Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0704110	11/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Nih Niddk Pecrb Decrs	1550 E Indian School Rd, Phoenix, AZ	

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 SARS CoV-2 patient test results, interview with the laboratory director and lack of reporting documentation for review, the laboratory failed to report SARS-CoV-2 test results as required for 2 of 2 days reviewed from September 30, 2021 through November 1, 2021. Findings include: 1. The laboratory performs SARS-CoV-2 testing utilizing the Cepheid SARS-CoV-2 Xpert Xpress real time RT-PCR test and since September 30, 2021. 2. SARS-CoV-2 test result from 11/01/21 (#32830) was reviewed during the survey on 11/02/21. 2 SARS-CoV-2 test results were not reported as required during the period of review. 3.No evidence was presented for review during the survey on 11/02/21 to indicate that the laboratory had reported SARS-CoV-2 test results (positive and negative) to the State authorities as required for patient testing performed by the laboratory on 9/30/21 and 11/01/21. 4. The laboratory director confirmed on 11/02/21 at 9.33 a.m. that the laboratory was not aware of SARS-CoV-2 test result reporting requirements and had not reported SARS-CoV-2 test results as required since initiating patient testing on 09/30/21.
D5403	PROCEDURE MANUAL

	CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of SARS CoV-2 patient test results and interview with the laboratory director on 11/02/2021, the laboratory failed to have a policy or procedure for reporting SARS CoV-2 patient results as required. 1. The laboratory performs SARS-CoV-2 testing utilizing the Cepheid SARS-CoV-2 Xpert Xpress real time RT-PCR test and since September 30, 2021. 2. Review of the laboratory's SARS-CoV-2 patient testing records from 09/30/21 to 11/01/2021 revealed that the laboratory did not have a written policy or procedure for required reporting of SARS-CoV-2 testing results to the State authorities, and has not been reporting patient test results as required. 3. The laboratory performed 2 SARS-CoV-2 tests during the period of review. 4.The laboratory director confirmed on 11/02/21 at 9.33 a.m. that the laboratory did not have a policy or procedure for reporting SARS-CoV-2 test results as required to the appropriate health authorities.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of laboratory policy, lack of instrument function check records for review and interview with the laboratory director, the laboratory failed to perform function checks certifying the biological safety cabinet (BSC) as being within established limits prior to performing patient testing. Findings include: 1. The

	laboratory began performing SARS-CoV-2, real-time RT-PCR patient testing on 09/30 /21 using the Cepheid GeneXpert system located in the NuAire LabGard ES biological safety cabinet, tag# 01582498. 2. No certification tag was observed on the BSC by the surveyor during a tour of the facility on 11/02/21. 3. No records were presented for review during the survey on 11/02/21 to indicate that function checks certifying the BSC as being within established limits were performed after installation and prior to performing SARS-CoV-2 RT-PCR patient testing initiated since 09/30 /21. 4. The laboratory performs an estimated annual test volume of 25,000 tests and performed 2 SARS-CoV-2 real-time RT-PCR tests on 9/30/21 and 11/01/21. 5. The laboratory director confirmed on 11/02/21 at 9.15 a.m. that the laboratory failed to perform function checks certifying the biological safety cabinet as being within established limits prior to performing SARS-CoV-2 real-time RT-PCR patient testing initiated since 09/30/21.