

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D0969790	<b>(X3) Date Survey Completed</b>  03/09/2021
<b>Name of Provider or Supplier</b>  Megamed Clinical Laboratories, Inc	<b>Street Address, City, State</b>  7302 Canby Ave, Reseda, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2077</b>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(c)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Association of Bioanalysts (AAB) proficiency testing records for the second event of 2020 (Q2-2020), five (5) randomly selected patients from 09/03/2019 to 02/13/2021, and interview with the technical supervisor (TS) and testing personnel (TS); the laboratory failed to participate a testing event for General Immunology which is unsatisfactory performance and resulted in a score of 0 for the testing event. The findings included: 1. Laboratory proficiency testing records showed the laboratory attained an overall score of 0% for General Immunology testing during Q2-2020 as follow: Anti-HIV = 0.0 % HBS AG = 0.0% ANTI-HBC = 0.0% 2. The TS and TP affirmed on March 9, 2021, at approximately 2:30 p.m. the unsatisfactory score of 0% obtained by the laboratory on General Immunology testing for Q2-2020. 3. Based on the annual test volume reported for 2020, the laboratory performed and reported approximately 50,000 tests for the specialty of General Immunology.</p>
<b>D2087</b>	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p>

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on review of the American Association of Bioanalysts (AAB) proficiency testing records and interview with the technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to attain a score of at least 80 percent of acceptable responses for multiple Chemistry analytes for the years 2019 and 2020. The finding included: 1. Based on review of PT records for 2019 and 2020, the AAB reported the following unsatisfactory scores for the following analytes: Q1-2019 Vitamin D = 50%, Q1-2020 Homocysteine = 50% and Albumin = 60%, Q3-2020 Homocysteine 0.0% and Q3-2020 High Sensitivity C-reactive Protein = 0.0%. 2. Based on the laboratory testing declaration submitted at the time of the survey on March 9, 2021 the laboratory analyzed and reported approximately 80,000 Routine and Special Chemistry tests for each year during the time the laboratory had unsatisfactory proficiency testing results. 3. The TS and TP affirmed on 03/9/2021 at approximately 2:30 p.m. that the laboratory received the above unsatisfactory proficiency testing scores.

**D3005**

**FACILITIES**

CFR(s): 493.1101(a)(3)

Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

This STANDARD is not met as evidenced by:

Based on direct observation of the facilities layout, observation of the of the laboratory's SARS-CoV-2 RNA (COVID-19) Polymerase Chain Reaction (PCR) testing, and interviews with the laboratory technical supervisor (TS) and testing personnel (TP) on March 9, 2021 on its molecular amplification procedure; it was determined that the laboratory failed to ensure that the molecular amplification procedures which are not contained in closed systems have a unidirectional flow with separate areas for specimen preparation, reagent preparation, RNA extraction, amplification, and RNA detection. The findings included: 1. The laboratory performed PCR testing for the presumptive detection of SARS-CoV-2 using the ABI7500 and Automatic Quant Studio. 2. During the laboratory tour on 03/09/2021 at approximately 3:30 p.m. the examiner observed that storage and preparation of reagents and PCR reaction using the QuantStudio and ABI7500 were all performed in the same area without unidirectional flow. 3. The TS and TP confirmed by interview on March 9, 2021 at approximately 4:00 p.m. that the laboratory's molecular PCR testing for the presumptive detection of SARS-CoV-2 RNA was not set up in unidirectional flow areas. 5. Based on laboratory records, the laboratory performed and reported approximately 46,300 SARS-CoV-2 Real time PCR molecular diagnostic tests since started testing by PCR molecular testing on 09/20/2020.

**D5415**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**

CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and

when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on observation of the laboratory's reagent materials used for preparation of the Master Mix used in the Polymerase Chain Reaction (PCR) and interview with the laboratory's Technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to label the PCR reagents to indicate the opening, preparation and expiration dates when such reagents are used for the PCR detection of SARS-CoV-2 RNA. The findings included: 1. Based on surveyor observation during the laboratory tour on March 9, 2021 at approximately 1:00 pm., the TP indicated that no opening, preparation, or expiration date labels were used and documented for reagents used for the preparation of the Master Mix used in the PCR reaction to detect SARS-CoV-2 RNA. 2. The laboratory's TS and TP affirmed in an interview conducted March 9, 2021 at approximately 2:00 p.m. that the Master Mix reagents were not labeled with opening, preparation, and expiration dates or documented. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 46,300 PCR samples since 09/09/2020.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 on the lack of laboratory's verification of performance documentation for the Quant Studio analyzer for performing high complexity SARS-CoV-2 RNA detection by the Polymerase Chain Reaction (PCR), an interviews with the laboratory technical supervisor (TS) and 2 randomly selected COVID-19 patient test records reviewed from 02/17/2021; the laboratory failed to demonstrate that it established performance specifications comparable to those established by the manufacturer. The Findings include: 1. The laboratory had no documentation to show that the SARS-CoV-2 RNA detection by PCR performance specifications were performed prior to reporting patient test results. The laboratory must be able to demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (A) Accuracy (B) Precision (C) Reportable range of test results for the test system (D) Sensitivity and (E) Specificity. 2. The laboratory was unable to provide for review additional documents using patient samples to establish the performance specifications in 1. 3. The TS affirmed at the time of the survey on 03/09/2021 at approximately 4:00 p. m. that no documents could be retrieved to show that the SARS-CoV-2 RNA detection by PCR performance specifications were performed prior to reporting patient test results when the laboratory went live testing and reporting COVID-19 diagnostic tests on 09/09/2020. 4. Based on the estimated annual tests volumes reported on 03/09/2021; the laboratory

has performed approximately 46,300 SARS-CoV-2 RNA by PCR test since 09/09 /2020. The accuracy, precision, and reliability of the reported results could not be assured.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation, lack of maintenance protocol and documentation, and interview with the laboratory's technical supervisor (TS) and testing personnel (TP); it was determined that the laboratory failed to establish and document a maintenance protocol for the Biological Safety Cabinet, vortex, mixer, automatic repeating pipettes, and thermometers that ensures its continued performance necessary for accurate and reliable test results. The findings included: 1. The laboratory uses a LABCONCO Biosafety Cabinet (BSC) for processing samples and preparation of reagents, and small equipment such as vortexes, mixers, automatic repeating pipettes, and thermometers for various procedures used in the laboratory. 2. Based on surveyor observation during tour of the laboratory on March 9, 2021 at approximately 10:45 a.m. the equipment described above used in the laboratory had no records of maintenance. 3. The TS and TP affirmed that the laboratory failed to establish a maintenance protocol for the BSC and small equipment described in 1. 4. Based on the laboratory's monthly testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 208,000 samples annually.

**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 American Association of Bioanalysts proficiency failures (D2077 and D2087), failure to ensure that the molecular amplification procedures have a unidirectional flow with separate areas for specimen preparation, reagent preparation, RNA extraction, amplification, and RNA detection (D3005); failure to ensure PCR reagents are labeled to indicate the opening, preparation, and expiration dates (D5415); failure to demonstrate that it established performance specifications comparable to those established by the manufacturer (D5421); and failure to establish and document a maintenance protocol for the Biological Safety Cabinet and small equipment used in the laboratory (D5433); it was determined that the laboratory

director failed to 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.

**D6115**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures for SARS-CoV-2 detection by the Polymerase Chain Reaction and interview with the testing personnel, it was determined that the technical supervisor failed to be responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including precision, accuracy, specificity, and sensitivity of the test system. See D3005, D5415, D5421, and D5433.