Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0672866	02/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mayaguez Endocrine & Clinical Lab	22 N Peral St, Mayaguez, 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
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of virology quality control records (September 30, 2020 to February 19, 2021) and laboratory technical supervisor interview on February 19, 2021 a 1:00 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for virology tests (Covid PCR test) . Refer to D 5405 (failed to follow the IFU when patient specimen were tested for Covid PCR tests by Biofire method)
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 Mycoplasma pneumoniae quality control records patient records review (April 8, 2020 to February 19, 2021) and interview with the laboratory technical supervisor on February 19, 202 at 9:30 A.M., it was determined that the laboratory failed to meet the requirements in the subspecialty of General Immunology. The

	finding includes: a. The laboratory did not include an external positive and a negative control material each day of patient testing. Refer to : 5449- The laboratory did not include positive and negative control material
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 Biofire Respiratory Panel 2.1 system and virology quality control records review since september 30, 2020 and laboratory technical supervisor interview on February 19, 2019 at 10:30 a.m. , it was determined that the laboratory failed to follow instructions for use (IFU) when patient specimens were tested for Covid molecular tests by the Biofire system. The findings include: 1. The laboratory uses Biofire Respiratory Panel 2.1 system to perform Covid molecular patient tests. 2. The manufacturer establishes that it is recommended that when using the BioFire RP2.1-EZ under Emergency Use Authorization (EUA), external controls be tested at minimum: a. When receiving a new shipment of pouches b. When training a new user c. Other commercial external control materials (positive and negative) may be available and appropriate for use with the BioFire RP2.1-EZ. Use in accordance with the manufacturers ' instructions and appropriate accrediting organization requirements, as applicable. 3. The laboratory establishes that external controls be tested when receiving a new shipment of pouches. 4. The laboratory technical supervisor confirmed on February 19, 2021 at 10:30. a.m. that the laboratory failed to follow the accrediting organizations requirements. 5. The laboratory processed and reported 586 Covid PCR tests since September 30, 2020.
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 review of Mycoplasma pneumonia IgM quality control results(April 8, 2021 to February 19, 2021) patient test results records and interview with the laboratory technical supervisor on February 19, 2019 at 10: 30 A.M. it was found that the laboratory did not include a positive and a negative control material each day of patient testing. The findings include: 1. The laboratory began to perform patient's test for Mycoplasma pneumonia on April 8, 2020. 2. Review of the quality control and patient test results records, showed that positive and negative controls were included when a new reagent box was opened. 3. The laboratory technical supervisor stated on February 19, 2021 at 10:30 A.M., that they included a negative and a positive control material when a new reagent box was opened and documented the procedural control

	with each patient. 4. The patient test records showed that the laboratory performed and reported a total of 335 patient's samples. since April 8, 2020.
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 Virology quality control records review (September 30, 2020 to February 19, 2021) , Mycoplasma pneumonia IgM quality control records (April 8, 2020 to February 19, 2021) and interview with the laboratory technical supervisor on February 19, 2021 at 10:40 AM, it was determined that the laboratory director failed to fulfill his responsibilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D6093 .
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 Virology quality control records (September 30, 2020 to February 19, 2021) , Mycoplasma pneumonia IgM quality control records (April 8, 2020 to February 19, 2021) and interview with the laboratory technical supervisor on February 19, 2021 at 10:40 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5405 (the laboratory failed to follow instructions for use (IFU) when patient specimens were tested for Covid molecular tests by the Biofire system.) and D5449 (the laboratory did not include a positive and a negative control material each day of patient testing.)
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 virology quality control records review (September 30, 2020 to February 19, 2021), Mycoplasma pneumonia IgM quality control records (April 8, 2020 to February 19, 2021) and interview with the laboratory technical supervisor on February 19, 2021 at 12:30 PM, it was determined that the technical supervisor failed to follow laboratory quality control requirements. Refer to D5405 and D5449.