Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1081814	09/06/2023
Name of Provider or Supplier	**Street Address, City, State**	
Q Med Laboratory Llc	11355 Montwood Suite E, El Paso, TX	

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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based upon review of quality control records and interview of facility personnel, the laboratory failed to establish and maintain the quality control program for eight of eight Chemistry procedures tested using the UniCel DxI 600 (Serial number 902285) and 26 of 26 analytes tested on the DxC 700. The findings included: 1. Review of Quality control records for the Immunoassay control levels 1 and 3 (lot 3530821) for March 2023 found the laboratory had different acceptable values defined in the UniCel Dxi 600 (Serial number 902285) and the Schuylab laboratory information system for Vitamin D. a. UniCel DxI acceptable values were defined as follows: Lot 35308211 - Mean value of 19.3 ng/mL with an acceptable range of 15.44 to 23.16 Lot 35308213 - Mean value of 60.3 ng/mL with an acceptable range of 47.70 to 72.90 b. Schuylab acceptable values were defined as follows: Lot 35308211 - Mean value of 21.3 ng/mL with an acceptable range of 16.44 to 26.16 Lot 35308213 - Mean value of 56.8 ng/mL with an acceptable range of 45.24 to 68.36 2. Review of quality control records for the Techpath level 1 and 3 controls (lot 1150621) for March 2023 found the laboratory had different acceptable values defined in the DxC 700 and the

	Schuylab laboratory information system for Sodium. a. DxC700 acceptable values were defined as follows: Level 1 lot 11506211 - Mean value of 119.8 mEq/L with an acceptable range of 97.6 to 146.4. Level 3 lot 11506213 - Mean value of 169.4 mEq/L with an acceptable range of 136.8 to 205.2. 3. During interview of testing person four on the CMS Report 209 Laboratory Personnel report conducted September 6, 2023 at 1:22 PM, he confirmed that he did not maintain the quality control values in the UniCel DxI and the DxC 700 to detect immediate error.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Review of the laboratory's own IQCP's, quality control records, patient test records, and interview of facility personnel found that the laboratory director failed to ensure that the quality control program had been established and maintained. (see D 5445)
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based upon review of policies and procedures, personnel records and interview of facility personnel, the technical consultant failed to perform semi-annual competency assessments for one of five testing personnel performing Hematology and Chemistry testing in the first year of employment. The findings included: 1. Review of policies and procedures found on page 1 of the policy titled LABORATORY PERSONNEL COMPETENCY: " All Clinical Laboratory Technologists in Q Med are to be tested every 6 months and annually for competency in all areas of laboratory." 2. Review of personnel files found no semi-annual competency assessments for testing person two (hire date 02/22/2022). One annual competency assessment was performed 05/15 /2023. 3. During interview of testing person four on the CMS Report 209 Laboratory Personnel Report conducted 09/05/2023 at 11:54 AM, he confirmed there were no semi-annual competency assessments for testing person two available for review.