,154 Complete Blood Count (CBC) hematology tests from March 2, 2024 to May 28, 2026. The findings include: 1. The laboratory used the Sysmex KX-21N Analyzer to perform hematology Complete Blood Count (CBC) tests. 2. On May 28, 2026 at 10:39 AM, review of the hematology calibration verification records (years 2024 - 2026), showed that the laboratory did not perform the calibration verification procedure since March 2, 2024. 3. The laboratory director confirmed on May 28, 2026 at 10:44 AM, that the calibration verification was not performed every six months, since March 2, 2024 to May 28, 2026, when the laboratory processed and reported processed and reported 4,154 out of 4,154 CBC hematology tests from March 2, 2024 to May 28, 2026.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:
Based on lack of Quality Assessment (QA) activities records (years 2025-2026) and interview with the laboratory director on May 28, 2026 at 11:50 AM, the laboratory failed to evaluate and monitor the analytic laboratory systems related to: test procedures, test systems, equipment, instruments, reagents, materials, supplies for accuracy and reliability, specimen and reagent storage conditions, instrument and test system maintenance and function checks, establishment and verification of method performance specifications, calibration and calibration verification, control procedures, comparison of test results, corrective actions and test records, since January 2025. The findings include: 1. On May 28, 2026 at 11:45 AM, the laboratory analytic system QA 2025-2026 records were requested. The analytic system QA was not available for evaluation. 2. The laboratory director confirmed on May 28, 2026 at 11:50 AM, that the laboratory QA analytic system activities records were not available in the laboratory, and that the laboratory failed to monitor the analytic laboratory systems related to: test procedures, test systems, equipment, instruments, reagents, materials, supplies for accuracy and reliability, specimen and reagent storage conditions, instrument and test system maintenance and function checks, establishment and verification of method performance specifications, calibration and calibration verification, control procedures, comparison of test results, corrective actions and test records, since January 2025.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on lack of Quality Assessment (QA) activities records (years 2025-2026) and interview with the laboratory director on May 28, 2026 at 12:16 PM, the laboratory

	<p>failed to evaluate and monitor the post-analytic laboratory systems related to: patient test reports and turn around time, since January 2025. The findings include: 1. On May 28, 2026 at 12:10 PM, the laboratory post-analytic system QA 2025-2026 records were requested. The post-analytic system QA was not available for evaluation. 2. The laboratory director confirmed on May 28, 2026 at 12:16 PM, that the laboratory QA post-analytic system activities records were not available in the laboratory, and that the laboratory failed to monitor the post-analytic laboratory systems related to: patient test reports and turn around time, since January 2025.</p>
<p>D6013</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii)</p> <p>(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and</p> <p>This STANDARD is not met as evidenced by: Based on hematology calibration verification records review (years 2024 - 2026), and laboratory director interview on May 28, 2026, at 10:44 AM, the laboratory director failed to ensure that the calibration procedures were performed at least every 6 months, for the hematology Complete Blood Count (CBC) tests. The laboratory processed and reported 4,154 out of 4,154 CBC patient samples from March 2, 2024 to May 28, 2026. Refer to D5439.</p>
<p>D6020</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</p> <p>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review (years 2025-2026), and laboratory director interview on May 28, 2026 at 12:16 PM, the laboratory director failed to ensure compliance with the quality assessment program. Refer to D5791, and D5891.</p>
<p>D6072</p>	<p>TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3)</p> <p>(b)(3) Adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed;</p> <p>This STANDARD is not met as evidenced by: Based on hematology calibration verification records review (years 2024 - 2026), and laboratory director interview on May 28, 2026, at 10:44 AM, the laboratory testing personnel failed to perform the calibration verification, at least every 6 months, for the hematology Complete Blood Count (CBC) tests. The laboratory processed and reported 4,154 out of 4,154 CBC patient samples from March 2, 2024 to May 28, 2026. Refer to D5439.</p>