Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D0658040	**(X3) Date Survey Completed** 04/25/2019
Name of Provider or Supplier Laboratorio Clinico Tropical By Villa Ana	**Street Address, City, State** Call Intendente Ramirez Num 2, Caguas, 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**
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 Mycoplasma IGM validation records, Mycoplasma IGM testing records (from February 4, 2019 to April 24, 2019) review and interview with the laboratory supervisor on April 25, 2019 at 10:00 AM, it was determined that the laboratory failed to include each day of testing a negative and a positive control materials when 49 out of 49 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from February 4, 2019 to April 24, 2019. The findings include : 1. The laboratory performed the validation of the Mycoplasma IgM qualitative tests by the Immuno Card Mycoplasma method on January 16, 2019. 2. On April 25, 2019 at 10:00 AM, the Mycoplasma IGM testing records showed that the laboratory did not include each day of testing the negative nor the positive control materials when 49 out of 49 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from February 4, 2019 to April 24, 2019. The laboratory included the negative and a positive control materials with every new lot of the Immuno Card Mycoplasma reagents Kit. 3. The general supervisor confirmed on April 25, 2019 at 10:00 AM, that the laboratory did not include each day of testing the negative nor the positive control materials. She stated that the laboratory includes the negative and the positive control materials with every new lot of the Immuno Card Mycoplasma reagents Kit.
D5479	CONTROL PROCEDURES

	CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Act 5 diff system quality control records (years 2018 and 2019), Act 5 diff control materials manufacturer instructions review, direct observation and general supervisor interview on April 25, 2019 at 9:15 AM, it was determined that the laboratory failed to follow the manufacturer's specifications for using the complete blood count (CBC) controls materials when it processed and reported 109 out of 109 CBC patients specimens from April 16, 2019 to April 25, 2019. The findings include: 1. The laboratory analyzed and reported the CBC patient's specimens by the Act 5 diff system. 2. The manufacturer instructed the laboratory to use the control materials with 15 consecutive days open-vial stability. 3. On April 25, 2019 at 9:15 AM, it observed that the three levels of Act 5 diff control material in use, were opened on March 30, 2019 (lot 360319, Lot 380319 and lot 370319). The laboratory used the three levels of control materials with exceeded manufacturer stability from April 16, 2019 to April 25, 2019. 4. The general supervisor confirmed on April 25, 2019 at 9:15 AM, that the three vials of control materials used from April 16, 2019 to April 25, 2019 were opened on March 30, 2019. 5. The laboratory processed and reported 109 out of 109 CBC patients specimens by the Act 5 diff system from April 16, 2019 to April 25, 2019.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) 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 Mycoplasma IGM validation records, Mycoplasma IGM testing records (from February 4, 2019 to April 24, 2019) review and interview with the laboratory supervisor on April 25, 2019 at 10:00 AM, it was determined that technical consultant failed to ensure compliance with the requirements for the analytic system of the qualitative Mycoplasma IgM test. Refer to D 5449 (The laboratory failed to include each day of testing a negative and a positives control materials when 49 out of 49 patients serum specimens were tested for qualitative Mycoplasma IgM tests from February 4, 2019 to April 24, 2019).
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 Mycoplasma IGM testing records (from February 4, 2019 to April 24, 2019), Act 5 diff system quality control records (years 2018 and 2019), Act 5 diff control materials manufacturer instructions review, direct observation and interview with the laboratory supervisor on April 25, 2019 at 10:00 AM, it was determined that laboratory director failed to comply with the analytic system requirements for the CBC and Mycoplasma qualitative tests. Refer to D 5449 (The laboratory failed to include each day of testing a negative and a positives control materials when 49 out of 49 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from February 4, 2019 to April 24, 2019). Refer to D 5479 (The the laboratory failed to follow the manufacturer's specifications for using the CBC controls materials when it processed and reported 109 out of 109 CBC patients specimens by the Act 5 diff system from April 16, 2019 to April 25, 2019).
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 Act 5 diff system quality control records (years 2018 and 2019), Act 5 diff control materials manufacturer instructions review, direct observation and general supervisor interview on April 25, 2019 at 9:15 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for the analytic systems of the CBC tests. Refer to D 5479 (The laboratory failed to follow the manufacturer's specifications for using the CBC controls materials).
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 Mycoplasma IGM testing records (from February 4, 2019 to April 24, 2019), Act 5 diff system quality control records (years 2018 and 2019), Act 5 diff control materials manufacturer instructions review, direct observation and interview with the laboratory supervisor on April 25, 2019 at 10:00 AM, it was determined that the testing personnel failed to follow quality control procedures for the CBC and Mycoplasma IGM qualitative tests from February 4, 2019 to April 25, 2019. Refer to D 5449 (The laboratory failed to include each day of testing a negative and a positives control materials when 49 out of 49 patients serum specimens were tested for qualitative Mycoplasma IgM by the Immuno Card Mycoplasma method from February 4, 2019 to April 24, 2019). Refer to D 5479 (The laboratory failed to follow

	the manufacturer's specifications for using the CBC controls materials when it processed and reported 109 out of 109 CBC patients specimens from April 16, 2019 to April 25, 2019).