Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658241	10/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ashford Medical Laboratory	Edificio Ashford Medical Suite 210 Condado, 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
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing record review from June 18, 2021 to July 31, 2021 and interview with the laboratory supervisor on October 28, 2021 at 10: 30 AM, it was determined that the laboratory failed to follow the manufacturer's instruction when 19 out of 19 patients specimens were tested and reported for of Mycoplasma pneumoniae from June 21, 2021 to July 31, 2021. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. 2. The manufacturer's instruction establishes to perform the test procedures at room temperature range from 22 to 25 C. 3. On October 28, 2021 at 10:300 AM, review of the Mycoplasma pneumoniae testing records showed that the laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from from June 21, 2021 to July 31, 2021. 4. The laboratory supervisor confirmed on October 28, 2021 at 10:30 AM, that the laboratory did not monitor nor document the room temperature when it processed the patients specimens for Mycoplasma pneumoniae test. 5. The laboratory processed and reported 19 patient samples for Mycoplasma pneumoniae test from June 21, 2021 to July 31, 2021.
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 (Mycoplasma pneumoniae test) quality control records review from June 18, 2021 to July 31, 2021 and interview with the laboratory supervisor on October 28, 2021 at 10:30 AM, it was determined that the laboratory did not include each day of testing an external positive and negative control material when 19 out of 19 patients specimens were tested and reported for of Mycoplasma pneumoniae patient testing from June 21, 2021 to July 31, 2021. The findings include: 1. The laboratory use the Immuno Card Mycoplasma Test Cassette to perform the Mycoplasma pneumoniae qualitative tests. 2. On October 28, 2021 at 10:300 AM, review of Mycoplasma pneumoniae quality control record showed that the laboratory performs patient testing from June 21, 2021 to July 31, 2021. The laboratory did not include each day of testing the external positive nor the external negative control material. 3. The laboratory supervisor confirmed on October 28, 2021 at 10:30 AM, that the laboratory failed to include each day of testing the external negative and positive control material . She stated that the laboratory run the external controls when it received a new reagent kit. 4. The laboratory processed and reported 19 patient samples for Mycoplasma pneumoniae test from June 21, 2021 to July 31, 2021.
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 Immuno Card Mycoplasma manufacturer's instructions, General Immunology (Mycoplasma pneumoniae) testing and quality record review from June 18, 2021 to July 31, 2021 and interview with the laboratory supervisor on October 28, 2021 at 10:30 AM, it was determined that the laboratory director failed to establish the quality control procedures for the Mycoplasma pneumoniae test. Refer to D 5405 (The laboratory did not monitor nor document the room temperature when patient's specimens were tested for Mycoplasma pneumoniae test). Refer to D 5449 (The laboratory did not include every day of testing the external positive and the negative control materials for Mycoplasma pneumoniae test).