Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0722888	09/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Miraflores	Ave Los Dominicos # 6 Bloque 14, Bayamon, 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
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 calibration verification records (years 2017 and 2018) review for the routine chemistry tests, laboratory work load record (years 2017 and 2018) review and interview with the laboratory director on September 21, 2018 at 9:40 AM, it was determined that the laboratory failed to retain the instrument (Daytona system) printouts for the calibration verification procedures performed from August 2017 to August 2018. Also the laboratory did not retained the insert of the calibrator materials used in the calibration verification procedures from August 2017 to August 2018. The findings include: 1. On September 21, 2018 at 9:40 AM, the calibration verification records showed that the laboratory processed the calibration verification for the routine chemistry tests in August 2017, February 2018 and August 2018. 2. The laboratory did not retain the Daytona system printouts for those calibration verification procedures performed from August 2017 to August 2018. Also the laboratory did not retained the insert of the calibrator materials used in the calibration verification procedures from August 2017 to August 2018. The records were documented with the calibrator lot number, not include the expiration date, the name of the calibrator nor calibrator manufacture name. 3. The laboratory director confirmed on September 21, 2018 at 9:40 AM, that the calibration verification records did not include the required information. 4. The laboratory work load record showed that the laboratory processed and reported 2,023 out of 2,023 CMP patients specimens from August 2017 to August 2018.
D5012	SYPHILIS SEROLOGY

	CFR(s): 493.1207 If the laboratory provides services in the subspecialty of Syphilis serology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on ASI manufacturer's instruction for rapid plasma reagin (RPR) qualitative test, RPR testing records (years 2017, 2018) review and laboratory director interview on September 21, 2018 at 11:30 AM, it was determined that the laboratory failed to meet the requirements for the subspecialty of Syphilis serology. Refer to D 5405 (The laboratory failed to follow manufacturer's instructions when 21 out of 21 patients specimens for RPR qualitative tests were processed and reported from March 29, 2017 to August 30, 2018).
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on ASI manufacturer's instruction for rapid plasma reagin (RPR) qualitative test, RPR testing records (years 2017, 2018) review and laboratory director interview on September 21, 2018 at 11:30 AM, it was determined that the laboratory failed to follow manufacturer's instructions when 21 out of 21 patients specimens for RPR qualitative tests were processed and reported from March 29, 2017 to August 30, 2018. The findings include: 1. The ASI manufacturer instructed the laboratory to include each day of testing the three levels of control materials (nonreactive, weakly reactive and reactive), to monitor the room temperature, to verify the needle calibration and the velocity of the rotator. 2. On September 21, 2018 at 11:30 AM, the RPR testing records showed that the laboratory did not include the three levels of control materials, did not monitor the room temperature, did not verify the needle calibration nor the velocity of the rotator when 21 out of 21 patients specimens for RPR qualitative tests were processed and reported from March 29, 2017 to August 30, 2018: Date processed number of patients and reported specimens tested March 27, 2017 7 specimens March 13, 2018 2 specimens May 17, 2018 3 specimens June 1, 2018 2 specimens June 21, 2018 3 specimens August 30, 2018 4 specimens 3. The laboratory director confirmed on September 21, 2018 at 11:40 AM, that the RPR testing records did not include the requirements information. She stated that the testing personnel performed the test as the manufacture requires but not recorded the information those days.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: 1. Based on Daytona system manufacturer's instruction, Daytona system preventive maintenance records (years 2016, 2017 and 2018), laboratory work load records (year 2018) review and interview with the laboratory director on September 21, 2018 at 10: 00 AM, it was determined that the laboratory failed to follow manufacturer instructions for the preventive maintenance of the Daytona system when 455 out of 455 patients comprehensive metabolic panel (CMP) specimens were processed and reported from March 1, 2018 to July 31, 2018. The findings include: a. The laboratory processed and reported the CMP patients specimens by the Daytona system. b. The Daytona manufacturer requires a monthly preventive maintenance for this system. c. On September 21, 2018 at 10:00 AM, the Daytona system preventive maintenance records showed that the laboratory did not perform the monthly preventive maintenance in the following moths: March 2018, May 2018, June 2018 and July 2018. d. The laboratory director confirmed on September 21, 2018 at 10:10 AM, that the preventive maintenance record did not include the preventive maintenance those months. e. The laboratory work load records showed that it processed and reported 455 out of 455 CMP patients specimens from March 1, 2018 to July 31, 2018. 2. Based on Cell Dyn 1700 system Manufacturer's instructions, Cell Dyn 1700 system preventive maintenance records (Years 2016, 2017, 2018) review, laboratory work load records (year 2018) review and interview with the laboratory director on September 21, 2018 at 10:40 AM it was determined that the laboratory failed to follow manufacturer instructions for the preventive maintenance of the Cell Dyn 1700 system when 401 out of 401 patients complete blood count (CBC) specimens were processed and reported from March 1, 2018 to June 30, 2018. The findings include: a. The laboratory processed and reported the CBC patients specimens by the Cell Dyn 1700 system. b. The Cell Dyn 1700 manufacturer requires a monthly preventive maintenance for this system. c. On September 21, 2018 at 10:40 AM, the Cell Dyn 1700 system system preventive maintenance records showed that the laboratory did not perform the monthly preventive maintenance in the following moths: March 2018, May 2018 and June 2018. d. The laboratory director confirmed on September 21, 2018 at 10:50 AM, that the preventive maintenance record did not include the preventive maintenance those months. e. The laboratory work load records showed that it processed and reported 401 out of 401 CBC patients specimens from March 1, 2018 to June 30, 2018.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on ASI manufacturer's instruction for rapid plasma reagin (RPR) qualitative test, RPR testing records (years 2017, 2018), Daytona system manufacturer's instruction, Cell Dyn 1700 system Manufacturer's instructions, Daytona system preventive maintenance records (years 2016, 2017 and 2018), Cell Dyn 1700 system preventive maintenance records (Years 2016, 2017, 2018) review and interview with the laboratory director on September 21, 2018 at 11:30 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to comply with the

	analytic system and records retention. Refer to D 6079 (The laboratory director failed to ensure that the laboratory retain for at least 2 years calibration verification records). Refer to D 6093 (The laboratory director failed to comply with the analytic system).
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 calibration verification records (years 2017 and 2018) review for the routine chemistry tests, laboratory work load record (years 2017 and 2018) review and interview with the laboratory director on September 21, 2018 at 9:40 AM, it was determined that the laboratory director failed to ensure that the laboratory retain for at least 2 years calibration verification records. Refer to D 3031.
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 ASI manufacturer's instruction for rapid plasma reagin (RPR) qualitative test, RPR testing records (years 2017, 2018), Daytona system manufacturer's instruction, Cell Dyn 1700 system Manufacturer's instructions, Daytona system preventive maintenance records (years 2016, 2017 and 2018), Cell Dyn 1700 system preventive maintenance records (Years 2016, 2017, 2018) review and interview with the laboratory director on September 21, 2018 at 11:30 AM, it was determined that the laboratory director failed to comply with the analytic system. Refer to D 5012 (The laboratory failed to meet the requirements for the subspecialty of Syphilis serology). Refer to D 5429 (1) (2) (The laboratory failed to follow manufacturer's instructions for preventive maintenance).
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 ASI manufacturer's instruction for rapid plasma reagin (RPR) qualitative test, RPR testing records (years 2017, 2018), Daytona system manufacturer's instruction, Cell Dyn 1700 system Manufacturer's instructions, Daytona system preventive maintenance records (years 2016, 2017 and 2018), Cell Dyn 1700 system preventive maintenance records (Years 2016, 2017, 2018) review and interview with the laboratory director on September 21, 2018 at 11:30 AM, it was determined that the general supervisor failed to comply with the analytic system. Refer to D 5405 (The laboratory failed to follow manufacturer's instructions when 21 out of 21 patients specimens for RPR qualitative tests were processed and reported from March 29, 2017 to August 30, 2018. meet the requirements for the subspecialty of Syphilis serology). Refer to D 5429 (1) (2) (The laboratory failed to follow manufacturer's instructions for preventive maintenance).