Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0673285	10/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Lab Clinico Gordo	71 Carazo St, Guaynabo, 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, Mycoplasma testing records and laboratory director interview on October 5, 2021 at 1:54 PM, it was determined that the laboratory failed to follow the manufacturer's instruction when 31 out of 31 patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from August 4, 2021 to September 29, 2021. The findings include: 1. The manufacturer's instruction establishes to perform the test procedures at room temperature from 22 to 25 C. 2. On October 5, 2021 at 1:54 PM, the Mycoplasma testing records showed that the laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from August 4, 2021 to September 29, 2021 3. The laboratory director confirmed on October 5, 2021 at 1:54 PM, that the laboratory did not follow the manufacture's instructions for the temperature of processing. 4. The laboratory processed and reported 31 out of 31 patients specimens for mycoplasma test by Immuno Card Meridian method from August 4, 2021 to September 29, 2021.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the

	manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of validation records for Vitamin D performed by the Dimension system and laboratory director interview on October 5, 2021 at 1:34 PM, it was determined that the laboratory failed to verify that the manufacturer's reference intervals (established normal values) were appropriate for the laboratory's patient population. The findings include: a.During review of records on October 5, 2021 the Dimension system validation records showed that the laboratory performed the validation procedures for Vitamin D test on November 24, 2020. However, the laboratory did not verify that the manufacturer's Vitamin D test reference intervals (established normal values) are appropriate for the laboratory's patient population before reporting patient results on February 10, 2021. b.The Laboratory director confirmed on October 5, 2021 at 1:34 PM, that the laboratory did not verify that the manufacturer's Vitamin D test reference intervals (established normal values) before reporting patients results. c.The laboratory processed and reported 1,559 patients specimens for Vitamin D from February 10, 2021 to October 5,2021.
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 (COVID-19 IgM/IgG) quality control records review and manufacturer instructions for use (IFU) from August 1, 2021 to September 30, 2021 and interview the laboratory director on October 5, 2021 at 12:13 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 August 1, 2021 to September 30, 2021, the laboratory did not include every day of testing the positive and the negative control materials. Instead the laboratory run the external controls once a week and when new reagent kit lot or shipment were received. d.From August 1, 2021 to September 30, 2021 the laboratory processed and reported 740 patient samples. e.The laboratory director confirmed on October 5,2021 at 12:13 PM, that the laboratory failed to include a negative and positive external control materials each day of testing.
D5783	CORRECTIVE ACTIONS

	CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on quality control records review, laboratory procedure manual and laboratory general supervisor interview on October 5, 2021 at 12:50 PM; it was determined that the laboratory failed to take and document remedial actions when control results fail to meet the laboratory's criteria for acceptability. The findings include: a.The laboratory performed triiodothyronine uptake (T3 uptake) by Dimension system. b. Quality control records were reviewed from January 2021 to October 2021. c.The laboratory procedure manual showed that if more than 6 control values fails above or below the one standard deviation (1SD), the laboratory must take and document a corrective action. d.Review of quality control graphs showed that the laboratory failed to take corrective action when the control material for T3 uptake (level normal) exceeded the laboratory limits with a trend above 1SD more than 6 plots. Two patient samples were processed and reported. e.The laboratory general supervisor confirmed on October 5, 2021 at 1:34 PM, that no corrective actions were taken.
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, testing record, validation records, corrective actions records review and laboratory director interview October 5, 2021 at 1:54 PM, it was determined that the laboratory director failed to ensure that quality control procedures are maintained in the laboratory. Refer to D 5405 (The laboratory did not monitor nor record the room temperature when patient's specimens were tested for Mycoplasma by Immuno Card Meridian method from August 4, 2021 to September 29, 2021). Refer to D 5421 (The laboratory did not verify that the manufacturer's Vitamin D test reference intervals are appropriate for the laboratory's patient population before reporting patient results on February 10, 2021). Refer to D 5449 (The laboratory did not include every day of testing the positive and the negative control materials for Covid rapid tests). Refer to D 5783 (The laboratory did not take corrective action when the control material exceeded the laboratory limits).