Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658271	(X3) Date Survey Completed 11/13/2024
Name of Provider or Supplier Laboratorio Clinico Mayaguez	**Street Address, City, State** 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
D0000	A complaint survey at Laboratorio Clinico Mayaguez was completed on November 13, 2024 by Puerto Rico state agency. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. Specific standard level deficiencies cited are as follows : D5311, D5317, D5801, D6093 and D6144.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on temperature checks records (year 2024), written protocol titled "Protocol for specimen arriving from outside the laboratory" and interview with the laboratory general supervisor on November 13, 2024, at 2:40 PM; it was determined that the laboratory did not follow the established procedure for specimen arrival. The findings include: 1. The laboratory general supervisor stated on November 13, 2024, at 2:40 PM, that Laboratorio Clinico Mayaguez acts as a reference laboratory for Doctor's Clinical Laboratory at: 1010 10ST Estate Thomas, St Thomas, VI 00802. 2. .Review of the "Protocol for specimen arriving from outside the laboratory" on November 13, 2024, at 2:40 PM, showed that after the opening of the samples package the laboratory must check for temperature adequacy according to sample requirements. 3. On November 13, 2024, at 2:42 PM, the temperature check records for specimens

	received from Doctor's Clinical Laboratory were requested. The laboratory general supervisor stated at 3:00 PM, there were no temperature records from samples received from Doctor's Clinical Laboratory.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of written procedures for sample collection and interview with the laboratory general supervisor on November 13, 2024, at 1:30 PM, it was determined that the laboratory did not provide to the referral laboratory written instructions for specimens handling. The findings include: 1. The laboratory acts as a reference laboratory for Doctor's Clinical Laboratory at: 1010 10ST Estate Thomas, St Thomas, VI 00802. 2. The laboratory general supervisor stated on November 13,2024 at 1:30 PM, that the referred samples could be tested at Laboratorio Clinico Mayaguez / doing business as (dba) Specialty Laboratories of Puerto Rico or another external reference laboratory contracted by Laboratorio Clinico Mayaguez. 3. During interview on November 13,2024 at 1:45 PM, laboratory general supervisor stated that those samples processed at Laboratorio Clinico Mayaguez /dba Specialty Laboratories of Puerto Rico, no specimen collection guide was available.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of patient specimens list referred by Doctor's Clinical Laboratory to Laboratorio Clinico Mayaguez and interview with the laboratory general supervisor on November 7, 2024, at 9:40 AM, it was found that Laboratorio Clinico Mayaguez did not process not reported 29 out of 29 patient's sample referred between October 7, 2024 and October 10,2024. The findings include: 1. The list of patient samples referred by Doctor's Clinical Laboratory was reviewed: a. The patient samples on October 7, 2024, were received at the Laboratorio Clinico Mayaguez on October 9, 2024. (Reviewed on November 7,2024 at 9:40 AM) b. The patient samples on October 10, 2024, were received at the Laboratorio Clinico Mayaguez on October 14, 2024. (Reviewed on November 7,2024 at 9:40 AM) 2. The laboratory general supervisor stated on November 7,2024 at 9:45 AM, that the samples were received in

	the laboratory, however, were not processed not reported, due nonpayment issues. 3. The general supervisor of the laboratory confirmed on November 7,2024 at 9:50 AM, that the samples were returned to Doctor's Clinical Laboratory on October 21, 2024.
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 temperature check records (year 2024) and laboratory general supervisor interview on November 13, 2024, at 5:45 P.M., it was determined that the laboratory director failed to assure that the receiving temperature of samples received at that laboratory, and the provide sample collection guide. Refer to: D5311 and D5317.
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 temperature check records (year 2024) and laboratory general supervisor interview on November 13, 2024, at 5:45 P.M, it was determined that the general supervisor did not assure that the personnel in charge of sample receiving monitor and documented the samples arriving temperature. Refer to: D5311 and D5317.