Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0941466	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio San Francisco De Asis Llc	Oficina 101 Edificio Copellia Calle, Aguada, 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 procedures manual, hematology quality control records review (years 2017-2019) and laboratory director interview on March 21, 2019 at 10:30 AM, 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. The findings include: 1. The laboratory establish in the procedures manual, that the laboratory check, each day of use, the Wright's stain used in hematology for intented reactivity to ensure predictable staining characteristics. 2. Review of hematology quality control records from May 2017 to March 20, 2019, showed that the laboratory did not check nor document the reactivity of Wright's stain reagent, each day of use, from January 2018 to April 2018. 3. The laboratory processed and reported one hundred ninty four (194) hematology differential manual those days. (75 - January 2018, 41 - February 2018, 40 - March 2018 and 38 - April 2018) 4. The laboratory director confirmed on March 21, 2019, that the laboratory did not check nor document the reactivity of Wrigth's stain reagent from January 2018 to April 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 procedures manual, hematology quality control records review (years 2017-2019) and laboratory director interview on March 21, 2019 at 10:30 AM, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. The finding includes: 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. Refer to D5473.
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 procedures manual, hematology quality control records review (years 2017-2019) and laboratory director interview on March 21, 2019 at 10:30 AM, , it was determined that the general supervisor failed to follow quality control procedures. The finding includes: 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. 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 hematology procedures manual, hematology quality control records review (years 2017-2019) and laboratory director interview on March 21, 2019 at 10:30 AM, , it was determined that testing personnel failed to follow quality control procedures. The finding includes: 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. Refer to D5473.