Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0709713	08/06/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Caleb	Ave Borinquen 2100 Box 14511, San Juan, 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
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 (PRPTP) records review from February 2020 to June 2021 and laboratory general supervisor interview on August 6, 2021 at 10:40 AM, 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. Puerto Rico Proficiency Testing Program records and results were reviewed from February 2020 to June 2021. 2. Review of PRPTP testing records, showed that the laboratory obtained unsatisfactory results of 80 percent in White Blood Cell (WBC) testing November 2020 (third testing event), 80 percent in Hematology Cell Identification, Hemoglobin (HGB), White Blood Cell (WBC), Erythrocyte Sedimentation Rate (ESR) tests on March 2021 (first testing event). No remedial actions were taken. 3. The laboratory general supervisor confirmed on August 6, 2021 at 10:40 AM, that the laboratory did not take corrective actions in those testing events.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel records review (years 2019, 2020 and 2021) and laboratory general supervisor interview on August 6, 2021 at 9:52 AM, it was found that the laboratory did not perform the competence of the following personnel: the clinical consultant and the testing personnel. The findings include: 1. The laboratory schedule for clinical consultant and testing personnel competence evaluation showed that it must be done every year. 2. The personnel records of the clinical consultant showed that the last competence was performed on December 2018. 3. The personnel records of the testing personnel showed that the last competence was performed on December 2018. 4. The laboratory general supervisor confirmed on August 6, 2021 at 9:52 AM, that the director failed to perform the annual competency evaluation to the clinical consultant and testing personnel from December 2018.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review from February 2020 to June 2021 and laboratory general supervisor interview on August 6, 2021 at 10:40 AM, it was determined that the laboratory failed to take and document corrective actions when it obtained an unsatisfactory results in hematology specialties. Refer to D2128.
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 personnel records review (years 2019, 2020 and 2021) and laboratory general supervisor interview on August 6, 2021, it was found that the laboratory director failed to ensure compliance with quality assessment requirements: personnel competence evaluation from December 2018. Refer to D 5209.