Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1081814	02/14/2020
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
D0000	Survey conducted October 28, 2019 through October 31, 2019, and exit conference held on October 31, 2019. On February 14, 2020, additional information was submitted to complete the survey. The laboratory was surveyed and failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1240 Condition: Preanalytic systems 493. 1441 Condition: Laboratories performing high complexity testing; laboratory director.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions for use, laboratory policies and procedures, verification studies, patient test records and interview with facility personnel, the laboratory failed to meet the requirements for pre analytic systems when testing patient blood specimens using the Diatron Abacus 5 hematology analyzer. The laboratory failed to follow the manufacturer's instructions for testing blood specimens for Complete Blood Count (CBC) within 7 hours of collection using the Diatron Abacus 5 hematology analyzer. (see D5311)
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of

	the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use, laboratory policies and procedures, patient test records and interview with facility personnel, the laboratory failed to follow the manufacturer's instructions for testing blood specimens for CBC using the Diatron Abacus 5 hematology analyzer. The findings included: 1. Review of the Abacus 5 Analyzer Operator's Manual (v2.0) found on page 53 under the heading Sample Collection and Handling:"Analyze blood samples within 7 hours of collection." 2. Review of the laboratory's written policy titled Criteria for Rejection of Hematology Specimens (dated 04/22/2019) found it was the policy of the laboratory to reject Blood Specimens "older than 24 hours" for Blood Counts. 3. Review of patient test records found the laboratory had tested approximately 11,756 patient specimens for CBC between March 15, 2019 and October 25, 2019. A random sampling of 25 patient reports from June 2019 and October 2019 found the laboratory tested 14 of 25 patient specimens that were greater than 7 hours old. a. Accession 190626012 - collected 06/25/2019 at 1:50 PM and tested 24 hours and 43 minutes later on 06/26/2019 at 2:33 PM. b. Accession 190626013- collected 06/25/2019 at 4: 40 PM and tested 21 hours and 52 minutes later on 06/26/2019 at 2:32 PM c. Accession 190627002 - collected 06/26/2019 at 09:00 AM and tested 27 hours and 31 minutes later on 06/27/2019 at 12:31 PM. d. Accession 190627003 - collected 06/26 /2019 at 09:05 AM and tested 27 hours and 24 minutes later on 06/27/2019 at 12:27 PM e. Accession 190628102 - collected 06/28/2019 at 08:30 AM and tested 7 hours and 53 minutes later on 06/28/2019 at 4:23 PM. f. Accession 191025046 - collected 10 /25/2019 at 09:00 AM and tested 7 hours and 39 minutes later on 10/25/2019 at 5:39 PM. g. Accession 191025095 - collected 10/25/2019 at 09:25 AM and tested 8 hours and 42 minutes later on 10/25/2019 at 6:07 PM h. Accession 191025089 - collected 10 /24/2019 at 5:10 PM and tested 25 hours and 1 minute later on 10/25/2019 at 6:11 PM. i. Accession 191025088 - collected 10/25/2019 at 09:30 AM and tested 8 hours and 8 minutes later on 10/25/2019 at 5:38 PM j. Accession 191025001 - collected 10 /24/2019 at 09:00 AM and tested 27 hours and 11 minutes later on 10/25/2019 at 12: 11 PM k. Accession 191025008 - collected 10/24/2019 at 08:00 AM and tested 28 hours and 10 minutes later on 10/25/2019 at 12:10 PM l. Accession 191025010 - collected 10/24/2019 at 11:07 AM and tested 23 hours and 45 minutes later on 10/25 /2019 at 12:08 PM. m. Accession 191025013 - collected 10/24/2019 at 12:20 PM and tested 23 hours and 45 minutes later on 10/25/2019 at 12:25 PM n. Accession 191025017 - collected 10/24/2019 at 09:15 AM and tested 26 hours and 56 minutes later on 10/25/2019 at 12:01 PM 5. Interview of the Technical Consultant on the CMS report 209 Laboratory Personnel Report confirmed that the laboratory would pick up specimens using their own courier services around 3:00 PM each day and bring them back to the laboratory for testing. Analytes included in the CBC : White Blood Cell (WBC) Red Blood Cell (RBC) Hemoglobin (Hgb) Hematocrit (Hct) Mean Corpuscular Volume (MCV) Mean Corpuscular Hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration (MCHC)
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on review of manufacturer's instructions for use, laboratory policies and procedures, establishment studies, patient test records and interview with facility personnel, the laboratory failed to ensure establishment studies for Analytical sensitivity, Analytical specificity to include interfering substances, and any other performance characteristics required for test performance were completed prior to testing patient specimens when using the Diatron Abacus 5 hematology analyzer to test specimens for Complete Blood Counts (CBC) , using specimens greater than seven hours old. The findings included: 1. Review of the Abacus 5 Analyzer Operator's Manual (v2.0) found on page 53 under the heading Sample Collection and Handling:"Analyze blood samples within 7 hours of collection." 2. Review of the laboratory's written policy titled Criteria for Rejection of Hematology Specimens (dated 04/22/2019) found it was the policy of the laboratory to reject Blood Specimens "older than 24 hours" for Blood Counts. 3. Review of the laboratory's establishment studies (signed by the Laboratory Director dated 03/15/2019) found: a. The laboratory failed to include verification studies including accuracy, precision and reportable range for the analyte Hemoglobin. b. The laboratory failed to establish the analytic sensitivity of each of the analytes included in the CBC When specimens were tested beyond the manufacturer's specifications of 7 hours. c. the laboratory performed an analytic specificity study but failed to include the assessment of potential interfering substances for each of the analytes included in the CBC when testing specimens older than 7 hours. d. The laboratory failed to establish other performance characteristics including specimen stability over time including variations in temperature and age of specimens. FDA approved tests that have been modified are considered high-complexity and the establishment of accuracy, precision, analytic sensitivity, analytic specificity including interfering substances, reportable range, reference intervals, and any other performance characteristic required for test performance are to be established by the laboratory as a laboratory developed test method. e. The laboratory failed to establish its own reference range for analytes included in the CBC using specimens that were greater than 30 minutes or less than seven hours. f. The laboratory failed to evaluate the establishment studies against the manufacturer's claims for acceptability of performance for analytes included in the CBC. 4. Review of patient test records found the laboratory had tested approximately 11,756 patient specimens for CBC between March 15, 2019 and October 25, 2019. 5. Interview of the Technical Consultant on the CMS report 209 Laboratory Personnel Report confirmed that the laboratory evaluated the establishment studies based upon the "pass or fail arguments" previously defined in the EP Evaluator formulas for accuracy, precision and reportable ranges. He went on to say the comparison studies were performed with the reference laboratory but he did not know the methodology used. Analytes included in the CBC : White Blood Cell (WBC) Red Blood Cell (RBC) Hemoglobin (Hgb) Hematocrit (Hct) Mean Corpuscular Volume (MCV) Mean

	Corpuscular Hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration (MCHC) Red Cell Distribution Width (RDW) Platelet (PLT) Mean Platelet Volume (MPV)
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 a review of laboratory policies and procedures, Diatron Abacus 5 establishment studies, patient test records, and interview of facility personnel, the laboratory director failed to provide overall management and direction of the laboratory services. (see D6082 and D6086)
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's instructions,verification records, and instructions to clients for the collection, storage and handling of specimens, the laboratory director failed to ensure the quality of services for preanalytical systems. The laboratory failed to have documentation of studies to support the stability of patient specimens tested for CBC more than seven hours after collection when using the modified FDA-approved Diatron Abacus hematology analyzer . (see D5311 and D5423)
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, manufacturer's instructions for use, establishment studies, patient test records and interview with facility personnel, the laboratory director failed to ensure establishment studies for Analytical sensitivity, Analytical specificity to include interfering substances, and any other performance characteristics required for test performance were completed when using the Diatron Abacus 5 hematology analyzer to test specimens for Complete Blood Counts (CBC) , using specimens greater than seven hours old. Analytes included in the CBC: White Blood Cell (WBC) Red Blood Cell (RBC) Hemoglobin (Hgb) Hematocrit (Hct) Mean

	Corpuscular Volume (MCV) Mean Corpuscular Hemoglobin (MCH) Mean Corpuscular Hemoglobin Concentration (MCHC) Red Cell Distribution Width (RDW) Platelet (PLT) Mean Platelet Volume (MPV) (see D5423)