Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D2253458	03/11/2022
Name of Provider or Supplier	**Street Address, City, State**	
Us Spa Corp Dba Medset Labs	809 E Arrowood Rd Suite 500, Charlotte, NC	

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
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 observation, interview with staff and phone interview with the laboratory director on 3/11/22, and email communication with the laboratory director 3/15/22 and 3/16/22, the laboratory failed to provide documentation that SARS-CoV-2 positive and negative test results were reported to the local or state public health authorities from December 2021 to March 2022. Findings: During tour of testing site 3 /11/22, the surveyor observed rapid antigen SARS-CoV-2 testing being performed using the Celltrion Diatrust Covid -19 rapid antigen test and specimens which had been collected and placed in VTM(viral transport medium). During interview at approximately 12:00 p.m. on 3/11/22, the on-site attendant confirmed testing began at the testing site around the end of December 2021. She stated that nasal swabs were being collected and the rapid antigen test was being performed on-site and specimens in VTM were being sent to the Chicago laboratory for the SARS-CoV-2 PCR (polymerase chain reaction) test. During phone interview at approximately 12:45 p.m. on 3/11/22, the laboratory director stated the SARS-CoV-2 test results were being reported to the state and he would submit documentation by email the following business day for the results being reported. In the email communication with the laboratory director on 3/15/22, the surveyor requested documentation showing that all positive and negative SARS-CoV-2 results from the testing site were being reported to the local or state public health department. In the laboratory director's response on 3 /15/22, he stated, "In accordance with the CARES act section 18115 with guidance for COVID-19 laboratory test reporting Being Human Medical reports all NAAT Tests

	performed at our facility to the local state department through a verifiable, centralized platform established and provided by the state of Illinois. The Illinois Department of Public Health then forwards the required information to appropriate entities including the CDC. See attached document..." The attached document provided was a copy of the COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115 March 8, 2022, Effective date: April 4, 2022. During email communication with the laboratory director on 3/16/22, the surveyor requested the laboratory's policy /procedure specific for SARS-CoV-2 test reporting and a sample of test records/ documentation of the SARS-CoV-2 test reporting from their laboratory for testing that was performed in our state. No further documentation was provided by the laboratory director to show the laboratory had reported all positive and negative SARS-CoV-2 test results as required.