Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	52D0921062	05/25/2021
Name of Provider or Supplier	**Street Address, City, State**	
Coppe Laboratories	W229 N1870 Westwood Dr, Waukesha, WI	

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	FACILITY ADMINISTRATION CFR(s): 493.1100 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. This CONDITION is not met as evidenced by: Based on surveyor review of testing records, observation of test orders, and interview with testing personnel and the technical supervisor, the laboratory failed to report approximately 2200 positive or negative SARS CoV-2 test results for samples received from a Clinical Research Organization (CRO) without a subject's name or address since the laboratory began testing for the CRO in May 2020. Findings include: 1. Review of worksheets for SARS CoV-2 testing showed the laboratory performed tests using the CDC (Centers for Disease Control and Prevention) and Euroimmun EUA (Emergency Use Authorization) test systems. 2. Observation of test orders on May 6, 2021 at 9:00 AM for SARS CoV-2 testing from a CRO showed the orders included the subject's initials, an identification number, and date of birth. An additional specimen identification number was also on the order added by the testing laboratory. The order did not include the subject's name or address. 3. Interview with testing personnel (staff A) on May 6, 2021 at 1:00 PM revealed the laboratory did not report positive or negative SARS CoV-2 test results to public health for samples received from a Clinical Research Organization (CRO) without a subject's name or address. 4. Interview with the technical supervisor (staff B) on May 6, 2021 at 2:00

	PM confirmed the laboratory did not report results to public health from samples received from a CRO without a subject's name or address. Further interview confirmed the contract between the laboratory and the CRO did not address the responsibility for reporting results from these samples to the state health department. 5. Email communication with staff B on May 7, 2021 at 12:01 PM confirmed the CRO laboratory did not report SARS CoV-2 test results from samples tested at this laboratory to state public health entities. 6. Email on May 25, 2021 at 1:59 PM confirmed the laboratory tested approximately 2200 samples without a subject's name or address from a CRO.