

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658059	(X3) Date Survey Completed 05/13/2025
Name of Provider or Supplier Lab Clinico Hospital General Castaner	Street Address, City, State Road #135 Rm 642, Castaner, 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 Hospital General Castaner, Inc on May 13, 2025. 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 13, 2025.
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on review of routine chemistry performance specifications records (September 2024) and laboratory director interview on May 13, 2025 at 11:15 A.M., it was determined that the laboratory failed to complete the evaluation of the performance specifications of the new routine chemistry and special tests system. The findings include: 1. The laboratory acquired on September 2024 a new system to perform routine chemistry and special tests. (Atellica CI 1900) 2. The performance specifications records showed that the laboratory did not verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 3. The laboratory director confirmed on May 13, 2025 at 11:15 A.M. , that the laboratory did not verify if the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population prior to begin testing patient's samples. 4. The laboratory processed and reported approximately 74,649 routine</p>

chemistry tests and 5,152 special tests performed by Atellica CI 1900 since September 2024.

D5429

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(a)(1)

(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on manufacturer's specifications, ABL 80 Flex routine procedures log review (years 2025) and laboratory director interview on May 13, 2025, at 11:57 A.M., it was determined that the laboratory failed to perform and document the preventive maintenance as required by manufacturer of the ABL 80 Flex blood gas analyzer, when processed and reported 35 out of 35 arterial blood gas from January 1, 2025 to May 13, 2025. The findings include: 1. The laboratory uses ABL 80 Flex system to perform arterial blood gas patient samples since May 2024. 2. The manufacturer's specifications establishes: clean the screen & exterior surface daily. 3. Review of ABL 80 Flex routine procedures log January 2025 to May 13, 2025, showed that the laboratory did not perform nor document the clean the screen & exterior surface daily. 4. The laboratory did not perform nor document the daily preventive maintenance the following days that performed patient samples: 1/17/25, 1/21/25, 1/23/25, 1/24/25, 2/4/25, 2/5/25, 2/8/25, 2/11/25, 2/12/25, 2/14/25, 2/15/25, 2/19/25, 2/25/25, 3/2/25, 3/11/25, 3/15/25, 3/16/25, 3/17/25, 4/2/25, 4/7/25, 4/12/25, 4/14/25, 4/15/25, 4/19/25, 4/28/25, 5/5/25, 5/6/25 and 5/7/25. 4. The laboratory processed and reported 35 out of 35 arterial blood gas those days. 5. The laboratory director confirmed on May 13 2025, at 1:30 P.M., that the laboratory failed to follow the manufacturer's specifications for the preventive maintenance of ABL 80 system.

D5439

CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(b)

(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.

This STANDARD is not met as evidenced by:

Based on arterial blood gas calibration verification records review (years 2025), and

laboratory director interview on May 13, 2025, at 11:00 AM , it was determined that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the arterial blood gas tests processed by the ABL 80 system ,when processed and reported 27 out of 27 arterial blood gas tests from November 2024 to February 27, 2025. The findings include: 1. The laboratory began to use the ABL 80 system to perform arterial blood gas tests since May 2024. 2. Review of calibration verification records showed that the laboratory did not perform , at least every 6 months, the calibration verification procedures for the arterial blood gas tests processed by the ABL 80 system. The records showed that calibration verification procedures were not performed on November 2024. 3. The laboratory director stated on May 13, 2025, at 11:00 AM, that the calibration verification was performed on February 27, 2025. 4. The laboratory processed and reported 27 out of 27 arterial blood gas analytes from November 2024 to February 2025.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(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;

This STANDARD is not met as evidenced by:
Based on routine chemistry and arterial blood gases quality control records review (years 2024-2025) and laboratory director interview on May 13, 2025 at 2:00P.M., it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5421, D5429 and D5439.

D6144

GENERAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1463

The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

This STANDARD is not met as evidenced by:
Based on routine chemistry performance specifications records, arterial blood gases calibration verification procedures, manufacturer's specifications records review (2024-2025) and laboratory general supervisor interview on May 13, 2025 at 2:00 P. M., it was determined that the general supervisor failed to follow quality control procedures. Refer to D5421, D5429 and D5439.