Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0672312	06/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Salud Publica De Puerto Rico	Calle Periferal, Edif A 2do Piso,Antiguo Hospital, 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	The Centers for Medicare & Medicaid Services (CMS) Survey Branch federal surveyors conducted an announced CLIA recertification survey at LABORATORIO SALUD PUBLICA DE PUERTO RICO from June 10, 2024 to June 11, 2024. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The following standard level deficiencies were found during the announced routine CLIA recertification survey ending on June 11, 2024.
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 a review of laboratory procedures, lack of received specimen documentation, and an interview with Technical Supervisor (TS) #6, the laboratory failed to document specimen acceptability for received (TB) specimens in for 2 of 2 years (June 2022 to June 2024). Findings include: 1. The Transportation of Specimen to the laboratory procedure states, "Samples should be transported in a bleach cooler or a box with ice or a chemical pad to keep them cold. The use of a thermometer is required to monitor the temperature inside the refrigerator. They should not be frozen or hot.."). 2. A review of the laboratory's specimen receipt log on June 11, 2024, revealed no documentation of the specimen disposition upon receipt into the laboratory for 2 of 2 years (June 2022 to June 2024). 3. Per the CMS 116 form, signed by the Laboratory Director on June 10, 2024, there are an estimated 2,509

	Mycobacteriology specimens performed annually. 4. The TS #6 and laboratory director confirmed the above findings during an interview on June 11, 2024 at 10:30 am.
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, review of media preparation records, microbiology testing worksheets, and interview with Testing Personnel (TP) #4, it was determined that the laboratory utilized dehydrated culture media that had exceeded its expiration date on two of two patients in 2024. Findings: 1. During the survey on June 11, 2024, at approximately 1:00 PM, the laboratory media preparation room was observed to contain an open container of BD: Difco Dehydrated Culture Media: Triple Sugar Iron Agar (Lot#8046922), which had an expiration date of 12-31-2022. 2. Review of the media preparation records indicated that the expired BD: Difco Dehydrated Culture Media: Triple Sugar Iron Agar was used to prepare a batch of Triple Sugar Iron Agar (TSI) on March 11, 2024. 3. Examination of microbiology testing worksheets from March 11, 2024 to June 11, 2024 revealed, that the TSI Agar made with the expired dehydrated culture media was utilized for two of two patient tests on April 19, 2024, and May 7, 2024. 4. An interview with TP#4 on June 11, 2024, at 1:30 PM confirmed that the laboratory used expired culture media for patient testing.
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 the lack of quality control records and interview with Technical Supervisor (TS) #6, the laboratory failed to perform quality control (QC) each day of patient testing for the Cepheid Xpert Xpress used for CoV-2 testing for 2 of 2 years (June 2022 to June 2024). Findings Include: 1. On the day of survey, June 11, 2024, the laboratory was unable to provide documentation of external positive and negative QC performed each day of patient testing for specimen analyzed on the Cepheid Xpert Xpress for CoV-2, performed for 2 of 2 years (June 2022 to June 2024). 2. Per the CMS 116, signed by the laboratory director on June 10, 2024, approximately 32,784 virology specimens are analyzed annually. 3. TS#6 confirmed the above findings on June 11, 2024 at 1:45 pm, as they stated QC was performed monthly and with each new lot.