Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0676839	04/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Manati	Marginal B6 Urb San Salvador, Manati, 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
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 manufacturer's instructions, syphilis serology testing records (2017,2018), syphilis serology quality control records (2017, 2018) review and general supervisor interview on April 6, 2018 at 10:30 AM, it was determined that the laboratory failed to ensure compliance with the analytic system requirements for syphilis serology tests. The finding includes: 1. The laboratory did not follow the Immunostix-rpr manufacturer's instruction when 13 out of 13 patients specimens were tested and reported for syphilis serology tests by the rapid plasma reagin (RPR) method from February 3, 2017 to March 14, 2018 November 7, 2017 to December 23, 2017. Refer to D 5405.
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, syphilis serology testing records (2017,2018), syphilis serology quality control records (2017, 2018) review and general supervisor

	interview on April 6, 2018 at 10:30 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 13 out of 13 patients specimens were tested for RPR (Rapid plasma reagin) by Immunosyphillis/rpr method from February 3, 2017 to March 14, 2018 . The findings include: 1. On April 6, 2018 at 10:30 AM, the manufacturer's instruction establishes that three levels of control material (non reactive, minimal to moderate and reactive) must be included each day of testing. 2. The syphilis serology testing and quality control records records showed that the laboratory did not include the three levels of control material when 13 out of 13 patients specimens were tested for RPR by Immunosyphillis/rpr method from February 3, 2017 to March 14, 2018: patients specimens #104199, #104237, #104240, #104241, #104243, #104244 and #104245 on February 3, 2017; patients specimens #107498, #107500 and #107501 on April 6, 2017; patients specimens #119531, #119552 and #119575 on February 2, 2018. 3. The engender supervisor confined on April 6, 2018 at 10:40 AM, that the syphilis serology quality control records showed no controls results on February 3, 2017, April 6, 2017 and February 2, 2018. She also stated that the testing personnel performed the quality control procedures but not recorded.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of validation records of the Coulter Act 5diff system for complete cell count (CBC) test and technical supervisor interview on April 6, 2018 at 10:00 AM, it was determined that the laboratory failed to complete the evaluation of the performance specifications of this new instruments in January 2018, before reporting 1,217 out of 1217 CBC tests results from February 1, 2018 to March 31, 2018. The findings include: 1. On April 6, 2018 at 10:00 AM, the Coulter Act 5diff validation records showed that the laboratory laboratory performed the validation procedures in January 2018 and it did not verify that the manufacturer's CBC reference intervals (normal values) are appropriate for the laboratory's patient population. 2. The technical supervisor confirmed on April 6, 2018 at 10:10 AM, that the laboratory did not verify that the Coulter Act 5diff system manufacturer's reference intervals (normal values) when it validated the system in January 2018. 3. The laboratory processed and reported 1,217 out of 1217 CBC patients specimens by the Coulter Act 5diff system from February 1, 2018 to March 31, 2018.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4)

	The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on testing records review of bacteriology (2017, 2018) and interview with the general supervisor on April 6, 2018 at 11:35 AM, it was determined that the laboratory failed to maintain the positive identification of 102 out of 102 patients cultures specimen in the bacteriology testing records from March 4, 2018 to April 5, 2018. The findings include: 1. On April 6, 2018 at 11:35 AM, the bacteriology testing records showed that the laboratory did not document the patients identification number from March 4, 2018 to April 5, 2018. The laboratory include the name and the last name as positive identification in 102 out of 102 patients urine cultures specimens from March 4, 2018 to April 5, 2018. 2. The general supervisor confirmed on April 6, 2018 at 11:45 AM, that the laboratory include the patient's name and last name as identification in the bacteriology testing records from March 4, 2018 to April 5, 2018.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate 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 manufacturer's instructions, syphilis serology testing records (2017,2018), syphilis serology quality control records (2017, 2018) review and general supervisor interview on April 6, 2018 at 10:30 AM, it was determined that testing personnel failed to follow manufacturer's instructions for quality control procedures when 13 out of 13 patients specimens were tested for RPR by Immunosyphillis/rpr method from February 3, 2017 to March 14, 2018. Refer to D 5405.
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 manufacturer's instructions, syphilis serology testing records (2017,2018), syphilis serology quality control records (2017, 2018), validation records of the hematology Coulter Act 5 diff system, bacteriology testing records review (2017, 2018) and interview with the general supervisor on April 6, 2018 at 11:35 AM, it was determined that the laboratory director failed to fulfill her responsibilities and duties to ensure compliance with the laboratory analytical system and quality assessment requirements. The finding includes: 1. The laboratory director did not comply with the analytical systems requirements. Refer to D 6093.
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 manufacturer's instructions, syphilis serology testing records (2017,2018), syphilis serology quality control records (2017, 2018), validation records of the hematology Coulter Act 5 diff system, bacteriology testing records review (2017, 2018) and interview with the general supervisor on April 6, 2018 at 11:35 AM, it was determined that the the laboratory director failed to ensure compliance with the requirements for the analytic system in syphilis serology, hematology and bacteriology specialties The findings include: 1. The laboratory director failed to ensure compliance with the requirements for the syphilis serology quality control program for the RPR tests. Refer to D 5012. 2. The laboratory director failed to ensure compliance with the requirements for the hematology quality control program for the CBC tests. Refer to D 5421. 3. The laboratory director failed to ensure compliance with the requirements for the bacteriology testing records. Refer to D 5787.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, syphilis serology testing records (2017,2018), syphilis serology quality control records (2017, 2018), validation records of the hematology Coulter Act 5 diff system, bacteriology testing records review (2017, 2018) and interview with the general supervisor on April 6, 2018 at 11:35 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems. Refer to D 5405, D 5421 and D 55787.