Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D1004749	(X3) Date Survey Completed 12/22/2021
Name of Provider or Supplier Cdt-Centro De Salud Mario Canales Torresola	**Street Address, City, State** 2 Calle Rosanta Aulet, Jayuya, 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
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on lack of Quality Assessment (QA) records and laboratory supervisor interview on December 22, 2021 at 10:00 AM, it was determined that the laboratory failed to did not establish written procedures to evaluate the positive identification of patient specimen. The findings include: 1. During the interview with the laboratory supervisor the (QA) procedure manual and evaluation was requested. 2. The laboratory general supervisor confirmed on December 22, 2021, at 10:00 AM the laboratory did not have a QA procedure manual, neither performed an evaluation to ensure positive identification and optimum integrity of a patient's specimen that are under the laboratory control.
D5205	COMPLAINT INVESTIGATIONS CFR(s): 493.1233 The laboratory must have a system in place to ensure that it documents all complaints and problems reported to the laboratory. The laboratory must conduct investigations of complaints, when appropriate. This STANDARD is not met as evidenced by: Based on lack of records in Quality Assessment and interview with the laboratory supervisor on December 22, 2021 at 10:00 AM. it was determined that the laboratory

	did not establish written procedures to evaluate any complaint submitted. The finding includes: 1. During interview with the laboratory supervisor the QA procedure manual and evaluation was requested. 2. The laboratory supervisor confirmed on December 22, 2021 at 10:00am that the laboratory did not have a QA procedure manual, neither performed or evaluate any complaint submitted to the laboratory since January 1, 2021.
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 lack of Quality Assessment procedures manual and laboratory general supervisor interview on December 22, 2021 at 10:00 AM, it was determined that laboratory did not establish written procedures to monitor and evaluate the following QA activities: a. Specimen identification and integrity. Refer (D5203) b. Complaint investigations. Refer (D5205)
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on lack Quality Assessment (QA) records and laboratory supervisor interview on December 22, 2021 at 10:00 AM, it was determined that the laboratory did not established Quality Assessment Program to monitor and evaluate the requirement for pre- analytic systems. The findings include: 1. The laboratory did not evaluate the following QA assessment for pre- analytic systems. since January 2021: a. Test requests b. Specimen submission, c. Specimen handling. 2. The laboratory supervisor confirmed on December 22, 2021 at 10:00 AM that the QA program was not evaluated.
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 review and laboratory general supervisor

	interview on December 22, 2021 at 10:00 a.m., it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5203, D5205, D5291, D5391.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records files and interview with the laboratoyr supervisor on December 22, 2021 at 9:35 AM, it was determined that the laboratory director did not specify the duties and responsabilities of the laboratory director and Clinical Consultant. The finding includes: 1. The laboratory director and the clinical consultant personnel files did not include written duties and responsibilities. 2. The laboratory supervisor confirmed on December 22, 2021 at 9:35 AM that the laboratory director failed to specify the duties and responsabilities of the laboratory director and clinical consultant.