Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2058420	12/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico La Morenita	Carr 174 Km 10 Hm 2, Bo Guaraguao Abajo, 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
D2067	SYPHILIS SEROLOGY CFR(s): 493.835(b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on Puerto Rico Department of Health Proficiency Testing Program score records (year 2018) and interview with the testing personnel on December 18, 2018 at 11:00 AM, it was determined that the laboratory failed to participate in the second event of the syphilis serology proficiency testing in August 2018. The findings include: 1. The laboratory did not participate in the second event of the syphilis serology proficiency testing in August 2018. 2. The Puerto Rico Department of Health Proficiency Testing Program score records (year 2018) showed that the laboratory obtained a O percent score for the second event of syphilis serology in August 2018. 3. The testing personnel confirmed on December 18, 2018 at 11:00 AM, that the laboratory did not participate in the second event for the syphilis serology proficiency testing (August 2018).
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)

	Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on Puerto Rico Proficiency Testing Program (PRPTP) records (years 2017 and 2018) review and testing personnel interview on December 18, 2018 at 11:00 AM, it was determined that the laboratory failed to retain all proficiency testing records for at least 2 years. The findings include: 1. On December 18, 2018 at 11:00 AM, the PRPTP records showed that the laboratory did not retain the proficiency testing results for the seconds event of syphilis serology proficiency testing samples (August 2018). 2. The testing personnel confirmed on December 18, 2018 at 11:00 AM, that the laboratory did not have this records due to the laboratory did not participate in the August 2018 event.
D5024	HEMATOLOGY CFR(s): 493.1215 If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on hematology procedures manual, Cell Dyn 1700 system validation records (October 19, 2016), manufacturer's instructions, complete cells count (CBC) quality control records review(years 2017 and 2018), laboratory director and testing personnel interview on December 18, 2018 at 10:35 AM, it was determined that the laboratory failed to meet with the analytic system requirements for CBC tests the Cell Dyn 1700 system since December 2016. Refer to D 5401 (The laboratory failed to have a written procedures manual for the CBC tests, processed by the Cell Dyn 1700 system since December 2016). Refer to D 5405 (The laboratory failed to follow manufacturer's instructions when 23 out of 23 CBC's patients specimens were tested by the Cell Dyn 1700 system from May 9, 2018 to July 6, 2018).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on hematology procedures manual, Cell Dyn 1700 system validation records (October 19, 2016) and testing personnel interview on December 18, 2018 at 10:35 AM, it was determined that the laboratory failed to have a written procedures manual for the CBC tests, processed by the Cell Dyn 1700 system since December 2016. The findings include: 1. On December 18, 2018 at 10:35 AM, the Cell Dyn 1700 system validation records showed that the laboratory performed the validation of the Cell Dyn 1700 system on October 19, 2016. 2. The hematology procedures manual showed that the laboratory did not include the information of the the Cell Dyn 1700 system (patients specimens processing, preventive maintenance and quality control

	procedures). Instead, the hematology procedures manual includes all the information of the former CBC system (Coulter Act Diff). 3. The testing personnel confirmed that the hematology procedures manual was not actualized with the Cell Dyn 1700 system procedures(patients specimens processing, preventive maintenance and quality control procedures).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on urinalysis procedure manual, urinalysis quality control records(years 2017 and 2018), urinalysis testing records review and interview with the laboratory director on December 18, 2018 at 10:00 AM, it was determined that the laboratory failed to follow written procedures for the step-by-step performance of the urine microscopic examination when it processed and reported 335 out of 335 urine microscopic examinations from July 13, 2018 to December 17, 2018. The findings include: 1. The procedures manual instructed the laboratory to centrifuge the urine specimens from 1,500 to 2,000 rpm for 5 minutes for the urine microscopic examination. 2. The urinalysis quality control records showed that the centrifuge used by the laboratory to processed the urine specimens was calibrated at 3,300 rpm on July 13, 2018. 3. The laboratory director confirmed on on December 18, 2018 at 10:10 AM, that the that the centrifuge used by the laboratory to processed the urine specimens was calibrated at 3,300 rpm on July 13, 2018. 4. From July 13, 2018 to December 17, 2018, the laboratory processed and reported 335 out of 335 urine microscopic examinations.
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 manufacturer's instructions, complete cells count (CBC) quality control records review(years 2017 and 2018) and laboratory director interview on December 18, 2018 at 9:25 AM, it was determined that the laboratory failed to follow manufacturer's instructions when 23 out of 23 CBC's patients specimens were tested by the Cell Dyn system from May 9, 2018 to July 6, 2018. The findings include: 1. The laboratory processed the CBC patients specimens by the Cell Dyn system since December 2016. 2. The Cell Dyn manufacturer establishes to run 3 levels of control material (low, normal and high) each day of testing. 3. On December 18, 2018 at 9:25 AM, the CBC quality control records showed that the laboratory did not include the 3 levels of control material when 23 out of 23 CBC's patients specimens were tested by the Cell Dyn system from May 9, 2018 to July 6, 2018: a. The laboratory did not include the normal control material on May 9, 2018; the laboratory processed and reported the following patients specimens: #7696, # 7698 and #7699. b. The laboratory did not include the normal nor the low control materials on June 14, 2018, June 15, 2018, June 20, 2018 and June 21, 2018; the laboratory processed and reported the following patients specimens: #5791, #15688, #7957, #7998, #16190, #14586, #8044, #15533, #6056, #8045, #8052, #8010, #8052, #8010 and #6705. c. The laboratory did not include the high control material on June 26, 2018; the laboratory processed and reported the following patients specimens: ##15728, #14487 and #15728. d. The laboratory did not include the normal nor the high control materials on July 3, 2018 and July 6, 2018; the laboratory processed and reported the following patients specimens: #7338, #321, #14920 and #6534. 4. The laboratory director confirmed On December 18, 2018 at 9:25 AM, that the laboratory did not follow the CBC quality control procedure.
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 Puerto Rico Proficiency Testing Program (PRPTP) records (years 2017 and 2018), proficiency testing remedial action records, hematology procedures manual, Cell Dyn 1700 system validation records (October 19, 2016), manufacturer's instructions, complete cells count (CBC) quality control records review(years 2017 and 2018), urinalysis procedure manual, urinalysis quality control records(years 2017 and 2018), urinalysis testing records, personnel files review, testing personnel and laboratory director interview on December 18, 2018 at 11:00 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system requirements and the overall management of the laboratory direction in accordance with 493.1445 of this subpart since December 18, 2016. The finding includes: 1.The laboratory director did not comply with the proficiency testing records retention. Refer to D 6079. 2. The laboratory director did not comply to take and document remedial action for unsatisfactory score obtained in the Puerto Rico Proficiency Testing program. Refer to D 6092. 3. The laboratory director did not comply with the analytical systems requirements. Refer to D 6093 and D 6106. 4. The laboratory director did not comply with the testing personnel competence requirements. Refer to D 6103.

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 (years 2017 and 2018) review and testing personnel interview on December 18, 2018 at 11:00 AM, it was determined that the laboratory director failed to ensure that the laboratory retain all proficiency testing records for at least 2 years. Refer to D 3037.
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 Department of Health Proficiency Testing Program score records (year 2018), proficiency testing remedial action records review and interview with the testing personnel on December 18, 2018 at 11:00 AM, it was determined that the laboratory director failed to take and document remedial action when it obtained a O percent score for the second event of syphilis serology in August 2018. Refer to D 2067.
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 hematology procedures manual, Cell Dyn 1700 system validation records (October 19, 2016), manufacturer's instructions, complete cells count (CBC) quality control records review(years 2017 and 2018), urinalysis procedure manual, urinalysis quality control records(years 2017 and 2018), urinalysis testing records, laboratory director and testing personnel interview on December 18, 2018 at 10:35 AM, it was determined that the laboratory director failed to ensure compliance with the analytic system requirements for CBC tests and urine microscopic examination requirements. Refer to D 5024 (The laboratory failed to meet with the analytic system requirements

	for CBC tests the Cell Dyn 1700 system since December 2016). Refer to D 5403 (The laboratory failed to follow written procedures for the step-by-step performance of the urine microscopic examination when it processed and reported 335 out of 335 urine microscopic examinations from July 13, 2018 to December 17, 2018).
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on personnel files review and part time testing personnel interview on December 18, 2018 at 11:10 AM, it was determined that the laboratory director failed to follow the written procedures to monitor and ensure the competency evaluations of the part-time testing personnel since December 18, 2016. The findings include: 1. On December 18, 2018 at 11:10 AM, the personnel files showed that the laboratory director did not evaluate annually the competence of the part-time testing personnel since December 18, 2016. 2. The part-time testing personnel confirmed on December 18, 2018, that her competence evaluations were not available since December 18, 2016.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on hematology procedures manual, Cell Dyn 1700 system validation records (October 19, 2016) and testing personnel interview on December 18, 2018 at 10:35 AM, it was determined that the laboratory director failed to ensure that an approved procedure manual for CBC is available to all personnel. Refer to D5401(The laboratory director did not have a written procedures manual for the CBC tests, processed by the Cell Dyn 1700 system since December 2016).
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on hematology procedures manual, Cell Dyn 1700 system validation records (October 19, 2016), manufacturer's instructions, complete cells count (CBC) quality

	control records review(years 2017 and 2018), urinalysis procedure manual, urinalysis quality control records(years 2017 and 2018), urinalysis testing records, laboratory director and testing personnel interview on December 18, 2018 at 10:35 AM, it was determined that testing personnel failed to follow quality control procedures. Refer to D 5403 and D 5405.