

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0709350	(X3) Date Survey Completed 08/05/2022
Name of Provider or Supplier Lab Clinico Santiago Irizarry	Street Address, City, State 30 Calle Luis Munoz Rivera, Adjuntas, 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
D2093	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 (2020-2022) and laboratory general supervisor interview on August 5, 2022 at 9:45 A.M., it was determined that the laboratory failed to report the routine chemistry proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed on August 5, 2022 at 9:40 A.M. from February 2020 to June 2022. 2. The deadline of the first testing event report of routine chemistry tests was February 19, 2021. (review at 9:55 A.M.) 3. The laboratory did not report the first testing event of routine chemistry tests within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event. (review at 9:57 a.m) 3. The laboratory general supervisor confirmed on August 5, 2022 at 11:45 A.M. the laboratory failed to report the routine chemistry proficiency testing results of the first testing event within the time frame established by the Proficiency Testing Program.</p>
D2104	<p>ENDOCRINOLOGY CFR(s): 493.843(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>

This STANDARD is not met as evidenced by:
Based on Puerto Rico Proficiency Testing Program records reviewed (2020-2022) and laboratory general supervisor interview on August 5, 2022 at 9:50 A.M., it was determined that the laboratory failed to report the endocrinology (human chorionic hormone) proficiency testing results within the time frame established by the program. The findings include: 1. Proficiency testing records were reviewed on August 5, 2022 at 9:55 A.M. from February 2020 to June 2022. 2. The deadline of the first testing event report of endocrinology test was February 19, 2021. (review at 9:55 A.M.) 3. The laboratory did not report the first testing event of endocrinology tests within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event. (review at 9:57 a.m.) 4. The laboratory general supervisor confirmed on August 5, 2022 at 11:45 A.M. the laboratory failed to report the endocrinology proficiency testing results of the first 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:
A- Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2020-2022) and laboratory general supervisor interview on August 5, 2022 at 10:00 A. M., it was determined that the laboratory failed to verify the accuracy of the routine chemistry and endocrinology 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 2020 to June 2022. (review at 10:00 A.M.) 2. In the PRPTP first testing event , the laboratory failed to report the proficiency testing results within the time frame established by the program. (review at 10:10 A.M.) 3. The laboratory did not report the first testing event of routine chemistry and endocrinology tests within the time frame established by the Proficiency Testing Program and results in a score of 0 % for the testing event. (review at 9:57 a.m.) 4. The laboratory proficiency testing records showed at 10:20 A.M., that the laboratory did not verify the accuracy of the routine chemistry , urinalysis and endocrinology tests in the first testing event of year 2021. 5. The general supervisor stated at 10:30 A.M., that the laboratory did not verify the accuracy of these tests. B-Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (2020-2022) and laboratory general supervisor interview on August 5, 2022 at 11:00 A.M., it was determined that the laboratory failed to verify the accuracy of the hematology specialty when the PRPTP did not have hematology samples in the second testing event performed in June 2021. The findings include: 1. Proficiency testing records were reviewed from February 2020 to June 2022. (review at 11:10 A. M.) 2. In the Hematology second testing event performed in June 2021 , the Puerto Rico Proficiency Testing Program office sent to the laboratory a letter that oriented them that in absence of an event the regulation establishes that the laboratory must be verify the accuracy of the tests (platelet, white blood cells, red blood cells, hemoglobin, hematocrit) . 3. The proficiency testing records showed that the laboratory did not verify the accuracy of the hematology specialty tests in June 2021. (

review at 11:15 A.M.) 4. The general supervisor confirmed at 11:20 A.M. that the laboratory did not have a mechanism to verify the accuracy of the hematology tests.

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 lack of records and laboratory general supervisor interview on August 5, 2022 at 11:20 A.M., it was determined that the laboratory failed to perform the evaluation of the performance specifications of the laboratory systems when the laboratory was relocate in a new facility. The findings include: 1. The laboratory was relocate in a new facility on October 2021. 2. The laboratory perform the following tests: routine chemistry (Imola system) urinalysis (Optima II) complete blood cell (Sysmex system) Influenza, Covid Ag, Syphilis serology, mycoplasma, hCg (review at 9:00A.M.) 3. The laboratory did not have records available that showed that the laboratory verified the performance specifications of the laboratory systems tests prior to begin to test patient samples in the new facility. (review at 11:20 A.M.) 4. The laboratory general supervisor confirmed , that the laboratory did not perform the evaluation of the performance specifications of the laboratory system tests when the laboratory was relocate on October 2021. (review at 11:25 A.M.)

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Program testing records review (2020-2022) and laboratory general supervisor interview on August 5, 2022 at 11:00 AM, it was determined that the laboratory director failed to ensure that proficiency testing samples were tested as required under Subpart H requirements. Refer to D2093 and D2104.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

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.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program records review (years 2021-2022) and laboratory general supervisor interview on August 5, 2022 at 11:50 A. M, it was determined that the laboratory director failed to evaluate any problems relate to PT performance. The findings include: 1. The laboratory failed to verify the accuracy of the hematology specialty when the PRPTP did not have hematology samples in the second testing event performed in June 2021. Refer to D5215. 2. The laboratory failed to verify the accuracy of the routine chemistry , urinalysis and endocrinology when the laboratory failed to report the proficiency testing results within the time frame established by the program. Refer to D5215

D6093

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

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.

This STANDARD is not met as evidenced by:
Based on lack of laboratory performance specifications records review (year 2021) and laboratory general supervisor interview on August 5, 2022 at 11:50 AM, it was found that the laboratory director did not assure that the laboratory perform the evaluation of the performance specifications of the laboratory systems when the laboratory was relocate in a new facility. Refer to D5421.