Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658241	08/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Ashford Medical Laboratory	Edificio Ashford Medical Suite 210 Condado, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on testing personnel records (Medical Technologist #1 and Medical Technologist #2) from years 2017 to 2019, personnel competence written procedures and policies and laboratory general supervisor interview on August 27, 2019 at 1:00 PM, it was determined that the laboratory failed to follow written policies to assess the testing personnel competency. The findings include: 1. The laboratory written policies showed that the testing personnel competence's must include the following criteria's: i. Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing. ii. Monitoring, recording and reporting of test results. iii. Review of intermediate test results or worksheets, quality control records, proficiency testing results and preventive maintenance records. iiii. Direct observation of performance of instrument maintenance and function checks. iiiii. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. Review of the testing personnel competence (Medical technologist #1 and Medical technologist #2) evaluation on August 27, 2019 at 1:00 PM, showed that the above criteria's were not included. 3 . The laboratory general supervisor stated that personnel competence evaluations must be performed every year. The laboratory did not evaluate the competence of the testing personnel (Medical technologist #1 and Medical technologist #2) since year 2018.
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: A. Based on hematology performance specifications records review and laboratory general supervisor interview at 12:30 PM on August 27, 2019, it was determined that the laboratory did not verify the manufacturer's reference intervals of the Act 5 diff AL hematology system when they verified the instrument performance verification in December 2017. The findings include: 1. The laboratory verified the performance specifications of the Act 5 diff AL hematology system in December 2017. 2. The verification of the performance specifications records showed that the laboratory did not verify that the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population. 3. The laboratory general supervisor confirmed on August 27, 2019, that the laboratory did not verify if the manufacturer's reference intervals (normal values) were appropriate for the laboratory's patient population prior to begin to test patient's samples. 4. The laboratory processed and reported approximately 6,012 (Six thousand twelve) Complete Blood Count (CBC) by Act 5 diff AL hematology system since January 2018. B. Based on hematology performance specifications records review and laboratory general supervisor interview at 12:30 PM on August 27, 2019, it was determined that the laboratory did not include the verification of the performance specifications of the WBC (White Blood Cells) differential parameters for the Act 5 diff AL hematology system. The findings include: 1. The laboratory verified of the performance specification of the Act 5 diff AL hematology system in December 2017. 2. The performance specifications records showed that laboratory did not include the verification of the WBC differential parameters prior to begin to test patient's samples. 3. The laboratory general supervisor confirmed on August 27, 2019, that the laboratory did not verify the automatized differential vs manual method comparison prior to begin to test patient's samples. 4. The laboratory processed and reported approximately 6,012 (Six thousand twelve) Complete Blood Count (CBC) by Act 5 diff AL hematology system since January 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 hematology performance specifications records review (December 2017) and laboratory general supervisor interview at 11:30 AM on August 27, 2019, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5421.