

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  36D0684157	<b>(X3) Date Survey Completed</b>  07/13/2021
<b>Name of Provider or Supplier</b>  Columbus Center For Human Services	<b>Street Address, City, State</b>  600 Industrial Mile Road, Columbus, OH	
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>D1001</b>	<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 record review and interviews with Laboratory Manager (LM) #1 and LM#2, the laboratory failed to follow their policy and procedure regarding COVID-19 result reporting on eight out of nine COVID-19 tests conducted from March 1, 2021 through June 22, 2021. Findings Include: 1. Review of the laboratory's "6.01 - Reporting of Communicable Disease to Health Department" policy and procedure, provided for inspection of the SARS-CoV-2 testing and reporting documentation found the following statement: "2. All positive and negative COVID-19 Coronavirus testing completed using on-site BINAX test are reported using the Navica application." 2. The laboratory's SARS-CoV-2 patient testing and result reporting documentation was reviewed from 03/01/2021 through 06/22/2021 and revealed one positive patient COVID-19 tested on 03/19/2021 was reported to the health department and found the following eight out of eight negative patient COVID-19 test results that were not reported to the health department: 03/19/2021 1 patient result - negative 03/30/2021 1 patient result - negative 04/06/2021 1 patient result - negative 04/14/2021 1 patient result - negative 04/20/2021 1 patient result - negative 04/28/2021 1 patient result - negative 05/03/2021 1 patient result - negative 05/04/2021 1 patient result - negative 3. The Inspector requested the laboratory's evidence that the above mentioned COVID-19 negative results were reported to the health department from LM#1 and LM#2. LM#1 and LM#2 both confirmed on 06/23/2021 at 11:45 AM, the laboratory did not report eight out of eight patient COVID-19 negative test results to the health department, did not follow their COVID-19 result reporting policy and procedure and were unable to provide the requested documentation.</p>

**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 interviews with Laboratory Manager (LM) #1 and LM#2 found that the laboratory failed to report all SARS-CoV-2 test results as required for eight out of nine patients tested and reviewed from March 1, 2021 through June 22, 2021. Findings Include: 1. Review of the laboratory's "6.01 - Reporting of Communicable Disease to Health Department" policy and procedure, provided for inspection of the SARS-CoV-2 testing and reporting documentation found the following statement: "2. All positive and negative COVID-19 Coronavirus testing completed using on-site BINAX test are reported using the Navica application." 2. The laboratory's SARS-CoV-2 patient testing and result reporting documentation was reviewed from 03/01/2021 through 06/22/2021 and revealed one positive patient COVID-19 tested on 03/19/2021 was reported to the health department and found the following eight out of eight tested and unreported patient negative COVID-19 test results were not reported: 03/19/2021 1 patient result - negative 03/30/2021 1 patient result - negative 04/06/2021 1 patient result - negative 04/14/2021 1 patient result - negative 04/20/2021 1 patient result - negative 04/28/2021 1 patient result - negative 05/03/2021 1 patient result - negative 05/04/2021 1 patient result - negative 3. The Inspector requested the laboratory's evidence that the above mentioned COVID-19 negative results were reported to the health department from LM#1 and LM#2. LM#1 and LM#2 both confirmed on 06/23/2021 at 11:45 AM, the laboratory did not report, to the health department, the eight out of eight patient COVID negative test results identified during the remote inspection and were unable to provide the requested documentation.