Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658271	03/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Mayaguez	Urb Perez Morris, Calle Mayaguez 142, San Juan, 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
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 observation, quality control records review (years 2019-2020) and laboratory general supervisor interview on March 5, 2020 at 11:45 AM, it was determined that the laboratory used the Wright stain reagent kit with exceeded expiration date. The findings include: 1. The laboratory uses Wright's One Step Stain for hematology manual differential count. 2. The records showed that the laboratory used the following Wright's One Step Stain reagent Lot # 4857-00, expiration date: August 2010 with exceeded expiration date from September 2019 to March 4, 2020. 3. The laboratory processed and reported twenty one (21) CBC manual differential count patient's samples 20 days during those days. 4. The laboratory supervisor confirmed that the laboratory used this Wright's One Step Stain reagent with exceeded expiration for the 100 % of manual differential count patient's samples stained for Wright's One Step Stain September 2019 to March 4, 2020.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and

	negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on endocrinology quality control records review (years 2019-2020) and laboratory general supervisor interview at 11:00 AM on March 5, 2020, it was determined that the laboratory did not evaluate the new lots of hCG (human chorionic gonadotropin) test for positive and negative reactivity prior to placed it in routine use. The findings include: 1. The laboratory quality control records were review from August 12, 2019 to March 3, 2020. 2. The laboratory received the following reagent kit and no evaluation of their reactivity was performed Lot. # Expiration Date #Tests 069943 6/30/2020 14 072242 7/31/2021 6 3. The laboratory processed and reported twenty (20) hCG (human chorionic gonadotropin patient's samples since August 12, 2019 to March 3, 2020. (August 12, 2019-January 28, 2020 = 14 hCG patient's sample tests and February 5, 2020 to March 2, 2020 = 6 hCG patient's sample tests) 4. The laboratory general supervisor confirmed that the laboratory did not evaluate the new lots of hCG (human chorionic gonadotropin) test for positive and negative reactivity prior to placed it in routine use.
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 hematology and endocrinology quality control records review (years 2019-2020) and laboratory general supervisor interview at 11:30 AM on March 5, 2020, it was found that the laboratory director did not assure that quality control procedures related to used the Wright stain reagent kit with exceeded expiration date and evaluation of new reagents lots were followed. The findings include: 1. The laboratory used the Wright stain reagent kit with exceeded expiration date. Refer to D5417. 2. The laboratory did not evaluate the new lots of hCG (human chorionic gonadotropin) test for positive and negative reactivity prior to placed it in routine use. Refer to D5471.
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 hematology and endocrinology quality control records review (years 2019-2020) and laboratory general supervisor interview at 11:30 AM on March 5, 2020, it was determined that the general supervisor did not assure that quality control procedures were followed by the testing personnel. The findings include: 1. The laboratory used the Wright stain reagent kit with exceeded expiration date. Refer to D5417. 2. The laboratory did not evaluate the new lots of hCG (human chorionic

	gonadotropin) test for positive and negative reactivity prior to placed it in routine use. Refer to D5471.