Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0940439	04/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Cooper Institute Reproductive Laboratory	7500 Beechnut St, # 308, Houston, 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 a review of the Letter of Authorization, a random review of patient test records from September 2020 to April 2021, and staff interview, it was revealed that the laboratory failed to have documentation of reporting SARS-CoV-2 test results as required for 3 of 3 patients whose specimens were run using the Elecsys Anti-SARS-CoV-2 immunoassay from September 2020 to April 2021. Findings include: 1. A review of the Letter of Authorization for the Elecsys Anti-SARS-CoV-2 immunoassay (dated November 25, 2020) revealed the following: "Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and public health authorities, as appropriate." 2. A random review of patient test records from September 2020 to April 2021 revealed the laboratory failed to have documentation of reporting SARS-CoV-2 test results as required for the following 3 patients: Patient ID: HT Run: 3/26/21 SARS-CoV-2 test result: non-reactive (negative) Patient ID: SM Run: 4/2/21 SARS-CoV-2 test result: non-reactive (negative) Patient ID: DL Run: 4/7/21 SARS-CoV-2 test result: reactive (positive) 4.

	An interview with the laboratory director on 4/22/21 at 1:00 p.m. in the break room, after review of the records, confirmed he was unaware that the laboratory was required to report SARS-CoV-2 test results.