

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2210191	<b>(X3) Date Survey Completed</b>  09/10/2024
<b>Name of Provider or Supplier</b>  Mega Lab-Health Care Svc, Llc	<b>Street Address, City, State</b>  2296 Optiz Blvd, Suite 260, Woodbridge, VA	
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>D0000</b>	An off-site CLIA proficiency testing desk review of Mega-Lab Health Care Svc, LLC was completed on September 9, 2024 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The laboratory was found not in compliance with the following Condition under 42 CFR part 493 CLIA Regulations: D2016 - 42 C.F.R. 493.803 (a)(b)(c) Condition- Successful Participation.
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report and College of</p>

American Pathologists (CAP) proficiency testing scores for 1. 2023 (Event three) and 2024 (Event one), the laboratory failed to successfully participate in a proficiency testing program approved by Health and Human Services (HHS) for the analyte Total Bilirubin (TBil). Refer to D2096 A. 2. 2024 (Events one, and two), the laboratory failed to successfully participate in a proficiency testing program approved by Health and Human Services (HHS) for the analytes Amylase (Amy), Total Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Creatine Kinase (CK), Iron (Fe), Triglyceride (Trig). Refer to D2096 B.

**D2096**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

A. Based on a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report, and College of American Pathologists (CAP) evaluation reports for 2023 (Events two and three) and 2024 (Events one and two), the laboratory failed to achieve satisfactory performance (80%) for the Chemistry analyte Total Bilirubin (TBil) for two (2) of four (4) events reviewed. The laboratory had unsatisfactory scores for TBil for two consecutive PT events (2023 Event 3, and 2024 Event 1) resulting in initial unsuccessful participation. The findings include: 1. Review of the CASPER-0155 report revealed the following unsatisfactory scores: 2023 Event 3: TBil = 40%, 2024 Event 1: TBil = 40%, 2. A review of the laboratory's 2023 events 2 and 3 and 2024 event 1 and 2 CAP PT scores for the analyte TBil confirmed the above findings resulting in initial unsuccessful participation for the analyte TBil. B. Based on a proficiency testing (PT) desk review of the laboratory's Certification and Survey Provider Enhanced Reporting (CASPER)-0155 report, and College of American Pathologists (CAP) evaluation reports for 2023 (Events two and three) and 2024 (Events one and two), the laboratory failed to achieve satisfactory performance (80%) for the Chemistry analytes Amylase (Amy), Total Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Creatine Kinase (CK), Iron (Fe), Triglyceride (Trig) for two (2) of four (4) events reviewed. The laboratory had unsatisfactory scores for Amylase (Amy), Total Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Creatine Kinase (CK), Iron (Fe), and Triglyceride (Trig) for two consecutive PT events (2024 Events 1 and 2) resulting in initial unsuccessful participation. The findings include: 1. Review of the CASPER-0155 report revealed the following unsatisfactory scores: 2024 Event 1: Amylase (Amy), Total Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Creatine Kinase (CK), Iron (Fe), and Triglyceride (Trig) = 0%, 2024 Event 2: Amylase (Amy), Total Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Creatine Kinase (CK), Iron (Fe), and Triglyceride (Trig) = 0%, 2. A review of the laboratory's 2023 events 2 and 3 and 2024 event 1 and 2 CAP PT scores for the Chemistry analytes above confirmed the findings resulting in initial unsuccessful participation for the analytes Amylase (Amy), Total Cholesterol (Chol), High Density Lipoprotein Cholesterol (HDL), Creatine Kinase (CK), Iron (Fe), and Triglyceride (Trig).