

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0675943	(X3) Date Survey Completed 02/07/2024
Name of Provider or Supplier Laboratorio Clinico Castillo	Street Address, City, State 65 De Infanteria # 42, Anasco, 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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2022-2023) and laboratory general supervisor interview on February 7, 2024 at 9:32 A.M. , it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The findings include: 1. Puerto Rico Proficiency testing records were reviewed from May 2022 to December 2023. (review at 9:32 a.m.) 2. The review of records showed that the laboratory director and laboratory general supervisor (testing personnel) did not sign the attestation statements of the Proficiency testing records from May 2022 to December 2023. (review at 9:34 a.m.) 3. The laboratory general supervisor confirmed on February 7, 2024 ay 9:35 a.m. that the laboratory director and general supervisor (testing personnel) failed to sign the attestation statements since May 2022.</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program records reviewed (2022-2023)</p>

and laboratory general supervisor interview on February 7, 2024 at 9:35 A.M., it was determined that the laboratory failed to report the hematology proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed from February 2022 to December 2023. 2. The deadline of the second testing event report of hematology tests was June 22, 2023. 3. The laboratory did not make sure to report the second testing event of hematology within the time frame established by the Proficiency Testing Program and results in a score of 0 for the testing event. 4. The laboratory director confirmed on February 7, 2024 at 9:45 A.M. that the laboratory did not report the hematology proficiency testing results of the second testing event within the time frame established by the Proficiency Testing Program.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2022-2023) and laboratory general supervisor interview on February 7, 2024 at 9:45 A.M., it was determined that the laboratory failed to verify the accuracy of the hematology specialty tests when the laboratory failed to report the proficiency testing results within the time frame established by the program. The findings include: 1. Puerto Rico Proficiency testing records were reviewed from February 2022 to December 2023. (review at 9:45 A.M.) 2. In the PRPTP second testing event , the laboratory failed to report the proficiency testing results within the time frame established by the program. (review at 9:50 A.M.) 3. The laboratory proficiency testing records showed at 9:50 A.M., that the laboratory did not verify the accuracy of the hematology tests in the second testing event of year 2023. 4. The general supervisor confirmed on February 7, 2024 at 9:55A.M., that the laboratory did not verify the accuracy of these tests.

D5391

PREANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242.

This STANDARD is not met as evidenced by:
Based on lack of quality assessment (QA) records (year 2023) and interview with the laboratory general supervisor interview on February 7, 2024 at 10:04 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test requests The findings include: 1. During the survey performed on February 7, 2024 , the evaluation of pre analytic system were requested. The general supervisor stated that the laboratory failed to perform the evaluations to patient test

	<p>request at least annually, since year 2022. 2. The laboratory director confirmed that evaluations to test requests scheduled for April 2022 was not performed. (review on February 7, 2024 at 10:04 A.M.)</p>
<p>D5891</p>	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on lack of quality assessment (QA) records (year 2023) and interview with the laboratory general supervisor interview on February 7, 2024 at 10:04 A.M., it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for preanalytic systems: patient test results The findings include: 1. During the survey performed on February 7, 2024 , the evaluation of pre analytic system were requested. The general supervisor stated that the laboratory failed to perform the evaluations to patient test results at least annually, since year 2022. 2. The laboratory director confirmed that evaluations to test results scheduled annually was not performed. (review on February 7, 2024 at 10:04 A.M.)</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by: 1. Based on Puerto Rico Proficiency Testing Program records review (years 2022-2023) laboratory director and laboratory general supervisor interview on February 7, 2024 at 11:30 A. M, it was determined that the laboratory director failed to evaluate any problems relate to PT performance. The finding includes: a. The laboratory failed to verify the accuracy of the hematology specialty when the laboratory failed to report the proficiency testing results within the time frame established by the program. Refer to D5215. 2. Based on Puerto Rico Proficiency Testing Program records review (years 2022-2023) laboratory director and laboratory general supervisor interview on February 7, 2024 at 11:30 A. M, it was determined that the laboratory director and testing personnel failed to sign the attestation statements. The finding includes: a. The review of records showed that the laboratory director and laboratory general supervisor (testing personnel) did not sign the attestation statements of the Proficiency testing records from May 2022 to December 2023. (review at 9:34 a.m.)</p>
<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the 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>

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) records review (year 2022-2023) and laboratory director interview on February 7, 2024 at 11:45 A..M., it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. Quality Assessment records (2022-2023) showed that the laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the requirements for laboratory general systems: preanalytic and postanalytic systems. (review on February 7, 2024 at 10:10a.m.) 2. The laboratory director confirmed on February 7, 2024 at 11:45 a..m. , that failed to evaluate the requirements for laboratory general systems: preanalytic and postanalytic systems. Refer to D5391 and D5891.