

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658059	(X3) Date Survey Completed 04/24/2023
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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on lack of procedure manual, quality control records, validation test and laboratory testing personnel interview on April 24, 2023 at 1:30 PM; it was determined that the laboratory failed to meet requirements for analytic systems. Refer to D 5401, D5421, D5445.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on lack of procedures manuals, quality control records review and testing personnel interview on April 24, 2023 at 11:50 AM; it was determined that the laboratory failed to have the procedures manuals for the Blood Gas sub-specialty since July 2021. The findings include: 1. On April 24, 2023 at 11: 28 AM, the</p>

procedure manuals was requested. The procedure manual was not available at the time of inspection. The laboratory did not have available a procedures manual that include the requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection. 2. On April 24, 2023 at 11:30 AM, the quality control showed that the laboratory performed the Blood Gas test in the laboratory. 3. On April 24, 2023 at 11:50 AM, the testing personnel confirmed that the laboratory failed to have the procedures manuals for the Blood Gas sub-specialty since July 2021.

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

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.

This STANDARD is not met as evidenced by:
Based on Blood Gas test on Stat profile prime (Nova) analyzer validation and laboratory testing personnel interview on April 24, 2023 at 11:45 AM, it was determined that the laboratory director fail to reviewed or approved the validation of the new analyzer since July 2021. The laboratory process and report 391 out 391 of patient specimens from July 21, 2021 The findings include: 1. On April 24, 2023 at 11:38 AM the validation of the new analyzer for Blood Gas was requested and showed that the laboratory director did not reviewed or approved the validation of the Stat profile prime since July 2021. The laboratory began to process and report patient specimens since July 2021. 2. On April 24, 2023 at 11:45 AM the testing personnel confirmed that the laboratory director fail to reviewed or approved the validation of the new analyzer since July 2021. The laboratory process and report 391 out 391 of patient specimens from July 21, 2021 to April 24, 2023.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

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.

This STANDARD is not met as evidenced by:
Based on Blood Gas manufacturer's instruction, quality control records (year 2022) and laboratory testing personnel interview on April 24, 2023 at 11:30 AM, it was determined that the laboratory failed to include every eight (8) hours at least one level of control material when 70 out of 70 patient specimens were tested for Blood Gas

	<p>test from August 1, 2022 to December 12, 2022. The findings include: a. On April 24, 2023 at 11:00 AM, the Blood Gas manufacturer's instructions was reviewed and states that during each eight (8) hours of testing, analyze one level of control. b. On April 24, 2023, at 11:15 AM, the Blood Gas quality control records was reviewed and showed that the laboratory run three (3) level of control at seven (7) AM and two (2) level at seven (7) PM. c. The laboratory testing personnel confirmed on April 24, 2017 at 11:30 AM, that the laboratory did not include every eight (8) hours at least one level of control material when 70 out of 70 patient specimens were tested for Blood Gas test from August 1, 2022 to December 12, 2022.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on lack of procedure manuals, quality control records and validation test and laboratory testing personnel interview on April 24, 2023, at 2:00 PM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory analytic systems. Refer to D6093 and D6095.</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Blood Gas subspecialty quality control records reviewed (year 2022) and interview with the laboratory testing personnel; it was determined that the laboratory director failed to ensure that the quality control was established the same manner as the manufacturer's instructions. Refer to D5417</p>
<p>D6095</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6)</p> <p>The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system.</p> <p>This STANDARD is not met as evidenced by: Based on lack of procedure manual, validation reviewed and laboratory testing personnel interview on April 24, 2023 at 2:00 PM; it was determined that the laboratory director failed to established and maintenance the procedure manual for the Blood Gas subspecialty. Refer to D 5401 and D 5421.</p>