Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2114379	(X3) Date Survey Completed 06/07/2021
Name of Provider or Supplier National Clinical Labs	**Street Address, City, State** 1025 Ogden Ave, Lisle, IL	

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 observation; review of patients' records; and interview with testing personnel, the laboratory failed to report SARS-CoV-2 test results to the Illinois Department of Public Health (IDPH) during the Public Health Emergency. Findings: 1. On survey date April 26, 2021 at 9:45 AM the surveyor observed 1 of 2 testing personnel performing SARS-CoV-2 testing using the GENEDIA COVID -19 Ag test kit. 2. On survey date April 26, 2021 at 10:30 AM, the surveyor observed that consent forms for SARS-CoV-2 Ag testing were stacked in the room where testing was performed, as well as in drawers near the drive-through were PCR specimens were collected. The surveyor noted that PCR testing was not performed at this location. 3. On survey date April 26, 2021 at 11:00 AM, the surveyor selected a total of 136 patients' consent forms and requested corresponding test reports for its SARS-CoV-2 test results. Testing personnel #1 was unable to provide the surveyor with test reports for 136 of 136 patients' consent forms. 4. On April 26, 2021 at 11:15 AM, the surveyor asked testing person #1 to show how the laboratory reports it SARS-CoV-2 test results to IDPH. The surveyor was told that the manager takes the reports. Testing Person #1 told the surveyor that she did not know if patients' test results are reported

	to IDPH. 5. There was no documentation or electronic record to show that SARS-CoV-2 test results were reported to IDPH for 136 of 136 patients. 6. On April 26, 2021 at 11:30 AM, testing person #1 confirmed the surveyor's findings.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on surveyor observation; review of manufacturer's instructions; review of laboratory records; and interview with testing personnel, the laboratory failed to retain records of test system performance specifications for its SARS-CoV-2 test for at least 2 years. Findings: 1. On April 26, 2021 at 10:30 AM, the surveyor observed the laboratory performing SARS-CoV-2 Ag testing using a test kit identified by the name GENEDIA COVID- 19 Ag test. 2. On April 26, 2021 at 10:45 AM, surveyor review of manufacturer's instructions found that the GENEDIA COVID-19 Ag test was not cleared by the Food and Drug Administration (FDA), nor an Emergency Use Authorization (EUA) issued. 3. There was no documentation made available to the surveyor to show the laboratory established test system performance specifications for its GENEDIA COVID-19 Ag test system. 4. On April 26, 2021 at 11:00 AM, testing person #1 of 2 testing persons confirmed the surveyor's findings.
D5010	VIROLOGY CFR(s): 493.1205 If the laboratory provides services in the subspecialty of Virology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. This CONDITION is not met as evidenced by: D5010 Based on surveyor observations; review of laboratory records; review of patients' test records; and interview with testing personnel, the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1265, and 493. 1281 through 493.1299. Findings: 1. The surveyor observed that the laboratory performs SARS - CoV-2 testing using GENEDIA COVID - 19 Ag test kits. 2. GENEDIA COVID -19 Ag test kits were neither Food and Drug Administration (FDA) cleared, nor and Emergency Use Authorization (EUA) issued. 3. There was no documentation to show the laboratory established test system performance specifications for its GENEDIA COVID-19 Ag test system prior to reporting patients' test results. See D5423 4. On survey date April 26, 2021 at 11:00 AM, surveyor review of 136 of 136 patients' test records show that patients' test results were reported prior to the laboratory establishing test system performance specifications for its SARS- CoV-2 Antigen testing.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces

	a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: On survey date April 26, 2021 at 11:00 AM, the surveyor selected a total of 136 patients' consent forms and requested corresponding test reports for its SARS-CoV-2 test results. Testing personnel #1 was unable to provide the surveyor with test reports for 136 of 136 patients' consent forms. Based on surveyor observation; review of manufacturer's instructions; review of laboratory records; and interview with testing personnel, the laboratory failed to establish test system performance specifications for its GENEDIA COVID Ag test kits . Findings: 1. On April 26, 2021 at 10:30 AM, the surveyor observed the laboratory performing SARS-CoV-2 Ag testing using a test kit identified by the name GENEDIA COVID- 19 Ag test. 2. On April 26, 2021 at 10:45 AM, surveyor review of manufacturer's instructions found that the GENEDIA COVID-19 Ag test was not cleared by the Food and Drug Administration (FDA), nor an Emergency Use Authorization (EUA) issued. 3. There was no documentation made available to the surveyor to show the laboratory established test system performance specifications for its GENEDIA COVID-19 Ag test system that include the following performance specifications: a. Accuracy b. Precision c. Analytical sensitivity d. Analytical specificity e. Reference intervals (normal values) 4. On survey date April 26, 2021 at 11:00 AM, the surveyor selected a total of 136 patients' consent forms where patients gave their permission for specimen collection, testing, and billing. Test dates ranged from February 2, 2021 through March 15, 2021. Testing personnel #1 was unable to provide the surveyor with test reports for 136 of 136 patients' consent forms. 5. On April 26, 2021 at 11:00 AM, testing person #1 of 2 testing persons confirmed the surveyor's findings.