Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658123	09/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Universal	Calle Munoz Rivera 56 Suite 1, Juncos, 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
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: 1. Based on Human chorionic gonadotropin (hCG) patient worksheet records review and laboratory director interview on September 15, 2023 at 11:10 AM, it was determined that the laboratory did not document the required information related to the reagent kits used by the laboratory, nor the identity of the personnel who performed the tests. The findings include: a. On September 15, 2023 at 11:10 AM, the laboratory director stated that the laboratory performs hCG tests with the AimStep kit. b. The hCG test worksheet records showed on September 15, 2023 at 11:10 AM, that the following information must be documented on the daily worksheets: kit, lot, expiration date, and the identity of the personnel who performed the tests. c. On September 15, 2023 at 11:15 AM, review of the hCG worksheets from January 2022 to September 2023 showed that none of the required information was documented. From January 1, 2022 to September 15, 2023, the laboratory processed and reported a total of 100 hCG patient tests. d. During Interview with the laboratory director on September 15, 2023 at 11:20 AM, she confirmed that the required information was not included. 2. Based on review of Mycoplasma Pneumoniae IgM worksheet records and interview with the laboratory director on September 15, 2023 at 12:00 PM, it was determined that the laboratory did not document the required information related to the reagent kits used by the laboratory, nor the identity of the personnel who performed the tests. The findings include: a. On September 15, 2023 at 12:00 PM, the

	laboratory director stated that the laboratory performs Mycoplasma Pneumoniae IgM tests with the Immunocard kit. b. The Mycoplasma Pneumoniae IgM test worksheet records showed on September 15, 2023 at 12:00 PM, that the following information must be documented on the daily worksheets: kit, lot, expiration date, and the identity of the personnel who performed the tests. c. On September 15, 2023 at 12:00 PM, review of the Mycoplasma Pneumoniae IgM worksheets from January 2022 to September 2023 showed that none of the required information was documented. From January 1, 2022 to September 15, 2023, the laboratory processed and reported a total of 591 patient tests. d. During Interview with the laboratory director on September 15, 2023 at 12:15 PM, she confirmed that the required information was not included. 3. Based on review of RPR (Rapid plasma reagin) worksheet records and interview with the laboratory director on September 15, 2023 at 1:45 PM, it was determined that the laboratory did not document the required information related to the reagent kits used by the laboratory, nor the identity of the personnel who performed the tests. The findings include: a. On September 15, 2023 at 1:45 PM, the laboratory director stated that the laboratory performs RPR tests with the AIM RPR Test kit. b. The RPR test worksheet records showed on September 15, 2023 at 1:45 PM, that the following information must be documented on the daily worksheets: kit, lot, expiration date, and the identity of the personnel who performed the tests. c. On September 15, 2023 at 1: 45 PM, review of the RPR worksheets from January 2022 to September 2023 showed that none of the required information was documented. From January 1, 2022 to September 15, 2023, the laboratory processed and reported a total of 2,711 patient tests. d. During Interview with the laboratory director on September 15, 2023 at 2:00 PM, she confirmed that the required information was not included.
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based on the worksheet records review of hCG, Mycoplasma Pneumoniae IgM and RPR tests from January 1, 2022 to September 15, 2023, and laboratory personnel interview on September 15, 2023 at 3:45 PM, it was determined that the testing personnel did not document the required information on the daily patient worksheets. Refer to D5787.