Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D1070834	05/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dr Alexander Lugo Janer	230 Eleonor Roosevelt Ave, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on histopathology preventive maintenance records review (year's 2017 and 2018) and Physician Office Laboratory (POL) director interview on May 10, 2018 at 10:55 AM, it was determined that the laboratory failed to follow manufacturer's instructions for the preventive maintenance of microscope and hood (Air Filtronix Head). The findings include: 1. The manufacturer's written procedures establishes that the laboratory must document and perform the microscope (each day of use), hood (Air Filtronix Head every 6 months) and hood (Air Filtronix vapor check ever 4 - 6 weeks). 2. The laboratory did not perform the microscope and hood preventive maintenance from January 14, 2017 to May 10, 2018. 3. The POL laboratory director confirmed on May 10, 2018, that the laboratory did not perform and document the microscope and hood preventive maintenance those months. 5. The POL perform 1,600 patients tests from January 14, 2017 to May 10, 2018.
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 histopathology procedures manual, quality control records review (year's 2017 and 2018) and Physician Office Laboratory (POL) director interview on May 10, 2018 at 10:16 AM, it was determined that the laboratory failed to check, each day of use, the Hematoxylin and Eosin stain used in histopathology for intended response and predictable staining characteristics. The findings include: 1. The Physician Office Laboratory (POL) establish in the procedures manual, that the laboratory check, each day of use, the Hematoxylin and Eosin (H/E) stain used in histopathology for intended reactivity to ensure predictable staining characteristics. 2. Review of histopathology quality control records, showed that the laboratory did not check nor document the reactivity of Hematoxylin and Eosin stain reagent, each day of use, from January 14, 2017 to May 10, 2018. 3. The POL director confirmed on May 10, 2018, that the laboratory did not check nor document the reactivity of Hematoxylin and Eosin (H/E) stain reagent from January 14, 2017 to May 10, 2018. 4. The POL perform 1,600 patients tests from January 14, 2017 to May 10, 2018.
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 (year's 2017 and 2018) and Physician Office Laboratory (POL) director interview on May 10, 2018 at 11:22 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. Review of the laboratory quality assessment manual showed that for each analytic process a log sheet was designate to keep track of the laboratory performance. 2. The laboratory did not evaluate aspects regarding the analytic systems: a. to follow manufacturer's instructions for the preventive maintenance of microscope and hood (Air Filtronix Head). Refer to D5429. b. to check, each day of use, the Hematoxylin and Eosin (H/E) stain used in histopathology for intended response and predictable staining characteristics. Refer to D5473.
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 histopathology quality control records review (year's 2017 and 2018) and Physician Office Laboratory (POL) director interview on May 10, 2018 at 11:25 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 1. The laboratory director did not assure that the laboratory: a. to follow manufacturer's instructions for the

	preventive maintenance of microscope and hood (Air Filtronix Head). Refer to D5429. b. to check, each day of use, the Hematoxylin and Eosin (H/E) stain used in histopathology for intended response and predictable staining characteristics. Refer to D5473.
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 histopathology quality control records review and Physician Office Laboratory (POL) director interview on May 10, 2018 at 11:28 AM, it was determined that testing personnel failed to follow quality control procedures. The finding includes: 1. The laboratory testing personnel failed the following quality control procedures: a. to follow manufacturer's instructions for the preventive maintenance of microscope and hood (Air Filtronix Head). Refer to D5429. b. to check, each day of use, the Hematoxylin and Eosin (H/E) stain used in histopathology for intended response and predictable staining characteristics. Refer to D5473.