Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D0698569	**(X3) Date Survey Completed** 10/12/2023
Name of Provider or Supplier Lab Hnos Mikasobe	**Street Address, City, State** C Betances St 68, Canovanas, 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 Mycoplasma pneumoniae test IgM quality control records review (years 2022-2023) and laboratory supervisor interview on October 12, 2023 at 11:57 AM, it was determined that the laboratory did not include an external positive and negative control material each day of Mycoplasma pneumoniae patient testing from September 15, 2023 to October 11, 2023. The laboratory process and report 38 out of 49 patient samples. The findings include: 1. Mycoplasma pneumoniae test IgM quality control records was reviewed on October 12, 2023 at 11:20 AM, and showed that the laboratory did not include the external positive and negative control material each day of patient testing from September 15, 2023 to October 11, 2023. 2. The laboratory supervisor confirmed on October 12, 2023 at 11:57 AM, that the laboratory failed to include an external negative and positive control material each day of patient testing from September 15, 2023 to October 11, 2023. The laboratory process and report 38 out of 49 patient samples.
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 Mycoplasma pneumonia test quality control records and interview with the laboratory supervisor on October 12, 2023 at 11:57 AM, it was determined that the laboratory director did not assure that the established quality control program for Mycoplasma pneumonia tests were followed. Refer to D5449.