Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0670892	09/06/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Modelo	Barbosa Street #170, Catano, 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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on BioSign Flu A&B manufacturer's instructions, Influenza A&B tests reports records review and general supervisor interview on September 4, 2019 at 11:00 AM, it was determined that the laboratory failed to follow manufacturer's instruction for report information when patients specimens were reported for Influenza A&B tests by BioSign Flu A&B from January 1,2019 to September 4, 2019. The findings include: 1 The laboratory uses the BioSign Flu A&B to detect the Influenza A&B antigen as Waived complexity. 2. The BioSign Flu A&B manufacturer's instructions for the intended uses establish that the negative test results are presumptive it is recommended this results be confirmed by viral culture and establish limitations for the negative test result (included in the insert). 3. On September 4, 2019 at 11:00 AM, the Influenza A&B tests reports records showed that the laboratory did not include the manufacturer required information. The laboratory reported the negative results Influenza A or B as final results. 4. The general supervisor confirmed on September 4, 2019 at 10:10 AM, that the Influenza A&B tests reports did not include the required information. 5. The laboratory reported the 100 percent of patients specimens for Influenza A&B tests by BioSign Flu A&B from January 1,2019 to September 4, 2019.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have

	deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on direct observation, white blood cell (WBC) differential exams records (years 2018 and 2019) review and interview with the general supervisor on September 6, 2019 at 11:10 AM, it was determined that the laboratory stained 822 out of 822 patients blood smears to performed WBC differential exams with Wright stain that exceeded the expiration date from April, 2018 to September 6, 2019. The findings include: 1. On September 6, 2019 at 11:10 AM, the laboratory used the Wright stain (Lot 712, expired in April, 2018) to stain patients blood smears. This stain was received on October 31, 2017 and was used with expired date from April, 2018 to September 6, 2019. 2. The general supervisor confirmed that the laboratory used the wright stain with expired date from April, 2018 to September 6, 2019. 3. The laboratory stained 822 out of 822 patients blood smears to performed WBC differential exams with Wright stain that exceeded the expiration date from April, 2018 to September 6, 2019.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: 1. Based on Clinitek system manufacturer's instructions, lack of Clinitek system preventive maintenance record and general supervisor interview on September 6, 2019 at 10:20 A.M., it was determined that the laboratory failed to follow written instructions for preventive maintenance when 2,284 urinalysis patients specimens were analyzed and reported by the Clinitek system from January 1, 2019 to September 6, 2019. The findings include: a. The laboratory analyzed the urine patients specimens for urinalysis tests by the Clinitek system. b. The manufacturer instructed that the laboratory perform a daily and periodic preventive maintenance for the Clinitek system. c. The laboratory did not performed nor document the preventive maintenance to the Clinitek system from January 1, 2019 to September 6, 2019. d. The general supervisor stated on September 6, 2019 at 10:20 A.M., that the laboratory performed the required preventive maintenance but not documented any records. e. The laboratory analyzed and reported 2,284 urinalysis patients specimens by the Clinitek system from January 1, 2019 to September 6, 2019. 2. Based on laboratory preventive maintenance records review (year 2017 and 2019) and general supervisor interview on September 6, 2019 at 10:20 A.M., it was determined that the laboratory failed to perform the annual calibration of the Dynac II centrifuge in March 2018, where 4,298 urine patients specimens were centrifuged to perform the microscopic examination from April 1, 2018 to September 6, 2019. The findings included: a. The laboratory centrifuges the urine patients specimens to perform the microscopic examination by the Dynac II centrifuge from April 1, 2018 to September 6, 2019. b. On September 6, 2019 at 10:20 A.M., the laboratory preventive maintenance records showed that the annual calibration of the Dynac II centrifuge was due in March 2018. c. The general supervisor confirmed on September 6, 2019 at 10:20 AM, that the calibration of the

	Dynac II centrifuge was due in March 2018. d. The laboratory performed and reported 4,298 urine patients specimens for microscopic examination from April 1, 2018 to September 6, 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 Clinitek system manufacturer's instructions, lack of Clinitek system preventive maintenance record, laboratory preventive maintenance records review (year 2017 and 2019) and general supervisor interview on September 6, 2019 at 10:20 A.M., t was determined that technical consultant failed to ensure compliance with the requirements for analytic systems of urinalysis. Refer to D 5429 (1) (The laboratory did not follow written instructions for preventive maintenance when 2,284 urinalysis patients specimens were analyzed and reported by the Clinitek system from January 1, 2019 to September 6, 2019). Refer to D 5429 (2) (The laboratory did not perform the annual calibration of the Dynac II centrifuge in March 2018, where 4,298 urine patients specimens were centrifuged to perform the microscopic examination from April 1, 2018 to September 6, 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 direct observation, white blood cell (WBC) differential exams records (years 2018 and 2019), Clinitek system manufacturer's instructions, lack of Clinitek system preventive maintenance record, laboratory preventive maintenance records review (year 2017 and 2019) and general supervisor interview on September 6, 2019 at 11:10 AM, it was determined that the laboratory director failed to comply with the requirements of the analytic system. Refer to D 5417 (The laboratory stained 822 out of 822 patients blood smears to performed WBC differential exams with Wright stain that exceeded the expiration date from April, 2018 to September 6, 2019). Refer to D 5429 (1) (The laboratory did not follow written instructions for preventive maintenance when 2,284 urinalysis patients specimens were analyzed and reported by the Clinitek system from January 1, 2019 to September 6, 2019). Refer to D 5429 (2) (The laboratory did not perform the annual calibration of the Dynac II centrifuge in March 2018, where 4,298 urine patients specimens were centrifuged to perform the microscopic examination from April 1, 2018 to September 6, 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 direct observation, white blood cell (WBC) differential exams records (years 2018 and 2019) review and interview with the general supervisor on September 6, 2019 at 11:10 AM, it was determined that technical supervisor failed to ensure compliance with the requirements for analytic systems in the hematology specialty. Refer to D 5417 (The stained 822 out of 822 patients blood smears to performed WBC differential exams with Wright stain that exceeded the expiration date from April, 2018 to September 6, 2019).