

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1079189	<b>(X3) Date Survey Completed</b>  01/21/2021
<b>Name of Provider or Supplier</b>  Us Med Care Llc	<b>Street Address, City, State</b>  7682 Hwy 23 Suite B, Belle Chasse, LA	
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 Initial/Complaint (LA 00056821) survey was performed at US Med Care, LLC-CLIA ID 19D1079189 on January 21, 2021. US Med Care, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1100 CONDITION: Facility administration
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) 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.</p> <p>This CONDITION is not met as evidenced by: Based on direct observation by surveyor and interview with the Testing Personnel, the laboratory failed to report patient test results for the Healgen Scientific, LLC COVID-19 IgG/ IgM Rapid Test to the state public health agency as required for eighty eight (88) of eighty eight (88) patients reviewed. Findings: 1. Observation by surveyor on January 21 2021 at 10:39 am revealed the laboratory had one (1) empty box of Healgen COVID -19 IgG/ IgM Rapid Test Cassette kit (Lot # 2006168EUA). 2. In interview on January 21, 2021 at 10:46 am, the Testing Personnel stated the laboratory began using the Healgen test kits two (2) to three (3) months ago. In further interview, the Testing Personnel stated the laboratory was out of the Healgen test kits and planned to use the waived Care Start COVID-19 Antigen tests. The Testing Personnel further stated the laboratory's policies were located on the computer that</p>

was in use for virtual visits. The laboratory did not provide the surveyor with their laboratory's policies and procedures during the on-site survey on January 21, 2021. 3. In interview on January 21, 2021 at 10:50 am , the Testing Personnel stated the laboratory does not report test results to any state agency. The Testing Personnel stated the test results are given to the person tested, who are to provide to their primary care physician. 4. The testing personnel provided eighty eight (88) patient COVID antibody test results from January 2, 2021 through January 14, 2021. 5. The laboratory did not provide to the surveyor patient test records prior to January 2021 or the date the laboratory began performing COVID-19 patient testing.