Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658075	07/17/2019
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Menonita Ponce	Road 506 Km 1 Bo Coto Laurel, Coto Laurel, 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
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation , hematology and routine chemistry procedures manuals review and hematology and routine chemistry areas supervisors interview on July 17, 2019 at 11:45 AM, it was determined that the laboratory failed to follow written policies for patient's specimen labeling. The findings include: 1. The hematology and routine chemistry procedures manuals establishes that all patient's specimen must be labeling with the date and time of sample collection and the signature or initials of the personnel who performed the sample collection. 2. On July 17, 2019 at 843 AM, it is observed that ten patients specimens were received and processed in the laboratory for complete blood cell (CBC) tests. Six out of ten patient's specimens labels did not include the time of sample collection nor the signature or initials of the personnel who collected the sample. 3. On July 17, 2019 at 11:45 AM, it is observed that fifteen patients specimens were received and processed in the laboratory for routine chemistry tests. Ten out of fifteen patient's specimens labels did not include the time of sample collection nor the signature or initials of the personnel who collected the sample. 4. The supervisors of the hematology and routine chemistry areas confirmed on July 17, 2019 at 11:45 AM, that those label of patients specimens did not include the require information.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1249(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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on Quality Assessment Program (QAP) records review (years 2018 and 2019) and laboratory general supervisor interview on July 17, 2019 at 2:00 PM, it was determined that the laboratory failed to establish and follow written policies to monitor and assess the preanalytic systems requirements since January 2018 (Patient's specimen labeling). The findings include: 1. On July 17, 2019 at 2:00 PM, the QAP records showed that the laboratory did not establish nor follow written policies to monitor and assess the patient's specimen labeling since January 2018. 2. The laboratory failed to follow written policies for patient's specimen labeling. Refer to D 5411. 3. The general supervisor confirmed on July 17, 2019 at 2:00 PM, that the laboratory did not assess the patient's specimen labeling in the QAP since January 2018.
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) records review (years 2018 and 2019) and and laboratory general supervisor interview on July 17, 2019 at 2:00 PM, it was determined that laboratory director failed to ensure compliance with the QA requirements (pre-analytic systems) since January 2018. Refer to D 5391.