

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2036210	(X3) Date Survey Completed 07/13/2021
Name of Provider or Supplier Five Rivers Health Centers Edgemont	Street Address, City, State 721 Miami Chapel Road, Dayton, 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
D3000	<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 an interview with the Laboratory Supervisor (LS) found that the laboratory failed to report all SARS-CoV-2 test results as required for three out of three patients tested and reviewed from February 15, 2021 through June 10, 2021. Findings Include: 1. Review of the laboratory's "Rapid COVID-19 Antigen Testing" policy and procedure, provided for inspection of the SARS-CoV-2 testing and reporting documentation found the following statement: "8) Results I. Positive Antigen Reports must be reported to Ohio Department of Health by reporting the results on the Ohio Confidential Reportable Disease form (HEA 3334 Rev.5/14) to the patients County of Residence." 2. The laboratory's SARS-CoV-2 patient testing and result reporting documentation was reviewed from 02/15/2021 through 06/10/2021 and found the following three out of three tested and unreported patient COVID-19 test results: 02/15/2021 1 patient result - negative 02/25/2021 1 patient result - negative 03/01/2021 1 patient result - negative 3. The Inspector requested the laboratory's evidence that the above mentioned COVID-19 results were reported to the health department from the LS. The LS confirmed on 06/21/2021 at 4:05 PM, the laboratory did not report, to the health department, the three out of three patient</p>

COVID test results identified during the remote inspection and was unable to provide the requested documentation.