Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0875318	02/18/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Menonita Humacao	Font Martelo 300, Humacao, 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
D0000	During a recertification survey on February 18, 2025, the laboratory was found out of compliance with the following condition: 42 CFR 493.1208 GENERAL IMMUNOLOGY
D5014	GENERAL IMMUNOLOGY CFR(s): 493.1208 If the laboratory provides services in the subspecialty of General immunology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Mono Test quality control /patient test worksheet records (years 2024-2025), written procedures for quality control records review and laboratory director interview on February 18, 2025, at 2:15 P.M., it was determined that the laboratory failed to ensure compliance with the analytic system requirements for Mono Test. The findings include: 1. The laboratory failed to include reactive and non-reactive control material each day of patient's testing. Refer to D5449.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on Mono Test quality control/patient test worksheet records (years 2024-2025), written procedures for quality control records review and laboratory director interview, on February 18, 2025, at 1:38 P.M, it was determined that the laboratory failed to include reactive and non-reactive control material each day of testing, when

	58 out of 62 Mono Test patient samples were processed and reported from January 18, 2024 to February 17, 2025. The findings include: 1. The laboratory used Asi Color Mono II Test system to perform Mono test patient samples. (Reviewed February 18, 2025, at 1:38 P.M.) 2. Review of the written procedures for quality control records stated that the controls must be processed with each day of patient's testing. (Reviewed February 18, 2025, at 1:40 P.M.) 3. On February 18, 2025, at 1:45 P.M, the Mono Test quality control and patient test worksheet records were reviewed. The records showed that the laboratory did not include reactive and non-reactive control material each day of patient's testing. 4. The laboratory processed and reported 58 out of 62 Mono Test patient samples from January 18, 2024, to February 17, 2025. 5. The laboratory director confirmed on February 18, 2025, at 2:00 P.M. that the laboratory failed to include reactive and non-reactive control material each day of patient's testing.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and 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 Mono Test quality control and patient test worksheet records review, written procedures for quality control records review and laboratory director interview on February 18, 2025, at 2:15 P.M., it was determined that the laboratory director failed to ensure that the general supervisor monitor the requirement for analytic systems for the Mono Test patient samples. Refer to D6144.
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 Mono Test quality control and patient test worksheet records review, written procedures for quality control records review and laboratory director interview on February 18, 2025, at 2:15 P.M., it was determined that the laboratory general supervisor did not assure to follow written procedures for quality control records for Mono test patient samples each day of patient's testing. Refer to D5449.