Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0709046	08/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Western Pathology & Cytology Lab	Calle Peral #14, Esq De Diego, Edificio La Palma, Mayaguez, 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
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 quality assessment (QA) written policies records (years 2016 to 2018) review and interview with the laboratory director on August 8, 2018 at 11:15 AM, it was determined that the laboratory failed to have a procedure to verify the accuracy twice annually of the cytology non gynecology smears examination (tests not regulated for the proficiency testing program Subpart I) from August 8, 2016 to August 8, 2018 . The findings include: 1. On August 8, 2018 at 11:15 AM, the QA written policies showed that the laboratory did not have procedures to verify the accuracy twice annually of the cytology non gynecology smears examination (tests not regulated for the proficiency testing program Subpart I) from August 8, 2016 to August 8, 2018. 2. The laboratory director confirmed on August 8, 2018 at 11:15 AM, that the laboratory did not have the written procedure of the general laboratory systems requirements . 3. The laboratory examined 111 cases of cytology non gynecology from January , 2018 to August 6, 2018 and the annual cytology volume records showed that the laboratory examined 953 of cytology non gynecology cases during the year 2017.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test

	procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on cytology written procedures, annual cytology statistic records (years 2017 and 2018), centrifuge annual calibration record (year 2017), histotechnologist and laboratory director interview on August 8, 2018 at 10:40 AM, it was determined that the laboratory failed to ensure that the step by step performance for the processing of non gynecological body fluids was follow in the laboratory from January 2017 to June 2018. The findings include: 1. The cytology written procedures instructed the laboratory step by step to centrifuge all the body fluids at 400 relative centrifuge force (RCF); setting 6 in the centrifuge. 2. The centrifuge annual calibration record showed that the laboratory calibrated the International centrifuge in August 2017; at the following velocities in revolutions per minutes (rpm): a. At 2,500 rpm setting 5 in the centrifuge. b. At 2,800 rpm setting 7 in the centrifuge. 2. By interview with histotechnologist on August 8, 2018 at 10:40 AM, it was determined that the laboratory did not follow the step by step performance for the processing of non gynecological body fluids from January 2017 to June 2018. The histotechnologist stated that the laboratory centrifuges the urine at 2,500 rpm (setting 5 in the centrifuge) and all other body fluid at 2,800 rpm (setting 7 in the centrifuge). 3. The laboratory director confirmed on August 8, 2018 at 10:40 AM, that there are discrepancies between the written procedures and the laboratory performance for the processing of non gynecological body fluids. 4. The annual cytology statistic records showed that the laboratory processed and reported the following from January 2017 to December 2017: Case Benign Malignant Unsatisfactory Urine 143 10 47 Body fluids 9 3 2 5. The annual cytology statistic records showed that the laboratory processed and reported the following from January 2018 to June 2018: Case Benign Malignant Unsatisfactory Urine 64 13 0 Body fluids 11 1 0
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by:

	Based on workload limit written policies review, annual cytology volume records (year 2017) and workload records (years 201 to 2018) review and laboratory director interview on August 8, 2018 at 11:15 AM, it was determined that the laboratory failed to follow written policies to perform at least every 6 months the workload limit adjustment from August 8, 2016 to August 8, 2018. The findings included: 1. The workload limit written policies establish that the workload limit of the testing personnel should be reassessed at least every 6 months and adjusted when necessary. 2. The laboratory director examined the cytology non gynecology cases in the laboratory from August 8, 2016 to August 8, 2018. 3. The laboratory did not have records for the workload limit adjustment of the laboratory director from August 8, 2016 to August 8, 2018. 4. The laboratory director confirmed on August 8, 2018 at 11: 15 AM, that his workload limit was not reassessed from August 8, 2016 to August 8, 2018. 5. The workload records showed that the laboratory director examined 111 cases of cytology non gynecology from January , 2018 to August 6, 2018 and the annual cytology volume records showed that the laboratory examined 953 of cytology non gynecology cases during the year 2017.
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 cytology written procedures, workload limit written policies review, annual cytology volume records (year 2017 and 2018), workload records (years 201 to 2018), centrifuge annual calibration record (year 2017) review , histotechnologist and laboratory director interview on August 8, 2018 at 11:15 AM, it was determined that the laboratory director failed to ensure to comply with the analytic system requirements from January 2017 to August 2018. Refer to D 5403 (The laboratory failed to ensure that the step by step performance for the processing of non gynecological body fluids). Refer to D 5637 (The laboratory failed to perform at least every 6 months the workload limit adjustment).
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) written policies records (years 2016 to 2018) review and interview with the laboratory director on August 8, 2018 at 11:15 AM, it was determined that the laboratory director failed to comply with the general laboratory system requirements from August 8, 2016 to August 8, 2018 . Refer to D 5291 (The laboratory failed to have a procedure to verify the accuracy twice annually of the cytology non gynecology smears examination (tests not regulated for the proficiency testing program Subpart I).