Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0672312	07/15/2026
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	An on-site recertification survey was conducted on July 15, 2026, with the following standard-level deficiencies cited:
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on personnel competency record review, laboratory policy review, and staff interview, the laboratory failed to follow its written policies and procedures for documenting competency assessments for one (1) of thirteen (13) testing personnel. Findings: 1. During a review of personnel competency records on July 15, 2026 at approximately 2:45 PM, Testing Personnel (TP #5) listed on the CLIA Laboratory Personnel Report (CMS-209) was found to have only one (1) competency assessment on file with a completion date of January 26, 2026. The employee's hire date was October 7, 2024, representing over two (2) years of employment with no initial, six (6) -month, or subsequent annual competency assessment documented prior to that date. 2. Review of the laboratory policy titled "Programa de Garantia de Calidad" states: "De ser empleado un empleado nuevo seran durante su etapa inicial (entrenamiento), a los seis meses y al ao del comienzo de sus labores. Luego sera anualmente durante el mes de vencimiento de la evaluacion anterior." The laboratory's own policy requires competency assessments at the initial training stage, at six (6) months, at one (1) year, and annually thereafter from the date of hire. 3. Interview with the Bacteriology Supervisor and Quality Assurance personnel on July 15, 2026 at approximately 3:15 PM confirmed that TP #5 had only one (1) competency assessment performed to date. No initial, six (6)-month, or annual competency assessment was completed in

	accordance with the laboratory's written policy prior to this date. No corrective action or documentation of a remediation plan was identified. 4. The laboratory reports thirteen (13) testing personnel listed on the CMS-209 form.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, temperature record review, and staff interview, the laboratory failed to comply with the manufacturer's required storage temperature for one (1) of one (1) box of Remel BactiDrop Oxidase reagent. Findings: 1. During a laboratory tour of the Bacteriology Room (204) on July 15, 2026, at approximately 1: 00 PM, one (1) box of 50 ampules of Remel BactiDrop Oxidase reagent (Lot #251588; Expiration Date: 01/09/2027) was observed in active use. The manufacturer's label printed on the box specifies a required storage temperature of 20-25C. 2. A review of the Bacteriology Room (204) temperature and humidity monitoring records for the period of January 1, 2026 through July 16, 2026, revealed 85 documented days during which the room temperature fell below the manufacturer's minimum required storage temperature of 20C. 3. On July 15, 2026, at approximately 1:20 PM, an interview with the Bacteriology Supervisor confirmed that there were multiple days during the review period when the room temperature was below the manufacturer's required minimum storage temperature for the Oxidase reagent. No corrective action or documentation of reagent assessment was identified. 4. The laboratory self-reported performing 5,355 bacteriology tests per year.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and interview, the laboratory failed to label and assign an expiration date for one (1) of one (1) bottle of Thermo Scientific N-Acetyl-L-cysteine chemical used in mycobacteriology testing. Findings: 1. During a laboratory tour of the Mycobacteriology Room (249) on July 15, 2026 at approximately 2:00 PM, one (1) bottle of 500g of Thermo Scientific N-Acetyl-L-cysteine (NALC) chemical (Lot #M10I011; Open Date: 06/28/2024) was observed in active use. The bottle was not labeled with an expiration date assigned by the manufacturer or assigned and labeled

	by the laboratory. 2. Interview with the Mycobacteriology Supervisor on July 15, 2026 at approximately 2:05 PM confirmed the NALC bottle was not labeled with an expiration date. 3. The laboratory reports performing 2,706 mycobacteriology tests per year.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on direct observation and interview, the laboratory failed to perform and document the calibration for two (2) of two (2) (random sampling) Traceable thermo-hygrometers used to monitor temperature and humidity in the laboratory. Findings: 1. During a laboratory tour of the Bacteriology Room (204) on July 15, 2026 at approximately 1:00 PM, one (1) Traceable thermo-hygrometer (S/N: 240460944) was observed in active use for monitoring the room temperature and relative humidity of the area. The thermo-hygrometer displayed a calibration sticker indicating the calibration had expired on June 7, 2026. 2. During a laboratory tour of the Mycobacteriology Room (249) on July 15, 2026 at approximately 2:00 PM, one (1) Traceable thermo-hygrometer (S/N: 240460952) was observed in active use for monitoring the room temperature and relative humidity of the area. The thermo-hygrometer displayed a calibration sticker indicating the calibration had expired on June 7, 2026. 3. Interview with the Bacteriology Supervisor on July 15, 2026 at approximately 1:30 PM and the Mycobacteriology Supervisor at approximately 2:30 PM confirmed the thermo-hygrometer calibrations had expired. No corrective action or documentation of an alternative calibration plan was identified. The supervisors stated that calibrations could not be performed at this time due to the fiscal budget window not being open. 4. The laboratory reports performing 5,355 bacteriology and 2,706 mycobacteriology tests per year.