Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	40D0658302	11/18/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratorio Clinico Quimed	Ave Borinquen 2036 Esq Bo Obrero, Santurce, 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
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on Immunohematology procedures manual, quality control records, and interview with the laboratory director, it was determined that the laboratory failed to meet the quality control requirements for the subspecialty of Immunohematology. Refer to D5551.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the Urinalysis quality control review and interview with the laboratory director; it was determined that the laboratory documented the microscopic quality control result from November 1, 2022 to November 30, 2022 even though the survey

	date was on November 18, 2022. The findings include: 1. The Urinalysis quality control was reviewed on November 18, 2022 at 11:55 am. 2. The laboratory documented the urinalysis microscopic control result from November 1, 2022 to November 30, 2022. The survey date was on November 18, 2022. 3. The laboratory director confirmed on November18, 2022 at 11:58am that she documented the microscopic control of the whole month.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of routine chemistry quality control Levey-Jennings charts and laboratory director interview; it was determined that the laboratory did not evaluate, document or take remedial actions when the quality control results showed deviations (outliers, shift or trends). The findings include: a. The laboratory use a Vitros 250 by Ortho Clinical Diagnostics for routine chemistry test. The menu included Basic metabolic panel Comprehensive metabolic panel, Renal Panel, Lipid Panel. b. On November 18, 2022 at 9:30 am the quality control Levey-Jennings charts were reviewed. From October 18, 2022 to October 19, 2022 the Total bilirubin, Chlorine and sodium Levey-Jennings quality control chart showed both control levels (Verifier I and Verifier II) materials showed over three (3) deviation (3SD) and no remedial action were documented. b. The laboratory processed and reported two (2) patient's sample for comprehensive metabolic panel. f. On November 21, 2022 at 9:52 am the laboratory director confirmed that no remedial action were documented when the Levey-Jennings quality control chart showed both control levels (Verifier I and Verifier II) materials showed over three (3) deviation (3SD).
D5551	IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f) (a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent. (f) Documentation. The laboratory must document all control procedures performed,

	as specified in this section. This STANDARD is not met as evidenced by: Based on immunohematology quality control records review and laboratory director interview, it was determined that the laboratory failed to perform quality control procedures for ABO and Rh group. The findings include: 1. On November 18, 2022 at 11:00 am the laboratory immunohematology quality control records showed, that the laboratory did not include any control material, when ABO and Rh group was performed from January 18, 2022 to October 3, 2022. 2. The laboratory processed and reported 12 patients for ABO & Rh group from January 18, 2022 to October 3, 2022. Thw forward and reverse result compare. 4. On November 18, 2022 the laboratory director confirmed that no quality control procedure was performed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on control records and and laboratory director interview on November 18, 2022, at 12:00 pm, it was determined that the laboratory director failed to fulfill his responsabilities and duties to ensure compliance with the laboratory quality control requirements. Refer to D5026 and D6093
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 routine chemistry quality control records, Urinalysis microscopic control and Immunohematology reviewed since January 2022 and laboratory director interview, it was determined that laboratory director failed to ensure compliance with the requirements for analytic systems. Refer to D5445, D5469 and D5551.