

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2210191	(X3) Date Survey Completed 01/25/2022
Name of Provider or Supplier Mega Lab-Health Care Svc, Llc	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced on-site CLIA initial survey was conducted at Mega Lab-Health Care Svc, LLC on January 25, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The survey included an entrance interview on December 21, 2021 and virtual record review conducted on January 18, 2022. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The inspector noted that the laboratory performs SARS-CoV-2 (COVID-19) testing and is in compliance with the applicable COVID-19 reporting requirements. The specific deficiency cited is as follows:
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a tour, review of the manufacturer's package insert, test result logs, and interviews, the facility failed to follow the manufacturer's instructions for the sample type while performing three (3) COVID-19 (SARS-CoV-2) tests for two (2) testing days between July 21, 2021 and January 21, 2022. Findings include: 1. During a tour of the laboratory on January 25, 2022 at approximately 11:30 AM, the inspector inquired of Testing Personnel A (TP A) regarding the laboratory protocol for "Inconclusive" COVID-19 patient results received when performing SARS CoV-2 (COVID-19) testing using the TaqPath COVID-19 Combo Kit on the QuantStudio 5. TP A stated that they repeat the test on the Accula SARS CoV-2 test system using the patient's viral transport media (VTM) solution. They take the swab provided with the Accula SARS CoV-2 kit and "swirl" it in the patient's VTM and proceed with the test according to the Accula kit manufacturer's instructions. 2. Review of the Accula SARS CoV-2 Test system's manufacturer's instructions for use (IFU) revealed the</p>

following statements, "LIMITATIONS-Collection of patient samples into media other than the supplied Accula SARS-CoV-2 Buffer (such as UTM, VTM, or saline), or dilution of previously collected samples out of UTM, VTM, or saline into the Accula SARS-CoV-2 Buffer is off-label use and has been shown to adversely impact test performance." 3. Review of the QuantStudio 5's COVID-19 patient test results from July 21, 2021 until January 21, 2022 revealed the following patient COVID-19 results analyzed as "Inconclusive": 07/21/2021-Accession number 0011-ML000265; 09/01/2021-Accession number 0011-ML000998; 01/21/2021-Accession number 0011-ML001821; 01/21/2021-Accession number 0011-ML005333. The surveyor requested to review the method used for the repeat testing of the above listed "Inconclusive" results. The laboratory provided the following documentation: 07/21/2021-Accession number 0011-ML000265-specimen repeated using the TaqPath Combo Kit with a positive result reported; 09/01/2021-Accession number 0011-ML000998-specimen repeated using the Accula kit with a positive result reported; 01/21/2021-Accession number 0011-ML001821-specimen repeated using the Accula kit with a negative result reported; and 01/21/2021-Accession number 0011-ML005333-specimen repeated using the Accula kit with a negative result reported. 4. In an exit interview with the Technical Supervisor and TP A on January 25, 2022 at approximately 12:00 PM, the above findings were confirmed.