Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2103412	08/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Neoclinico	Carr, Pr -2, Km 18, Hm 9, Comunidad Macun, 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
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 syphilis serology quality control records review and laboratory director and testing personnel interview on August 15, 2018 at 9:48 AM, it was determined that the laboratory failed to included meet the requirements for syphilis serology by Rapid Plasma Reagin (RPR) quantitative tests. Refer to D5451.
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, 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 general immunology quality control records review and laboratory director and testing personnel interview on August 15, 2018 at 10:12 AM, it was determined that the laboratory failed to included meet the requirements for general immunology by CRP (C-reactive protein) tests. Refer to D5449 (1).
D5020	ENDOCRINOLOGY CFR(s): 493.1212

	If the laboratory provides services in the subspecialty of Endocrinology, 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 endocrinology quality control records review and laboratory director and testing personnel interview on August 15, 2018 at 10:24 AM, it was determined that the laboratory failed to included meet the requirements for endocrinology by Alere hCG tests. Refer to D5449 (2).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on observations, Urinalysis procedures manual review and laboratory director and testing personnel interview on August 15, 2018 at 12: 20 PM, it was determined that the laboratory failed to follow written policies for urinalysis specimen processing. The findings include: 1. The Urinalysis procedures manual establishes that the urinalysis samples must perform within 1 hour after the sample was taken. 2. On August 15, 2018 at 12:20 PM, the laboratory had over the counter the following urinalysis samples without processing: Sample Id sample hour taken 43026 9:15 AM 43035 9:59 AM 43042 10:17 AM 43048 10:29 AM 43054 10:39 AM 43062 10:58 AM 43070 11:09 AM 3. The laboratory director and testing personnel confirmed that the laboratory did not follow urinalysis specimen written procedures.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on observations, urinalysis procedures manual, Quality Assessment (QA) records review, laboratory director and testing personnel interview on August 15, 2018 at 12:43 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for pre-analytic systems. The findings include: 1. The laboratory did not follow the written policies for urinalysis specimen processing, urinalysis samples must perform within 1 hour after the sample was taken, on August 15, 2018. Refer to D5311.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on bacteriology quality control records review from January 2, 2018 to August 15, 2018, bacteriology procedures manual, laboratory director and testing personnel interview on August 15, 2018 at 9:23 AM, it was determined that the laboratory failed to monitor and document the bacteriology room temperature, relative humidity and incubator temperature. The finding includes: 1. The laboratory procedures manual establishes to monitor and document daily the bacteriology room temperature, relative humidity and incubator temperature. 2. Review of the bacteriology quality control, showed that the laboratory did not monitor and document the bacteriology room temperature, relative humidity and incubator temperature from January 2, 2018 to August 15, 2018. 3. The laboratory director and testing personnel confirmed on August 15, 2018, that the laboratory failed to monitor and document the bacteriology room temperature, relative humidity and incubator temperatures. 4. The laboratory performed 81 patients samples for urine cultures from January 2, 2018 to August 15, 2018.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 1. Based on general immunology quality control records review from January 10, 2017 to August 15, 2018, laboratory director and testing personnel interview on August 15, 2018 at 10:12 AM, it was determined that the laboratory failed to include a negative and positive control material when performed CRP (C-reactive protein) tests. The findings include: a. The laboratory performed CRP (C-reactive protein) tests by TECO. b. General immunology quality control records review from January 10, 2017 to August 15, 2018. c. Review of general immunology quality control records, showed that the laboratory did not include a negative and positive control material on January 17, 2018 (ID # 22300), February 1, 2018 (ID # 23651), February 8, 2018 (ID # 24836, # 24856, # 24926), February 14, 2018 (ID # 25734), February 15, 2018 (ID # 25802), February 26, 2018 (ID # 26861), February 28, 2018 (ID # 27002) and March 2, 2018 (ID # 27401). d. The testing personnel confirmed on August 15, 2018, that the laboratory did not include nor document control material during those days. 2. Based on endocrinology quality control records review from January 10, 2017 to August 15, 2018, laboratory director and testing personnel interview on August 15, 2018 at 10:24

	AM, it was determined that the laboratory failed to include a negative and positive control material when performed hCG (human Chorionic Gonadotropin) tests. The findings include: a. The laboratory performed hCG (human Chorionic Gonadotropin) tests by Alere hCG reagents. b. Endocrinology quality control records review from January 10, 2017 to August 15, 2018. c. Review of endocrinology quality control records, showed that the laboratory did not include a negative and positive control material on March 22 2017 (ID # 03058 and # 03061), December 9, 2017 (ID # 20214) and December 12, 2017 (ID # 20450). d. The testing personnel confirmed on August 15, 2018, that the laboratory include but not document control material during those days.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on syphilis serology quality control records review from January 13, 2018 to August 15, 2018, laboratory director and testing personnel interview on August 15, 2018 at 9:48 AM, it was determined that the laboratory failed to include at least once a day, a negative control material and a control material with tittered reactivity when patients specimens were tested for syphilis serology by Rapid Plasma Reagin (RPR) quantitative tests. The finding includes: 1. The laboratory performed Rapid Plasma Reagin (RPR) by TECO RPR Reagents Set. 2. Review of syphilis serology quality control from January 13, 2018 to August 15, 2018, showed that the laboratory did not include at least once a day, a negative control material and a control material with tittered reactivity when the following patients specimen was processed and report: Identification number Date Results 25817 02/15/2018 R 1:4 dills. 28503 03/19/2018 R 1:8 dills. 28492 03/19/2018 R 1:8 dills. 35463 05/30/2018 R 1:4 dills. 38893 06/28 /2018 R 1:8 dills. 39202 07/05/2018 R 1:4 dills. 3. The testing personnel confirmed on August 15, 2018, that the laboratory did not include at least once day, a negative control material and a control material with tittered reactivity when patients specimens were tested for syphilis serology quantitative those days.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observations, procedures manual, quality control records review from January 2, 2017 to august 15, 2018, laboratory director and testing personnel interview on August 15, 2018 at 12:40 PM, it was determined that the laboratory

	failed to follow the established Quality Assessment Program to monitor and evaluate the following requirements for analytic systems: 1. Failed to monitor and document the bacteriology room temperature, relative humidity and incubator temperature. Refer to D5413. 2. Failed to include a negative and positive control material when performed CRP (C-reactive protein) tests. Refer to D5449 (1). 3. Failed to include a negative and positive control material when performed hCG (human Chorionic Gonadotropin) tests. Refer to D5449 (2). 4. Failed to follow the manufacturer's instructions when patient specimen were tested for quantitative RPR (Rapid Plasma Reagin) by TECO. Refer to D5451.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observations, procedures manual , quality control records review and laboratory director and testing personnel interview on August 15, 2018 at 12:48 PM, 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 requirement for analytical systems and quality assessment requirements. Refer to D6020 and D6021.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observations, quality control records review and laboratory director and testing personnel interview on August 15, 2018 at 12:45 PM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. Failed to monitor and document the bacteriology room temperature, relative humidity and incubator temperature. Refer to D5413. b. Failed to include a negative and positive control material when performed CRP (C-reactive protein) tests. Refer to D5449 (1). c. Failed to include a negative and positive control material when performed hCG (human Chorionic Gonadotropin) tests. Refer to D5449 (2). d. Failed to follow the manufacturer's instructions when patient specimen were tested for quantitative RPR (Rapid Plasma Reagin) by TECO. Refer to D5451.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	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, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) records review and laboratory director and testing personnel interview on August 15, 2018 at 12:48 PM, it was determined that laboratory failed to ensure compliance with quality assessment (QA) requirements. The finding includes: 1. The laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the following requirement for pre-analytic systems: a. failed to follow the written policies for urinalysis specimen processing, urinalysis samples must perform within 1 hour after the sample was taken, on August 15, 2018. Refer to D5311. 2. The laboratory did not evaluate the established Quality Assessment Program to monitor and evaluate the following requirement for analytic systems: a. failed to monitor and document the bacteriology room temperature, relative humidity and incubator temperature. Refer to D5413. b. failed to include a negative and positive control material when performed CRP (C-reactive protein) tests. Refer to D5449 (1). c. failed to include a negative and positive control material when performed hCG (human Chorionic Gonadotropin) tests. Refer to D5449 (2). d. failed to follow the manufacturer's instructions when patient specimen were tested for quantitative RPR (Rapid Plasma Reagin) by TECO. Refer to D5451.
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 observations, quality control records review and laboratory director and testing personnel interview on August 15, 2018 at 12:48 PM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory testing personnel failed the following quality control procedures: a. to monitor and document the bacteriology room temperature, relative humidity and incubator temperature. Refer to D5413. b. to include a negative and positive control material when performed CRP (C-reactive protein) tests. Refer to D5449 (1). c. to include a negative and positive control material when performed hCG (human Chorionic Gonadotropin) tests. Refer to D5449 (2). d. to follow the manufacturer's instructions when patient specimen were tested for quantitative RPR (Rapid Plasma Reagin) by TECO. Refer to D5451.