Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0861654	05/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Pajuil	Carretera 490 Km 4 Hm 5, Hatillo, 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
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (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 records reviewed (2016 to 2018) and laboratory general supervisor interview on May 25, 2018 at 10:00 A..M., it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in routine chemistry specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records were reviewed from February 2016 to February 2018. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in creatinine test and total bilirrubin test in the second testing event performed in June 2016. No remedial actions were taken. 3. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results in the following analytes in the first testing event performed in February 2017 and no remedial actions were taken : test score albumin 60 % total bilirrubin 40 % chloride 60 % creatinine 60 % sodium 40 % 4. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in urinalysis sediment test in the second testing event performed in June 2017. No remedial actions were taken. 5. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in total bilirubin test in the first testing event performed in February 2018. No remedial actions were taken. 6. The laboratory general supervisor confirmed on May 25, 2018

	at 10:00 A.M. , that the laboratory failed to take and document remedial actions when obtained unsatisfactory results in routine chemistry specialties.
D2128	HEMATOLOGY CFR(s): 493.851(e) (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 records reviewed (2016 to 2018) and laboratory general supervisor interview on May 25, 2018 at 10:00 A..M., it was determined that the laboratory failed to take and document corrective actions when it obtained unsatisfactory results in hematology specialties. The findings include: 1. Puerto Rico Proficiency Testing Program records were reviewed from February 2016 to February 2018. 2. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 40 percent in hematocrit test in the third testing event performed in November 2016. No remedial actions were taken. 3. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in hematocrit test and 80 percent in hemoglobin test in the first testing event performed in March 2017. No remedial actions were taken. 4. Review of Proficiency Testing results showed that the laboratory obtained unsatisfactory results of 60 percent in hematology cell identification in the second testing event performed in July 2017. No remedial actions were taken. 5. The laboratory general supervisor confirmed on May 25, 2018 at 10:00 A.M. , that the laboratory failed to take and document remedial actions when obtained unsatisfactory results in hematology tests.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on routine chemistry calibration verification records review (2016-2017) and laboratory general supervisor interview on May 25, 2018 at 10:50 A.M., it was determined that the laboratory failed to take and document remedial actions when calibration materials results fail to meet the laboratory's criteria for acceptability. The findings include: 1. The laboratory performed routine chemistry tests by Mindray system. 2. Calibration verification records were reviewed from November 2016 to November 2017. 3. Review of calibration verification control results in November

	2016 showed that the laboratory failed to take corrective actions when the calibration control results for the tests albumin, calcium, potassium, total bilirrubin, and total protein exceeded the laboratory's criteria for acceptability. 4. Review of calibration verification control results in May 2017 showed that the laboratory failed to take corrective actions when the calibration control results for the tests albumin and potassium exceeded the laboratory's criteria for acceptability. 5. Review of calibration verification control results in November 2017 showed that the laboratory failed to take corrective actions when the calibration control results for the tests calcium, cholesterol, total protein and triglicerides exceeded the laboratory's criteria for acceptability. 6. The laboratory reported and reported 8,937 routine chemistry patient samples on 2017. 7. The laboratory general supervisor confirmed on May 25, 2018 at 10:50A.M. that no corrective actions were taken when calibration materials results fail to meet the laboratory's criteria for acceptability.
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 quality assessment (QA) records review and laboratory general supervisor interview on May 25, 2018 at 11:00 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. Review of the laboratory quality assessment manual showed that the laboratory establishes an annually assessment for each analytic process to keep track the laboratory performance. 2. From November 2016 to November 2017, the laboratory did not evaluate aspects regarding the analytic system in the following areas: routine chemistry. Refer to D 5783.
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 (2016 to 2018) and laboratory general supervisor interview on May 25, 2018 at 11:30 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 D2094 and D2127.
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 routine chemistry calibration verification records review (2016-2017) and laboratory general supervisor interview on May 25, 2018 at 11:30 AM, it was determined that laboratory failed to ensure compliance with the requirements for analytic systems. Refer to D5783.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on routine chemistry calibration verification records review (2016-2017) and laboratory general supervisor interview on May 25, 2018 at 11:30 AM, it was determined that the general supervisor failed to follow calibration verification procedures. The finding includes: 1. The laboratory general supervisor did not evaluate aspects regarding: calibration verification procedures. Refer to D5783.