Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1081814	09/17/2025
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based upon observations, review of policies and procedures, manufacturer's instructions, quality control records, patient test records and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions when performing 197 Rapid Plasma Reagin (RPR) tests between July 1, 2025 and August 31, 2025. The findings included: 1. Observations made during the demonstration of the procedure on September 17, 2025 at 9:35 AM found testing person 3 dispensed one drop of the non- reactive and reactive control material or serum specimen into each circle needed for testing. He then dispensed one free falling drop of the carbon antigen (using the dropper bottle) into the circles that contained controls or serum specimens. He then placed the test card onto the rotator and started the timer for the 8 minute rotation. Upon completion of testing, he placed the cap on the dropper bottle and and placed it in the refrigerator until needed. Testing person 3 was then asked to read the procedure and repeat the testing. Testing person 3 removed a plastic coated card from the drawer and labeled each of the circles for each of the controls and patient specimens to be tested. He then used the control bottles to dispense the non-reactive, weakly reactive and reactive controls into the appropriate circles and used the dispensters to dispense the patient specimens into each of the circles. He removed the cap from the antigen bottle and was about to dispense a drop of RPR antigen (using the dropper bottle) into each of the circles for testing. He was stopped and asked to reread the procedure before continuing. He applied the needle to the dropper bottle and dispensed the antigen into each circle. He took the card to the rotator and

	set the timer for 8 minutes. 2. Review of the laboratory's own written policy (approved 02/15/2024) found on page 2 under the heading Rapid Plasma Reagin (RPR): Bring reagents and samples to room temperature. Place 0.05 mL of patient serum onto the designated circles of the RPR card. Add one drop of Germaine RPR antigen reagent. Gently rotate card for 8 minutes at 100 rpm. Read results macroscopically under a strong light." 3. Review of the Aim RPR Test manufacturer's instructions found under the heading PRECAUTIONS: "5. The needle assembly must be thoroughly washed in distilled or deionized water and air dried after each use. Place the needle back into the plastic sleeve. Do not remove the dropper bottle tip when washing the needle assembly. Let the assembly air dry. Before the next use, make sure that no large water droplets remain in the dropping bottle and needle by shaking and squeezing the bottle assembly." Continued review found under the heading Materials required but not provided: Mechanical Rotator adjustable to 100 rpm + 5 rpm, circumscribing 3/4 inch diameter w/ humidity cover." under the heading Qualitative test Procedure: "Place the Test Card on the rotator and cover to maintain humidity. Rotate at 100 rpm (+ 5 rpm) for eight (8) minutes." 4. Review of patient test records found the laboratory tested 196 patient specimens for RPR between July 1, 2025 and August 31, 2025 6. During interview of testing person 3 conducted September 17, 2025 at 9:35 AM, he confirmed he did not follow the manufacturer's instructions for adding carbon antigen to each of the test circles when testing specimens for RPR. He went on to confirm that he did not use the dispensing needle to dispense the carbon antigen, and he did not always test all 3 controls with each run. He went on to confirmed that the laboratory did not have a humidity cover for the mechanical rotator to maintain humidity during the rotation of RPR testing.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based upon review of the manufacturer's instructions, the open stability chart, observations, patient test records and interview of facility personnel the laboratory failed to ensure BioRad Specialty Immunoassay Controls were not used beyond their opened stability to assess the quality of Parathyroid Hormone (PTH) results. 26 patient specimens were tested for PTH using the expired control material between September 15, 2025 and September 17, 2025. The findings included: 1. Review of the BIO RAD Lyphochek Specialty Immunoassay Control instructions for use found under the heading STORAGE AND STABILITY: " Reconstituted and refrigerated: After reconstituting and storing tightly capped at 2-8 C, the product will be stable as follows: All Analytes 30 days Except: PTH (Intact): 4 days Continued review found under the heading LIMITATIONS: "The product should not be used past the expiration." 2. The opened stability chart located on the wall defined an open stability date of 4 days for PTH. 3. Observations made on September 17, 2025 at 12:08 PM found the laboratory had documented 09/11/20225 as the date of opening on the BioRad Specialty Immunoassay Controls level 1 and 3 controls (lot 88760 expiration 2027-04-30) located in the refrigerator in the tray of quality control materials currently in use. The laboratory did not document a new expiration date for the controls. 4. Review of patient test records found the laboratory tested patient specimens using the quality control materials that exceeded the manufacturer's open

	stability date: a. 09/15/2025 - 5 patients tested for PTH as follows: Specimen 250915023 Specimen 250915028 Specimen 250915016 Specimen 250915048 Specimen 250915029 b. 09/16/2025 - 20 patient specimens were tested for PTH follows: Specimen 250915065 Specimen 250915083 Specimen 250915062 Specimen 250915066 Specimen 250915158 Specimen 250915180 Specimen 250915176 Specimen 250915063 Specimen 250915063 Specimen 250915169 Specimen 250915030 Specimen 250915080 Specimen 250915107 Specimen 250915087 Specimen 250916033 Specimen 250916062 Specimen 250916061 Specimen 250916080 Specimen 250916075 Specimen 250916055 Specimen 250916074 c. 09/17 /2025 - Specimen 250916159 was tested for PTH. 5. During interview of testing person 5 conducted September 17, 2025 at 12:08 PM, he confirmed that the laboratory used the Specialty Immunoassay Controls levels 1 and 3 for 3 days days after reconstitution and did not document a new expiration date when the bottles had been opened.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based upon review of Creatine Kinase (CK) verification studies, manufacturer's instructions for use, patient reports and interview of facility personnel, the laboratory failed to verify the manufacturer's reference range used for CK were appropriate for their patient population. The reference range defined for CK on 5 of 5 patient reports tested between May, 2025 and September 2025 was not the same as the manufacturer's The findings included: 1. Review of the verification study for CK (added March 2025) found no evaluation of reference ranges to ensure the manufacturer's ranges were appropriate for the laboratory's patient population. 2. Review of the Beckman Coulter CK Instructions for use found on page 6 under the heading EXPECTED RESULTS: "Adults 30-223 U/L. Expected values may vary with age, sex, diet and geographical location. Each laboratory should determine its own expected values as dictated by good laboratory practice." 3. Review of 5 final patient reports found the laboratory had defined a reference interval for CK as 30-170 U/L. 4. During interview of testing person 5 conducted September 17,2025 at 11:02 AM, he confirmed the laboratory did not verify the manufacturer's reference range was acceptable for their patient population. He went on to say the reference range defined on the final report was the same as used for a reference laboratory.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

	This STANDARD is not met as evidenced by: Based upon review of Creatine Kinase (CK) verification studies, manufacturer's instructions for use, patient reports and interview of facility personnel, the laboratory failed to verify the manufacturer's reference range used for CK were appropriate for their patient population. (See D5421)
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based upon observations, review of policies and procedures, manufacturer's instructions, quality control records, patient test records and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions when performing 197 Rapid Plasma Reagin (RPR) tests between July 1, 2025 and August 31, 2025. (See D5411)