Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0901411	05/16/2018
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Plaza Carolina Inc	Ofc #12 3rd Floor Plaza Carolina Mall, Carolina, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory personnel records (years 2016 to 2018) review and testing personnel interview on May 16, 2018 at 1:25 PM, it was determined that the laboratory failed to follow the written policies to assess the annual competency of the following laboratory personnel since May 16, 2016: clinical consultant, general supervisor and testing personnel. The findings include : 1. On May 16, 2018 at 1:25 PM, the laboratory personnel records showed that the laboratory did not perform the annual competency of the following laboratory personnel since May 16, 2016: clinical consultant, general supervisor and testing personnel. 2. The testing personnel confirmed on May 16, 2018 at 1:25 PM, that the annual competency of the following laboratory personnel were not since May 16, 2016: clinical consultant, general supervisor and testing personnel.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by:

	Based on quality assessment procedure manual, quality assessment personnel competence records (years 2016 to 2018) review and testing personnel interview on May 16, 2018 at 1:25 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the annual competency of the following laboratory personnel since May 16, 2016: clinical consultant, general supervisor and testing personnel The findings include: 1. Review of the quality assessment procedure manual showed that evaluations of the personnel competence must be performed annually. 2. The laboratory did not performed the annual competence evaluation of the laboratory personnel since May 16, 2016. Refer to D 5209.
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 written procedures, syphilis quality control records (years 2016 to 2018) review and interview with the testing personnel on May 16, 2018 at 10:47 AM, it was determined that the laboratory failed to follow written procedures for parallel check of new lot of syphilis serology reagents by Rapid plasma reagin (RPR) method. The findings include: 1. The laboratory written procedures establish to perform and document parallel check for every new lot of syphilis serology reagents (RPR method) prior to place in routine use. 2. On May 16, 2018 at 10:47 AM, the syphilis quality control records showed that the laboratory placed in routine use the new lot of RPR reagents (lot 7C22R6) on August 1, 2017. However, the laboratory did not performed the parallel check for this new lot. 3. The testing personnel confirmed on May 16, 2018 at 10:47 AM, that the laboratory did not perform nor document parallel check for this lot of RPR reagents prior to place in routine use on August 1, 2017 and used until September 1, 2017. 4. From August 1, 2017 to September 1, 2017, the laboratory processed and reported 12 out of 12 patients specimens for RPR with this reagents lot.
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 syphilis serology quality control records(years 2016 to 2018) review and testing personnel interview on May 16, 2018 at 9:35 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 2 out of 2 patient specimen were tested for syphilis serology by Rapid plasma reagin (RPR) method. The findings include: 1. On May 16, 2018 at 9:35 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. Also, must be checked and

	monitored the room temperature, the rotator's rpm and needle calibration each day of testing. 2. From January 10, 2016 to May 15, 2018, the syphilis serology quality control records showed that the laboratory did not include the tree levels of control material nor monitored the room temperature, the rotator's rpm and needle calibration when it processed and reported 2 out of 2 patients specimens for syphilis serology by RPR method on June 17, 2017 (patients specimens #2525 and #2527) . 3. The testing personnel confirmed on May 16, 2018 at 9:35 AM, that the syphilis serology quality control record did not include the control procedures results on June 17, 2017. She stated that the quality control procedures was performed but not documented.
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: Based on rheumatoid arthritis (RA) quality control records(years 2016 to 2018) review and testing personnel interview on May 16, 2018 at 10:30 AM, it was determined that the laboratory failed to include a negative and positive control material when patient specimen were tested for RA quantitative tests. The findings include: 1. On May 16, 2018 at 10:30 AM, from January , 2016 to May 15, 2018, the RA quality control records showed that the laboratory did not include the negative and positive control material when it processed and reported the patient specimen # 342 for RA quantitative on June 14, 2017. 2. The testing personnel confirmed on May 16, 2018 at 10:35 AM, that the RA quality control record did not include the controls results on June 17, 2017. She stated that the quality control procedures was performed but not documented.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of complete cell count (CBC) tests quality control Levy-Jennings charts records (years 2017 to 2018) review and testing personnel interview on May 16, 2018 at 1:10 PM, it was determined that the laboratory did not evaluate , document or take remedial actions when the quality control results showed deviations (outliers, shift or trends). The findings include: 1. The laboratory validated the CBC tests by the Act 5 Diff. system in July 2017. 2. On May 16, 2018 at 1:10 PM, from April 18, 2018 to May 16, 2018, the red blood cells (RBC) and hematocrit (HCT) Levy-Jennings quality control chart showed trends above the established mean of the three levels of control materials and no remedial action were taken nor documented. 3. The testing personnel confirmed on May 16, 2018 at 1:10 PM, that the laboratory did not take remedial action for those trends deviations from April 18, 2018 to May 16,

	2018. 4. From April 18, 2018 to May 16, the laboratory processed and reported 73 out of 73 CBC patients specimens by the Act 5 Diff system.
D5809	TEST REPORT CFR(s): 493.1291(e) The laboratory must, upon request, make available to clients a list of test methods employed by the laboratory and, as applicable, the performance specifications established or verified as specified in 493.1253. In addition, information that may affect the interpretation of test results, for example test interferences, must be provided upon request. Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results or interpretation of test results. This STANDARD is not met as evidenced by: Based on CBC tests reported records (year 2017 and 2018) review and interview with the testing personnel on May 16, 2018 at 1:25 PM, it was determined that the laboratory failed to perform the pertinent updates information for the 73 out of 73 CBC tests results reported and processed by the new system Act 5 Diff from April 18, 2018 to May 16, 2018. The findings include: 1. The laboratory validated the Act 5 Diff system in July 2017. 2. The laboratory processed 73 out of 73 CBC patients specimens by the Act 5 Diff system from April 18, 2018 to May 16, 2018. 3. On May 16, 2018 at 1:25 PM, the CBC tests reported records showed that the laboratory included in the 73 out of 73 CBC results, the former CBC analyzer system information (normal values and method T890 system) from April 18, 2018 to May 16, 2018. 4. The testing personnel confirmed on May 16, 2018 at 1:25 PM, that the laboratory did not perform the pertinent updates information for the 73 out of 73 CBC tests results reports processed by the new system Act 5 Diff from April 18, 2018 to May 16, 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 CBC tests reported records (year 2017 and 2018) and interview with the testing personnel on May 16, 2018 at 1:25 PM, written procedures, syphilis serology quality control records (years 2016 to 2018), rheumatoid arthritis (RA) quality control records (years 2016 to 2018), CBC tests quality control Levy-Jennings charts records (years 2017 to 2018), quality assessment procedure manual, quality assessment personnel competence records (2016-2018) review and testing personnel interview on May 16, 2018 at 1:25 PM, it was determined that the laboratory director failed to fulfill his 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 ensure that the CBC tests results included the pertinent updates information from April 18, 2018 to May 16, 2018. Refer to D 6079.

	2. The laboratory director did not comply with the analytical systems requirements. Refer to D 6093. 2. The laboratory director did not comply with the quality assessment requirements. Refer to D 6094.
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 CBC tests reported records (year 2017 and 2018) and interview with the testing personnel on May 16, 2018 at 1:25 PM, it was determined that the laboratory director failed to ensure that the CBC tests results included the pertinent updates information from April 18, 2018 to May 16, 2018. Refer to D 5809.
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 written procedures, syphilis serology quality control records (years 2016 to 2018), rheumatoid arthritis (RA) quality control records (years 2016 to 2018), CBC tests quality control Levy-Jennings charts records (years 2017 to 2018) review and testing personnel interview on May 16, 2018 at 1:10 PM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements of syphilis serology. Refer to D 5401 and D 5405. 2. The laboratory director failed to ensure compliance with the analytic system requirements of general serology. Refer to D 5449. 3. The laboratory director failed to ensure compliance with the requirements of hematology. Refer to D 5481.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 quality assessment procedure manual, quality assessment personnel competence records (2016-2018) review and testing personnel interview on May 16, 2018 at 1:25 PM, it was determined that laboratory director failed to ensure compliance with general system quality assessment requirements. The finding includes: 1. The laboratory director failed to to assess the general laboratory systems for the laboratory personnel competency requirement. Refer to D 5291.
D6141	GENERAL SUPERVISOR CFR(s): 493.1459 The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart. This CONDITION is not met as evidenced by:
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 written procedures, syphilis serology quality control records (years 2016 to 2018), rheumatoid arthritis (RA) quality control records(years 2016 to 2018), CBC tests quality control Levy-Jennings charts records (years 2017 to 2018) review and testing personnel interview on May 16, 2018 at 1:10 PM, it was determined that the general supervisor failed to perform day-to-day supervision for the personnel that performing testing and reporting test results. Refer to D 5401, D 5405, D 5449, 5481 and D 5809.
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 written procedures, syphilis serology quality control records (years 2016 to 2018), rheumatoid arthritis (RA) quality control records(years 2016 to 2018), CBC tests quality control Levy-Jennings charts records (years 2017 to 2018) review and testing personnel interview on May 16, 2018 at 1:10 PM, it was determined that testing personnel failed to follow quality control procedures. The findings include: 1. The testing personnel failed to follow quality control procedures for syphilis serology. Refer to D 5401 and D 5405. 2. The testing personnel failed to follow quality control procedures for general serology. Refer to D 5449. 3. The testing personnel failed to follow quality control procedures for hematology. Refer to D 5481.