

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D2170334	(X3) Date Survey Completed 08/04/2022
Name of Provider or Supplier Laboratorio Clinico Yabory	Street Address, City, State Carretera Numero 2, Km 138, Hm4, Bo Naranjo, Aguada, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2021 to June 2022 and laboratory testing personnel interview on August 4, 2022, it was determined that the laboratory failed to maintain a copy of the proficiency testing event records. The findings include: 1. The PRPTP records were reviewed from February 2021 to June 2022. 2. On August 4, 2022 at 9:48 AM, the PRPTP records showed that the laboratory did not have the following proficiency testing records for February 2021, March, 2021, April 2021, May 2021, June 2021, September 2021, October 2021, November 2021 and December 2021. 3. The laboratory testing personnel confirmed on August 4, 2022 at 11:43 AM, that those proficiency testing event records were not available in the laboratory.</p>
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p>

(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2021 to June 2022 and laboratory testing personnel interview on August 4, 2022, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. The findings include: 1. The PRPTP records and results were reviewed from February 2021 to June 2022. 2. Review of proficiency testing (PRPTP) records on August 4, 2022 at 9:50 AM, showed that the laboratory obtained unsatisfactory results of 60 percent in Hematocrit (HCT) tests in April 2022 (PRPTP first testing event), 60 percent in Hematocrit (HCT) tests in June 2022 (PRPTP second testing event) and 60 percent in Platelet Count tests in June 2022 (PRPTP second testing). No remedial actions were taken. 3. The testing personnel confirmed on August 4, 2022 at 11:44 AM, that the laboratory did not take corrective actions in April 2022 and June 2022 testing events.

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on Puerto Rico Proficiency Testing Program (PRPTP) records from February 2021 to June 2022 and laboratory testing personnel interview on August 4, 2022, it was determined that the laboratory failed to retain all proficiency testing records for at least 2 years. The findings include: 1. The PRPTP proficiency testing records were reviewed, on August 4, 2022 at 9:48 AM, from February 2021 to June 2022. 2. The laboratory did not have the proficiency testing (PRPTP) records scores the February 2021 (routine chemistry PRPTP first testing event), March 2021 (hematology PRPTP first testing event), April 2021 (general immunology PRPTP - first testing event), May 2021 (routine chemistry PRPTP second testing event), June 2021 (hematology PRPTP second testing event), September 2021 (general immunology PRPTP second testing event), October 2021 (routine chemistry PRPTP- third testing event), November 2021 (hematology PRPTP third testing event) and December 2021 (general immunology PRPTP third testing event). 3. The laboratory testing personnel confirmed on August 4, 2022 at 11:44 AM, that the laboratory did not have these PRPTP testing records.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The

laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on hematology quality control records review from January 2020 to August 2022 and laboratory testing personnel interview on August 4, 2022, it was determined that the laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. The findings include: 1. The laboratory performed automatic cell differential by Medonic hematology system. 2. Review of the quality controls records on August 4, 2022 at 11:18 AM, showed that the laboratory did not performed the relationship between the manual cell differential and automatic cell differential since December 2020. 3. The laboratory testing personnel confirmed on August 4, 2022 at 11:18 AM, that the laboratory failed to evaluate twice a year a relationship between the manual cell differential and automatic cell differential by hematology system since December 2020.

D5801

TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on hematology quality controls records from January 2020 to August 2022, laboratory written policies review and laboratory testing personnel interview on August 4, 2022, it was determined that the laboratory failed to verify the accuracy of transmitted calculated results. The finding includes: 1. The laboratory uses Medonic system to perform Complete Blood Count (CBC) samples tests. 2. The hematology quality control records were reviewed on August 4, 2022 at 11:18 AM, from January 2020 to August 2022. 3. The laboratory written policies establishes on August 4, 2022 at 11:18 AM, that the laboratory verify each six months the transmitted results of the hematology media (MCV, MCH and MCHC). 4. The laboratory testing personnel confirmed on August 4, 2022 at 11:43 AM, showed that the laboratory did not verify the hematology results reported from calculated data since December 2020.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:
Based on Puerto Rico proficiency testing records review and laboratory testing personnel interview on August 4, 2022 at 9:48 AM, it was determined that the laboratory director failed to establish and follow a corrective action plan when the laboratory obtained an unsatisfactory result. The finding includes: 1. The laboratory obtained unsatisfactory results of 60 percent results in Hematocrit (HCT) tests in April 2022 (PRPTP first testing event), 60 percent in Hematocrit (HCT) tests in June 2022 (PRPTP second testing event) and 60 percent in Platelet Count tests in June 2022 (PRPTP second testing). No remedial actions were taken. Refer to D2128.

D6020

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on quality control records review from January 2020 to August 2022 and laboratory testing personnel interview on August 4, 2022 at 11:48 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5775 (laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential).