

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D2236818	<b>(X3) Date Survey Completed</b> 07/13/2022
<b>Name of Provider or Supplier</b> Joseph House Inc	<b>Street Address, City, State</b> 1526 Republic St, Cincinnati, 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><b>CERTIFICATE OF WAIVER TESTS</b> 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 the Laboratory Director and the Joseph House Program Director (JHPD), the laboratory failed to report SARS-Co-V-2 test results as required. This deficient practice had the potential to affect one out of one positive COVID patient tested from 03/07/2022 through 06/08/2022. Findings Include: 1. Review of the laboratory's "Joseph House COVID Standard Operating Procedures", policy and procedure provided for inspection of the SARS-CoV-2 testing and reporting found the following: "The occurrence of cases or suspected cases of a disease classified as class "A", class "B", or class "C" shall be reported, in detail, by health care providers and laboratories to the board of health on forms as prescribed and provided by the director and shall be reported in accordance with this rule and Chapter 3701-3 of the Administrative Code. The following diseases are classified as class "A" - diseases of major public health concern because of the severity of disease or potential for epidemic spread and shall be reported immediately via telephone in accordance with rules 3701-3-03, 3701-3-04, and 3701-3-05 of the Administrative Code: ...novel virus infection..." "Joseph House is required to report all test results to the Ohio Department of Health (At this time, Joseph House has been unable to fulfill with requirement due to web site difficulties.)" 2. The laboratory's SARS-CoV-2 patient result reporting documentation, provided for inspection review, was reviewed from 03/07/2022 through 06/08/2022 and found one individual tested and resulted as positive for COVID-19. 3. The Inspector requested the laboratory's evidence that the above mentioned COVID-19 test result was reported to the Ohio Department of Health from the Laboratory Director. The Laboratory Director confirmed via a phone</p>

conversation on 06/16/2022 at 2:20 PM that the laboratory did not report any results to any health department, only to the Veteran's Association (VA). Additionally, the JHPD confirmed via an electronic mail (email) on 06/21/2022 at 8:21 AM that COVID results have not been reported to the health department due to unresolved issues with the reporting portal. The requested documentation was unable to be provided on the date of the inspection.

**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 interviews with the Laboratory Director and the Joseph House Program Director, the laboratory failed to report all SARS-Co-V-2 test results as required for one out of one patient tested from 03/07/2022 through 06/08/2022.  
Findings Include: 1. The laboratory failed to report SARS-Co-V-2 test results as required. (Refer to D1001)