

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 40D0658302	(X3) Date Survey Completed 10/04/2024
Name of Provider or Supplier Laboratorio Clinico Quimed	Street Address, City, State 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
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of chemistry quality control records review and interview with the laboratory director on October 4, 2024; it was determined that the laboratory failed to meet requirements for analytic systems. Refer to D 5445 and D6093.</p>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Routine Chemistry quality control records, patient's record and interview</p>

with the laboratory director on October 4, 2024 at 12:04 PM; it was determined that the laboratory failed to include two levels of control material each day that processed patient's sample for potassium test by the Vitros 250 instrument. The laboratory processed 189 out of 338 potassium test without a control material from January to May 2024. The findings include: 1. The laboratory used the Vitros 250 by Orthodiagnosics to performed the chemistry test. 2. On October 4, 2024 at 10:17 AM, the monthly Levey Jennings graphs were reviewed and showed that the laboratory only run 2 levels of controls material for the potassium analyte, once or twice a month. The laboratory processed the 2 levels of controls on the following dates: January 9, 2024; January 26, 2024; February 2, 2024; February 22, 2024; March 15, 2024; April 19, 2024, and May 17 2024. 3. On October 4, 2024 at 11:10 AM; the patient record of chemistry was reviewed from January 2024 to May 2024, and showed that the laboratory processed the Comprehensive Metabolic Panel (CMP), that include the potassium analyte, on the following dates: January 9, 2024; January 19, 2024; January 26, 2024; February 2, 2024; February 9, 2024; February 22, 2024; March 1, 2024; March 8, 2024; March 15, 2024; March 27, 2024; April 8, 2024; April 19, 2024; April 26, 2024; May 3 2024; May 10, 2024; May 17, 2024; May 24, 2024; May 31, 2024. 4. On October 4, 2024 at 12:04 PM the laboratory director confirmed that the laboratory failed to include the two level of control material each day of patient testing for the potassium analyte. Also confirmed, that the laboratory processed and reported 189 out of 338 without the 2 level of control metrial of potassium analyte.

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 chemistry records review (year 2024), patients record review and interview with the laboratory director (sole practitioner) on October 4, 2024 at 12:04 PM; it was determined that the laboratory director failed to ensure that the two levels of control material for potassium were included each day of patient testing. Refer to D5445.