Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0907839	02/09/2023
Name of Provider or Supplier	**Street Address, City, State**	
Lab Alejandrino, Inc, Corporation	Carr 177 Km 3, Hm 4, Lomas Verdes Ave, 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
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on Quality Assessment (QA) activities records review and laboratory general supervisor interview on February 9, 2023 at 10:10 AM, it was determined that laboratory failed to evaluate and monitor the specimen identification and integrity in the General Laboratory system from August 2022 to November 2022. The findings include: 1. On February 9, 2023 at 9:44 AM, the laboratory QA was requested. The QA showed that the laboratory has established in the sample identification and integrity that the verification were evaluated monthly. 2. On February 9, 2023 at 9:50 AM the QA showed that the laboratory failed to evaluate and monitor the sample identification and integrity requirements from August 2022 to November 2022. 3. The laboratory general supervisor confirmed on February 9, 2023 at 10:10 AM that the laboratory failed to evaluate and monitor the sample identification and integrity from August 2022 to November 2022.
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 Immuno Card Mycoplasma pneumonia manufacturer ' s instructions, Mycoplasma testing records review and laboratory general supervisor interview on February 9, 2023 at 11:50AM , it was determined that the laboratory failed to follow the manufacturer ' s instructions when 6 out of 6 patient specimens were testes for Mycoplasma by Immuno Card Meridian method from November 18 , 20233 to January 4, 2023. The findings include: 1. On February 9, 2023 at 11:45 AM The manufacturer ' s instruction were reviewed and the manufacturer's establishes to perform the mycoplasma test procedures at room temperature from 22 to 25 C. 2. On February 9, 2023 at 11:48 AM the Mycoplasma testing records showed that the laboratory did not follow the manufacturer instruction when it processed patient results the following dates: November 18, 2022; December 7, 2022; December 8, 2022; December 13, 2022; December 14,2022; January 4, 2023. 3. The laboratory general supervisor confirmed on February 9, 2023 at 11:50 AM that the laboratory failed to follow the manufacturer ' s instructions when 6 out of 6 patient specimens were testes for Mycoplasma by Immuno Card Meridian method from November 18 , 20233 to January 4, 2023.
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 rapid test manufacturer's instructions, mycoplasma test records and interview with the laboratory supervisor on February 9, 2023 at 11:50 AM, it was determined that the laboratory director fail to assure that the established quality control program for Mycoplasma pneumonia tests were followed. Refer to D5417.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment 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 Quality Assessment (QA) records reviewed and laboatory general supervisor interview on February 9, 2023 at 10:10 AM ; it was determined that the laboratory director failed to ensure compliance with QA requirements. Refer to D5291.