

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658083	(X3) Date Survey Completed 08/17/2021
Name of Provider or Supplier Lab Clinico Y De Referencia Del Este	Street Address, City, State 303 General Valero Avenue, Fajardo, 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
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on COVID 19 test report, Puerto Rico Department of Health (PRDOH) COVID 19 state reporting requirement and laboratory general supervisor interview on August 17, 2021 at 12:10 PM, it was determined that the laboratory did not follow the state COVID 19 test reporting requirements. The findings include: 1. The PRDOH requires that all COVID 19 tests report must be informed within 24 hours of the final report, to the Bio Portal platform. 2. The laboratory used the Healgen rapid test for antibody (IgG / IgM) test kit, SARS COV19 Antigen FIA (SOFIA) for antigen test kit and Id Now (Abbott) for molecular COVID 19 test. 3. The test report records showed that 2 out of 4 days from April 22, 2021 to April 25, 2021 and 3 out of 6 days from May 14, 2021 to May 21, 2021. The laboratory did not report the SARS-CoV-IgG / IgM (Healgen), antigen (FIA) and molecular (ID NOW) patients results in the required frequency (24 hrs) by the Bio Portal: Date Patients Date test tested specimens reported 04/23/2021 22 04/26/2021 IgG/IgM 04/23/2021 87 04/26/2021 Antigen FIA 04/23/2021 31 04/26/2021 Molecular (ID NOW) 04/24/2021 10 04/26/2021 IgG/IgM 05/17/2021 10 05/19/2021 IgG/IgM 05/17/2021 01 05/25/2021 IgG/IgM 05/17/2021 44 05/19/2021 Antigen FIA 05/19/2021 07 05/25/2021 IgG/IgM 05/19/2021 37 05/25/2021 Antigen FIA 05/19/2021 32 05/25/2021 Molecular (ID NOW) 05/20/2021 12 05/25/2021 IgG/IgM 05/20/2021 59 05/25/2021 Antigen FIA 05/20/2021 20 05/25/2021 Molecular (ID NOW) Total of report greater than 24 hours: 352 reports. 4. The laboratory general supervisor confirmed on August 17, 2021 at 12:10 PM, that the before mentioned tests were not reported within the 24 hours of the final test report.</p>
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1239(b)(c)

(b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) procedures manual, general system laboratory assessment records (2021), sample integrity (phlebotomy and rejections) problem cases (2021) records and general supervisor interview on August 17, 2021 at 11:40 AM, it was determined that the laboratory failed to follow written procedures to take corrective actions and to review of the effectiveness of this actions to prevent recurrence of the problems for the sample integrity assessment from January 2021 to August 2021. The findings include: 1. The QA procedures manual for the general laboratory system require to take and document corrective actions and review of the effectiveness of this actions to prevent recurrence of the problems for the sample integrity assessment . 2. On August 17, 2021 at 11:40 AM, the sample integrity (phlebotomy and rejections) problem cases records showed that occurred 11 cases with routine chemistry specimens and 6 cases with hematology samples from January 2021 to August 2021. 3. The General laboratory System assessment records were not documented for corrective action taken to prevent recurrence of the problems in the sample integrity assessment from January 2021 to August 2021. 4. The general supervisor confirmed on August 17, 2021 at 11:40 AM, that the laboratory did not follow QA written procedures for the documentation of the general laboratory system assessment from January 2021 to August 2021.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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 analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on QA procedures manual, analytic system assessment records (2021) review and general supervisor interview on August 17, 2021 at 12:10 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the analytic systems requirements since January 2021. The findings include: 1. Review of the laboratory quality assessment manual showed that the laboratory establishes a monthly assessment for each analytic process to keep track the laboratory performance. The laboratory must do the assessment at the end of the month. 2. On August 17, 2021 at 12:10 PM, the analytic system assessment records showed that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for the analytic systems. The laboratory documents a check mark as evidence that it monthly carried the assessment since January 2021. However, the current August 2021 month was checked as done. 3. The general supervisors confirmed on August 17, 2021 at 12:10 PM, that the current August 2021 month was checked as done.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1299(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on QA procedures manual, post-analytic systems assessment records review (2020-2021) and laboratory general supervisor interview on August 17, 2021 on 11:55 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the post-analytic systems the requirement (results reports information). The findings include: 1. The QA procedures manual requires to evaluate ten indicators to assess the patient's result report requirement. The laboratory must do this evaluation with ten patient's results reports (already reported) and must document a check mark in the evaluation sheet for those indicators that not meet the requirement. The laboratory must take and document a corrective action. 2. On August 17, 2021 on 11:55 AM, the post-analytic systems assessment records showed that the laboratory performed the result report evaluation on May 28, 2021 . The laboratory did not follow the written instruction to perform this assessment. The evaluation sheet showed that the laboratory marked all the 10 indicators for each patient's result reports as all indicators meet the requirements. It is important to mention that the indicator number 2 requires that the patient's result report includes the laboratory name and address. However, 10 out 10 of the patient's results reported did not include the laboratory name nor the address. 3. The general superviosr confirmed on August 17, 2021 on 11:55 AM, that the laboratory documented this evaluation and stated that the laboratory did not use the paper with the laboratory information to print those results.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

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.

This STANDARD is not met as evidenced by:

Based on quality assessment (QA) procedures manual, general system laboratory assessment records, analytic system assessment records, post-analytic systems assessment records review (2020-2021) and laboratory general supervisor interview on August 17, 2021 on 12:10 PM, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. The findings include: 1. The laboratory director failed to assess the general laboratory system requirement. Refer to D 5293. 2. The laboratory director failed to assess the analytic system requirement. Refer to D 5791. 3. The laboratory director failed to assess the Post analytic system requirement. Refer to D 5891.