Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2177298	01/27/2021
Name of Provider or Supplier	**Street Address, City, State**	
Medfast Urgent Care Centers Llc	5500 Stadium Parkway, Melbourne, FL	

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 unannounced complaint survey, #2020018672 was conducted on January 27, 2021. Medfast Urgent Care Centers LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to report SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) test results for positive and negative Coronavirus Disease 2019 (COVID-19) for immunoglobulin G (IgG) and immunoglobulin M (IgM) antibody test from 04/22/2020 to 01/27/2021. The laboratory failed to report SARS-CoV-2 for the COVID-19 antigen test results at such time and frequency as prescribed. Findings: 1. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed by the Laboratory Director on 1/27/21 showed the laboratory was currently using "Assure Tech FaStep COVID-19 IgG/IgM Antibody Fingerprick test." Review of an email received on 2/2/2021 from the Chief of Operations, the laboratory had performed 1,707 antibody tests. During an interview on 01/27/2021 at 2:07 PM, the Chief of Operations stated they had not reported the results from the antibody tests to the Florida Department of Health. During a phone interview on 1/29/2021 at 3:30 PM, the Chief of Operations stated the lab started performing antibody testing on 4/22/20. 2. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed by the Laboratory Director on 01/27/2021, showed the laboratory was currently using the "CareStart - Rapid Covid-19 Antigen Test" and the "Sofia

	SARS Antigen FIA (Fluorescent Immunoassay)." Review of an email received on 2/2/2021 from the Chief of Operations, noted the laboratory had performed 7,946 antigen tests. During an interview on 01/27/2021 at 2:10 PM, the Chief of Operations stated they were currently working on reporting antigen testing from 01/21/2021. During a phone interview on 1/29/2021 at 3:30 PM, the Chief of Operations stated the lab started performing antigen testing on 8/5/20.