

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D1005284	<b>(X3) Date Survey Completed</b>  04/15/2021
<b>Name of Provider or Supplier</b>  Medhelp Narrows	<b>Street Address, City, State</b>  151 Narrows Parkway, Suite 110, Birmingham, AL	
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>D3000</b>	<p>FACILITY ADMINISTRATION 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 record review and interview, the laboratory failed to report SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) test results for negative Coronavirus Disease 2019 (COVID-19) performed on the Abbott ID NOW COVID-19, Abbott COVID-19 Antigen BinaxNow, BD Veritor COVID antigen, CareStart COVID-19 antigen, and COVID-19 IgG/IgM Rapid Test from January 8, 2021 [the date State Surveyors received CMS guidance for surveying on this deficiency] to April 15, 2021. The laboratory failed to report negative results for SARS-CoV-2 for the COVID-19 antigen test results to the Alabama Department of Public Health and positive results were reported to the Report Card for Alabama Department of Public Health (which is not the mechanism to use to report a patient that has a reportable disease). Findings include: 1. A review of SARS-CoV-2 test results revealed patients were tested for SARS-CoV-2 using the Abbott COVID-19 Antigen BinaxNow, BD Veritor COVID antigen, and CareStart COVID-19 antigen test, starting September 24, 2020 through April 15, 2021. A total of 2530 test were performed (472 Positives and 2058 Negatives) during this time period. A review of SARS-CoV-2 test results revealed patients were tested for SARS-CoV-2 using Abbott ID NOW COVID-19</p>

test, starting October 01, 2020 through April 15, 2021. A total of 254 test were performed (48 Positives and 206 Negatives) during this time period. 2. During an interview on April 15, 2021 at 09:20 AM, Laboratory Supervisor stated positive results were reported to the Novel Coronavirus (COVID-19) Report Card to the Alabama Department of Public Health. The Report Card has the following statement "If you are a Laboratorian, reporting on behalf of a laboratory, blood bank, or plasma center, the REPORT Card is not the mechanism you should use to report a patient that has a reportable disease or health condition." Laboratory Supervisor confirmed the laboratory had reported only positives (to the Report Card) but none of the negative SARS-CoV-2 patient test results were reported to the Alabama Department of Public Health.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:  
Based on a review of a test report and an interview with the Laboratory Supervisor, the laboratory failed to include the name and address of the laboratory where the test was performed on the test report. This was noted on one out of one test report for Complete Blood Count (CBC) reviewed by the surveyor. The findings include: 1. A review of a CBC test report revealed under performing lab "MDP - Relaymed results Winter Park, FL 32789". Performing laboratory of this CBC was Medhelp the Narrows - 151 Narrows Parkway Suite 110 Birmingham, AL 35242. 2. During an interview on 04/15/2021 at 01:30 PM, Laboratory Supervisor confirmed the laboratory name and address are not on the test report of the CBC test report reviewed.