Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2126577	05/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
Metro Pavia Clinic - Aguadilla	Carretera 107 Barrio Camaseyes, Aguadilla, 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
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review in years 2017-2018 and laboratory general supervisor interview at 10:10 a.m. on May 18, 2018, it was determined that the laboratory failed to follow manufacturer's instruction when patient's samples were tested for qualitative C-reactive protein (CRP) by Detector-crp method. The findings include: 1. The laboratory uses Detector-crp method to perform C-reactive protein (CRP) patient's samples. 2. The Detector-crp manufacturer's instructed the laboratory to check all negative seras by retesting at 1:10 glycine dilution due to a prozone phenomena. 3. Review of records from November 20, 2017 to May 17, 2018, the records showed that the laboratory did not dilute fifty nine (59) patient's specimens before it reported as negative C-reactive protein. 4. The laboratory general supervisor confirmed on May 18, 2018 that the laboratory did not dilute fifty nine (59) patient's specimens before it reported as negative C-reactive protein. 5. The laboratory processed and reported fifty nine (59) negative patient's samples without 1:10 glycine dilution retest.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. (c) The

	laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on quality assessment (QA) records review in years 2017-2018 and laboratory general supervisor interview on May 18, 2018 at 10:10 AM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirement for analytic systems. The findings include: 1. The laboratory failed to follow manufacturer's instructions when patient's samples were tested for qualitative C-reactive protein (CRP) by Detector-crp method. Refer to D5479.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review in years 2017-2018 and laboratory general supervisor interview at 10:10 AM on May 18, 2018, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5479.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review in years 2017-2018 and laboratory general supervisor interview on May 18, 2018 at 10:10 AM, it was determined that testing personnel failed to follow quality control procedures. The findings include: 1. The laboratory uses Detector-crp method to perform C-reactive protein (CRP) patient's samples. 2. The Detector-crp manufacturer's instructed the laboratory to check all negative seras by retesting at 1:10 glycine dilution due to a prozone phenomena. 3. Review of records from November 20, 2017 to May 17, 2018, the records showed that the laboratory did not dilute fifty nine (59) patient's specimens before it reported as negative C-reactive protein. 4. The laboratory general supervisor confirmed on May 18, 2018 that the laboratory did not dilute fifty nine (59) patient's specimens before it reported as negative C-reactive protein. 5. The laboratory processed and reported fifty nine (59) negative patient's samples without 1:10 glycine dilution retest. Refer to D5429.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES

	CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, general immunology quality control records review in years 2017-2018 and laboratory general supervisor interview on May 18, 2018 at 10:10 AM, it was determined that the general supervisor failed to follow quality control procedures. Refer to D5479.