Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1107086	11/05/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Media Luna	Carr Pr-865 Km 1 Hm 3 Bo Media Luna Luna, Toa Baja, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (years 2018 to 2019 and laboratory director interview on November 5, 2019 at 9:30 A.M., it was determined that the laboratory failed to maintain a copy of all the proficiency testing program attestation statements in record (signed by the analyst and the laboratory director) for a minimum of two years. The findings include: 1. The PRPTP records were review from February 2018 to October 2019. 2. On November 5, 2019 at 9:30 A.M, the PRPTP records showed that the laboratory did not maintain a copy of the proficiency testing program attestation statement for the first 2019's proficiency testing event (February 2019). 3. The laboratory director confirmed on November 5, 2019 at 9:30 A.M, that the copy of the proficiency testing program attestation statement of February 2019 was not maintained in records.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on routine chemistry calibration verification records (years 2018 and 2019) reviewed and laboratory director interview on November 5, 2019 at 10:30 AM., it was determined that the laboratory failed to retain all the printout of the calibration verification procedures for the routine chemistry tests processed by the Daytona system. The findings include: 1. The laboratory performed the following tests by the Daytona system: glucose, triglycerides, cholesterol and HDL-cholesterol. 2. On November 5, 2019 at 10:30 AM, the routine chemistry calibration verification records showed that the laboratory performed a calibration verification procedures on October 24, 2019. However, the laboratory did not have available the printout of this calibration verification procedures. 3. The laboratory director confirmed on November 5, 2019 at 10:30 AM, that the printout for the calibration verification procedures was not available.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on review on calibration verification records for the routine chemistry tests (years 2018 to 2019) and laboratory director interview on November 5, 2019 at 10:45 A.M., it was determined that the laboratory failed to take and document corrective actions when occurs discrepancies in the information included in the statistical evaluation sheets of the calibration verification procedures and the printout of the calibration verification results, to ensures accurate and reliable patient routine chemistry test results and reports during the year 2018. The findings include: 1. The laboratory performed the following tests by the Daytona system: glucose, triglycerides, cholesterol and HDL-cholesterol 2. On November 5, 2019 at 10:45 A.M, the calibration verification records for the routine chemistry tests showed discrepancies in the information included in the statistical evaluation sheets of the calibration verification procedures performed on August 21, 2018 and the printout of theses procedures. The statistical evaluation sheets included the run date on August 21, 2018 and include a results as maximum value of 500 calibrator for the calibration verification for glucose tests. However, the printout for those calibration verification procedures showed that the run date was on July 2, 2018 and showed no evidence of the glucose 500 calibrator results. 3. The laboratory did not take nor document corrective action for those discrepancies. 4. The laboratory director confirmed on November 5, 2019 at 10:45 A.M., the discrepancies of those records. 5. The laboratory processed and reported 930 routine chemistry tests during the year 2018.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)

	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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records review (years 2018 to 2019), routine chemistry calibration verification records (years 2018 and 2019) and laboratory director interview on November 5, 2019 at 10:45 A.M., it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory retention records and calibration verification procedures requirements Refer to D 2015 (The laboratory failed to maintain a copy of all the proficiency testing program attestation statements in record (signed by the analyst and the laboratory director) for a minimum of two years). Refer to D 3031 (The laboratory failed to retain all the printout of the calibration verification procedures for the routine chemistry tests processed by the Daytona system). Refer to D 5779 (The laboratory failed to take and document corrective actions when occurs discrepancies in the information included in the statistical evaluation sheets of the calibration verification procedures and the printout results).