Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0970067	11/02/2018
Name of Provider or Supplier	**Street Address, City, State**	
Metro Pavia Clinic Hato Rey	426 Calle Agueybana Urb El Vedado, 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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on lack of procedures manual, validations records, syphilis serology and general serology testing records review and laboratory director interview on November 2, 2018 at 10:00 AM, it was determined that the laboratory failed to have a procedures manual for the following tests from December 1, 2017 to November 2, 2018: rheumatoid factor (RA), C reactive protein (CRP) and rapid plasma reagin (RPR). The findings include: 1. The laboratory did not have the procedures manual for the following tests from December 2017 to November 2, 2018: RA, CRP and RPR. 2. The validations records showed that the laboratory validated the RA and the CRP tests on December 13, 2017 and the RPR tests on November 13, 2017. 3. The laboratory director confirmed on November 2, 2018 at 10:00 AM, that the laboratory did not have the procedures manual for those tests from December 2017 to November 2, 2018. 4. The syphilis serology and general serology testing records showed that the laboratory processed and reported 600 RPR tests, 180 CRP tests and 160 RA tests from December 1, 2017 to November 2, 2018
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 manufacturer's instructions, general immunology testing records records review and interview with the general superviosr on November 2, 2018 at at 11:20 AM, it was determined that the laboratory failed to follow manufacturer's instruction when 14 out of 14 patient's samples were tested for qualitative C reactive protein (CRP) by the Detector/crp method from February 1, 2018 to October 27, 2018. The findings include: 1. The Detector/crp manufacturer's instructed the laboratory to check all negative seras by retesting at 1:10 dilution due to a prozone phenomena. 2. The general immunology testing records showed that the laboratory did not check (by retesting at 1:10 dilution), 14 out of 14 patient's specimens prior to report as CRP qualitative negative results from February 1, 2018 to October 27, 2018 (processed on February 1, 2018, April 26, 2018, May 5, 2018, July 4, 2018, July 18, 2018, August 22, 2018, August 25, 2018, September 29, 2018 and October 27, 201). 3. The general superviosr confirmed on November 2, 2018 at at 11:20 AM, that the testing records did not include the results of the 1:10 dilution for those samples.
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 lack of validation records of the Mission U500 system, laboratory director and general supervisor interview on November 2, 2018 at 10:30 AM, it was determined that the laboratory failed to perform the validation of the new Mission U500 system placed in routine use on January 11, 2018. The findings include: 1. The laboratory did not perform the validation of the new Mission U500 system placed in routine use on January 11, 2018. 2. The general supervisor and laboratory director confirmed on November 2, 2018 at 10:30 AM, that the laboratory did not perform the validation of the new Mission U500 system. 3. The laboratory processed and reported 6,060 urine patient specimens by the Mission U500 system from January 11, 2018 to November 1, 2018.
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 manufacturer's instructions, general immunology testing records review,

	lack of validation records of the Mission U500 system, laboratory director and general supervisor interview on November 2, 2018 at 11:20 AM, it was found that the laboratory director failed to ensure compliance with the analytic system requirements. The findings include: 1. The laboratory director failed to ensure compliance with the analytic system requirements of CRP tests. Refer to D 5405. 2. The laboratory director failed to ensure compliance with the analytic system requirements of urinalysis. Refer to D 5421.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on personnel file review and laboratory director interview on November 2, 2018 at 1:00 PM, it was determined that the laboratory director failed to ensure that the new testing personnel have the appropriate training prior to testing patients' specimens. The findings include: 1. The personnel file of the general superviosr did not include the training of the following new tests in the laboratory(processed since December 2017): RPR, RA and CRP. 2. The personnel file of the new part time testing personnel (hired on June 20, 2017) did not include the training of the following tests that she processed: complete blood cell (CBC), urinalysis and CRP. 3. The laboratory director confirmed on November 2, 2018 at 1:00 PM, that those training were not documented.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on lack of procedures manual, validations records, syphilis serology and general serology testing records review and laboratory director interview on November 2, 2018 at 10:00 AM, it was determined that the laboratory director failed to did not ensure that procedures manuals for rheumatoid factor (RA), C reactive protein (CRP) and rapid plasma reagin (RPR) test were prepared and were available to the personnel from December 1, 2017 to November 2, 2018. Refer to D 5401.
D6177	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(3) Each individual performing high 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 testing records records review and interview with the general superviosr on November 2, 2018 at at 11:20 AM, it was determined that the testing personnel failed to follow manufacturer's instruction when 14 out of 14 patient's samples were tested for qualitative C reactive protein (CRP) by the Detector/crp method from February 1, 2018 to October 27, 2018. Refer to D 5405.