Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658133	(X3) Date Survey Completed 07/16/2019
Name of Provider or Supplier Laboratorio Clinico Colon	**Street Address, City, State** Calle Antonio R Barcelo #21, Maunabo, 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
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Polymedco Sedimentation Rate Control manufacturer's instructions, sedimentation rate (SR) testing records review and general supervisor interview on July 16, 2019 at 10:20 AM, it was determined that the laboratory failed to follow the manufacturer's specifications for using the SR controls materials when 23 out of 23 patients specimens were processed and reported for SR test from July 1, 2019 to July 15, 2019 by the Sedimat 15 system. The findings include: 1. The laboratory processed and reported the SR patient's specimens by the Sedimat 15 system. 2. The laboratory used the Polymedco Sedimentation Rate Control. 3. The Polymedco Sedimentation Rate Control manufacturer instructed the laboratory to use the control materials with 31 consecutive days open-vial stability. 4. On July 16, 2019 at 10:20 AM, the SR testing records showed that the laboratory used the lot 11504181 normal control and the lot 11504181 abnormal control with exceeded open vial stability date from July 1, 2019 to July 15, 2019. 5. The general supervisor confirmed on July 16, 2019 at 10:20 AM, that the laboratory used those control materials with exceeded open vial stability date from July 1, 2019 to July 15, 2019. 6. The laboratory processed and reported 23 out of 23 patients specimens for SR tests from July 1, 2019 to July 15, 2019 by the Sedimat 15 system.
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 Polymedco Sedimentation Rate Control manufacturer's instructions, sedimentation rate (SR) testing records review and general supervisor interview on July 16, 2019 at 10:20 AM, it was determined that the laboratory director failed to ensure compliance with the requirements for hematology analytic systems (SR tests) Refer to D 5479 (The laboratory failed to follow the manufacturer's specifications for using the SR controls materials when 23 out of 23 patients specimens were processed and reported for SR test from July 1, 2019 to July 15, 2019 by the Sedimat 15 system).
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 Polymedco Sedimentation Rate Control manufacturer's instructions, sedimentation rate (SR) testing records review and general supervisor interview on July 16, 2019 at 10:20 AM, it was determined that the general supervisor failed to perform day-to-day supervision for the processing and reporting of the SR tests. Refer to D 5479 (The laboratory failed to follow the manufacturer's specifications for using the SR controls materials when 23 out of 23 patients specimens were processed and reported for SR test from July 1, 2019 to July 15, 2019 by the Sedimat 15 system).