Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1043419	08/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Worldwide Clinical Trials	2455 Ne Loop 410 Suite 150, San Antonio, TX	

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 review of the manufacturer's instructions, review of patient test records from January 2021 - July 2021 and staff interview, it was revealed the laboratory failed to report 81 SARS-COV-2 IgM antibody and 81 SARS-COV-2 IgG antibody test results as required by 400.200 for 28 of 28 days reviewed. Findings include: 1. Review of the Instructions for Use for the Architect AdviseDx SARS-COV-2 IgM assay (6R87, H14977R01) under the section titled "Intended Use" revealed: "Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities." 2. Review of the Instructions for Use for the Architect AdviseDx SARS-COV-2 IgG assay (6R86, H14806R05) under the section titled "Intended Use" revealed: "Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities." 3. Review of the laboratory policies available revealed no documentation of a policy/procedure related to reporting COVID antibody test results. 4. Review of the laboratory's SARS-COV-2 IgM patient test records from January 1, 2021 to July 1, 2021 revealed no documentation the laboratory reported 81 patient antibody results on 28 days of testing. Refer to SARS-COV-2 IgM antibody Patient Alias list. a) January 2021 14

	negative results not reported 2 positive results not reported 2 test days b) February 2021 6 negative results not reported 2 positive results not reported 2 test days c) March 2021 1 negative result not reported 2 positive results not reported 3 test days d) April 2021 10 negative results not reported 1 positive result not reported 6 test days e) May 2021 10 negative results not reported 2 positive results not reported 4 test days f) June 2021 24 negative results not reported 6 positive results not reported 10 test days g) July 2021 1 negative result not reported 1 test day 5. Review of the laboratory's SARS-COV-2 IgG patient test records from January 1, 2021 to July 1, 2021 revealed no documentation the laboratory reported 81 patient antibody results on 28 days of testing. Refer to SARS-COV-2 IgG antibody Patient Alias list. a) January 2021 12 negative results not reported 4 positive results not reported 2 test days b) February 2021 7 negative results not reported 1 positive results not reported 2 test days c) March 2021 3 negative result not reported 3 test days d) April 2021 10 negative results not reported 1 positive result not reported 6 test days e) May 2021 11 negative results not reported 1 positive results not reported 4 test days f) June 2021 27 negative results not reported 3 positive results not reported 10 test days g) July 2021 1 negative result not reported 1 test day 6. An interview with the laboratory manager 08/10/2021 at 1440 hours over the phone revealed the laboratory did not report COVID IgG and IgM antibodies as required. This confirmed the findings.