Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2026774	11/15/2021
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico La Victoria	Road 446 Km 3, Hm 5 Bo Robles, San Sebastian, 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
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 General Immunology (COVID-19 IgM/IgG) quality control records review and manufacturer instructions for use (IFU) from April 19, 2021 to June 1, 2021 and interview the laboratory director on November 15, 2021 at 3:16 PM, it was determined that the laboratory did not include an external positive and negative control material each day of COVID-19 rapid test patient testing. The findings include: a. The laboratory use the Healgen COVID-19 IgG/IgM Rapid Test Cassette to perform rapid immunology IgM/IgG patient test. b. The quality control section of the IFU stated that: additional controls may be required according to guidelines or local, state and/or federal regulations (such as 42 CFR 493.1256) or accrediting organizations. c. Review of COVID-19 IgM/IgG quality control at patient results records showed that the laboratory performs patient testing from April 19, 2021 to June 1, 2021, the laboratory did not include every day of testing the positive and the negative external control materials. Instead the laboratory run the external controls when new reagent kit lot or shipment were received. d. From April 19, 2021 to June 1, 2021 the laboratory processed and reported 30 patient samples. e. The laboratory director confirmed on November 15, 2021 at 3:16 PM, that the laboratory failed to include a negative and positive external control materials each day of testing.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Healgen COVID-19 rapid test (IgM/IgG) manufacturer's instructions, COVID-19 IgM/IgG testing records and laboratory director interview by phone on November 15, 2021 at 3:16 PM, it was determined that the laboratory director did not fulfill her responsibilities to ensure that the external control material was run each day of patient testing from April 19, 2021 to June 1, 2021. Refer D5449.