Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 40D1037837	**(X3) Date Survey Completed** 12/13/2023
Name of Provider or Supplier Bcw Puerto Rico	**Street Address, City, State** Urb Las Vegas Calle Calle 8, Aa-6, Catano, 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**
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on Mycoplasma pneumoniae IgM quality control records, Mycoplasma pneumoniae IgM patients reports worklist review (years 2022-2023), and laboratory general supervisor interview on December 13,2023 at 11:00 A.M, it was determined that the laboratory failed to evaluate the new lots of Mycoplasma pneumoniae IgM for positive and negative reactivity prior to placing it in routine use when 567 out of 700 patients specimens were tested and reported from July 7, 2022 to September 22, 2023. The findings include: 1. The laboratory use the Immunocard Mycoplasma tests to perform the Mycoplasma pneumoniae IgM qualitative test. (Reviewed on December 13, 2023 at 11:00 A.M) 2. The Mycoplasma pneumoniae IgM quality control records were reviewed from July 7,2022 to December 12,2023. (Reviewed on December 13, 2023 at 11:00 A.M) 3. The Mycoplasma pneumoniae IgM patient reports worklist (years 2022-2023) showed on December 13,2025 at 11:10 A.M, that the laboratory failed to evaluate the new lots of ImmunoCard Mycoplasma Test for positive and negative reactivity: Lot number Date opened Patient testing 709030P174 07/07/2022 63 709030P196 08/31/2022 27 709030P198 09/22/2023 31 709030P189 10/06/2022 35 709030P200 10/20/2022 166 709030P208 12/27/2022 26 709030P175 01/10/2023 160 709030P212 05/08/2023 32 709030Q230 07/13/2023 27 4. The laboratory general supervisor confirmed on December 13, 2023 at 11:25 A.M., that the

	laboratory did not evaluate the new lots of Mycoplasma pneumoniae IgM tests for positive and negative reactivity prior to placing it in routine use. 5. The laboratory tested and reported 567 out 700 patient's samples for Mycoplasma pneumoniae IgM from July 7, 2022 to September 22,2023.
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 Mycoplasma pneumoniae IgM quality control record review from July 7, 2022 to December 12, 2023, Mycoplasma patient reports worklist (years 2022-2023) and laboratory general supervisor interview on December 13, 2023 at 2:00 P.M. it was determined that the laboratory director failed to ensure compliance with the requirement for analytic systems. The findings include: 1. The laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM test for positive and negative reactivity prior to placing it in routine use. Refer to D5471.
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 Mycoplasma pneumoniae IgM quality control records review from July 7, 2022 to December 12, 2023, Mycoplasma patient reports worklist (years 2022-2023) and laboratory general supervisor interview on December 13, 2023 at 2:00 P.M. it was determined that the general supervisor failed to ensure compliance with the requirement for analytic systems. The finding includes: 1. The laboratory did not evaluate the new lots of Mycoplasma Pneumoniae IgM test for positive and negative reactivity prior to placing it in routine use. Refer to D5471.