

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D1004472	(X3) Date Survey Completed 08/05/2021
Name of Provider or Supplier Ohio Northern University Raabe	Street Address, City, State 525 South Main, Ada, OH	
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	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>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 interviews with the Laboratory Director and Director of ONU Healthwise & Pharmacy Residency Programs (DoONU) found that the laboratory failed to report all SARS-Co-V-2 test results as required for 1756 out of 1794 patients tested and reviewed from April 1, 2021 through August 2, 2021. Findings Include: 1. Review of the laboratory's "COVID-19 Screening and Testing On-Campus" policy and procedure, provided for inspection of the SARS-CoV-2 testing and reporting documentation found the following statement: "7. The pharmacy will report positive results to Kenton Hardin Health Department, the VP of Student Affairs (if a student), the Director of Human Resources (if an employee), the student health center, the COVID-19 coordinator the head athletic trainer (if an athlete), and the university president." 2. The laboratory's SARS-CoV-2 patient testing and result reporting documentation was reviewed from 04/01/2021 through 08/02/2021 and found 38 positive patient COVID-19 test results reported to the local and Ohio departments of health. Further review found 1725 out of 1725 negative patient test results and 14 out of 14 inconclusive patient test results were not reported. 3. The Inspector requested the laboratory's evidence that the above mentioned negative and inconclusive COVID-19 results were reported to the Ohio Department of Health from the Laboratory Director and the DoONU. The Laboratory Director and the DoONU both confirmed on 07/28/2021 at 9:25 AM, that the laboratory did not report 1756 out of 1756 patient COVID-19 negative and inconclusive test results identified during the remote inspection and were unable to provide the requested documentation.</p>