Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D2009432	07/06/2018
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Aguadillano	Road 110 Km 0 Hm 3 Bo Ceiba Baja, 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
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on hematology quality control records review in year 2016-2018 and laboratory general supervisor at 10:00 AM on July 6, 2018, it was determined that the laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics by Stain Wright III. The findings include: 1. The laboratory uses Stain Wright III to stain hematology slides for manual differential. 2. Review of hematology quality control records from October 2016 to July 2018, the records showed that the laboratory did not check the reactivity of Wright's stain reagent, each day of use, since January 2018. 3. The laboratory processed and reported six (6) manual differential in the following days: Date #slides 1 /25/18 1 6/1/18 1 6/2/18 1 6/5/18 1 6/13/18 1 6/25/18 1 4. The laboratory general supervisor stated that the laboratory failed to check the reactivity of Wright stain reagent, each day of use those days.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The

	laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on hematology quality control records review in year 2016-2018 and laboratory general supervisor interview at 11:00 AM on July 6, 2018, it was determined that the laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential. The finding includes: 1. The laboratory did not evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential since January 2017. 2. Review of hematology quality control records from October 2016 to July 2018, the records showed that the laboratory did not evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential since January 2017. 3. The laboratory general supervisor confirmed that the laboratory failed to evaluate twice a year the relationship between the manual cell differential and automatic cell differential processed by the Cell Dyn Emerald analyzer since January 2017.
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 control records review in years 2016-2018 and laboratory general supervisor interview at 11:30 AM on July 6, 2018, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the requirements for analytic systems. The findings include: 1. The laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics by Stain Wright III since January 2018. Refer D5473. 2. The laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential since January 2017. Refer to D5775.
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 quality control records review in years 2016-2018 and laboratory general supervisor interview at 11:00 AM on July 6, 2018, it was determined that the laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5473 and D5775.
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) program review in years 2016-2018 and laboratory general supervisor interview at 11:00 AM on July 6, 2018, it was determined that laboratory director failed to ensure compliance with quality assessment (QA) requirements. Refer to D5791.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on personnel records review in years 2016-2018 and laboratory general supervisor interview at 11:00 AM on July 6, 2018, it was determined that the laboratory director failed to follow written procedures to monitor and ensure the competency evaluations of the clinical consultant since January 2017. The findings include: 1. The laboratory schedule that the competence evaluation of the clinical consultant be done annually. 2. The laboratory did not perform the competence evaluation of the clinical consultant since January 2017.
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 hematology quality control review in years 2016-2018 and laboratory general supervisor interview at 11:00 AM on July 6, 2018, it was determined that the general supervisor failed to follow quality control procedures. The findings include: 1. The laboratory failed to check, each day of use, the Wright's stain used in hematology for intended reactivity to ensure predictable staining characteristics by Stain Wright III since January 2018. Refer D5473. 2.The laboratory failed to evaluate and define twice a year the relationship between the manual cell differential and automatic cell differential since January 2017. Refer to D5775.