

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0384266	<b>(X3) Date Survey Completed</b>  01/13/2022
<b>Name of Provider or Supplier</b>  Kossuth Regional Health Center	<b>Street Address, City, State</b>  122 W Ramsey St, Bancroft, IA	
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>D0000</b>	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.
<b>D3000</b>	<p><b>FACILITY ADMINISTRATION</b> 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 &amp; Annual Volume form and confirmed by laboratory personnel identifier #1 (refer to the Laboratory Personnel Report) at approximately 12:45 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 128 patients from 7/16/2021 - 1/13/2022. The findings include: 1. The Waived Laboratory Test List &amp; Annual Volume form stated the laboratory performed SARS-CoV-2 antigen testing using the Binax Now test system. 2. The laboratory began performing the SARS-CoV-2 antigen testing on 7/16/2021 and have since performed testing on 128 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>