

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0384458	(X3) Date Survey Completed 01/13/2022
Name of Provider or Supplier Family Practice Clinic-West Bend	Street Address, City, State 107 West Division Street, West Bend, IA	
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
D0000	The laboratory was found to be in substantial compliance with the CLIA regulations (42 CFR Part 493, effective April 24, 2003). No deficiencies were cited.
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 the Waived Laboratory Test List & Annual Volume form and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 2:55 pm on 1/13/2022, the laboratory failed to report positive and negative SARS-CoV-2 results to the Iowa Department of Public Health for 157 patients from 12/1/2020 - 12/27/2021. The findings include: 1. The Waived Laboratory Test List & Annual Volume form stated the laboratory performed SARS-CoV-2 testing using the Binax Now and Abbott ID Now test systems. 2. From 12/1/2020 - 12/27/2021, the laboratory performed SARS-CoV-2 testing on 157 patients. 3. At the time of the survey, the laboratory had not reported the positive and negative SARS-CoV-2 test results to the Iowa Department of Public Health.</p>