Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1081814	08/12/2021
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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Review of manufacturer's instructions and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the CareStart COVID-19 Antigen Test. The findings included: 1. Review of the manufacturer's instructions found under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using your product must include with the test result reports, all authorized Fact Sheets." 2. Interview of testing person 4 on the CMS report 209 Laboratory Personnel Report conducted on August 11, 2021 at 11:03 AM confirmed that the laboratory did not include the Fact Sheets with the patient test results for COVID-19 Antigen testing.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Review of the CMS 209 Laboratory Personnel Report, proficiency testing records and interview of facility personnel found that the laboratory failed to ensure that all testing personnel performing moderately complex testing participated in proficiency testing

	for Chemistry and Hematology testing events in 2020 (three events each year). The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report provided during the survey found the laboratory listed four testing personnel performing moderate complexity testing. 2. Review of the American Proficiency Institute (API) Chemistry and Non-Chemistry attestations for 2020 found testing person 4 performed three of three events for both Chemistry and Non-Chemistry with testing person 1 performing Hemoglobin A1C and Human Chorionic Gonadotropin (HCG) testing in the 1st, 2nd and 3rd testing events for Chemistry. Testing persons 2 and 3 (both hired in 2019) did not participate in proficiency testing events. 3. Interview of testing person 4 conducted on August 11, 2021 at 10:14 AM confirmed that he had done most of the proficiency testing events. He went on to say that he was "going to let them do one".
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Review of proficiency testing records, patient test records and interview of the facility personnel found the laboratory failed to verify the accuracy of results for SARS/Covid testing at least twice each year in 2020 and 2021. The findings included: 1. Review of the American Proficiency Institute (API) proficiency testing records for 2020 and 2021 (three events each year) found that the laboratory had no proficiency records for SARS/Covid testing using the Healgen COVID-19 IgG/IgM Rapid test cassette. 2. Documentation of verification of accuracy of results for SARS/Covid testing using the Healgen COVID-19 IgG/IgM Rapid test cassette was requested but not provided. 3. Review of patient test records found 6320 patients tested using the Healgen COVID-19 IgG/IgM Rapid test cassette between April 28, 2020 and august 11, 2021. $. Interview of testing person 4 on the CMS report 209 Laboratory Personnel Report conducted August 11, 2021 at 11:08 AM confirmed that the laboratory did not enroll in a proficiency testing program or have another means to verify the accuracy of results obtained using the Healgen COVID-19 IgG/IgM Rapid test cassette.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: Review of manufacturer's instructions, patient test records and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the Healgen COVID-19 IgG/IgM Rapid Test Cassette in 2020 and 2021. The findings included: 1. Review of the manufacturer's instructions found under the heading CONDITIONS OF AUTHORIZATION FOR LABORATORY " Authorized laboratories using the Healgen COVID-19 IgG/IgM Rapid Test Cassette must include with result reports, all authorized Fact Sheets." 2. Review of patient test records found

	the laboratory tested 6320 patient specimens using the Healgen COVID-19 IgG/IgM Rapid Test Cassette between April 28, 2020 and August 11, 2021. 3. Interview of testing person 4 on the CMS report 209 Laboratory Personnel Report conducted on August 11, 2021 at 11:03 AM confirmed that the laboratory did not include the Fact Sheets with the patient test results for COVID-19 IgG/IgM.