Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2216112	07/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Nova Diagnostics Labs	2340 S Highland Ave Ste 275, Lombard, 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 record review and interview, the laboratory failed to report the Nucleic Acid Amplification Test (NAAT) SARS-CoV-2 test results as required for three out of five days reviewed affecting for 1563 patients. Findings include: 1. The Nova Diagnostic Laboratory's State reporting lists for 07/13/2022, 05/25/2022, 02/04/2022, 12/21/2021, and 10/12/2021 and the laboratory's procedures manual were reviewed. 2. The Nova's State reporting lists revealed that SARS-CoV-2 test results were not reported as required for 3 selected dates: 10/12/2021, 12/21/2021, and 02/02/2022. 3. 1563 test results were not reported as required during the period reviewed. 4. Staff #1 confirmed the above findings on July 13, 2022 at 11:25 AM.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation.

	This STANDARD is not met as evidenced by: Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to ensure for five of five days the uni-directional workflow established by the laboratory minimized contamination affecting 1653 patients' tests. Findings Include: 1. On July 12, 2022 at 2:10 PM during a tour of the laboratory, the surveyor observed the following workflow of the laboratory: Receiving area (office lobby) - Accessioning (down the hall, the Room behind the receiving area) - Clean /Extraction Room (back down the hall, second room to the left from the office lobby) - Amplification Room (located at the end of the hall, past the Clean/Extraction room). 2. The Nova Diagnostic Laboratory's State reporting lists for 07/13/2022, 05/25/2022, 02/04/2022, 12/21/2021, and 10/12/2021, the laboratory's procedures manual, and decontamination logs were reviewed. 3. Interview with Staff #1 on July 12, 2022 at 3: 33 PM, the surveyor ask if the laboratory had a "Wipe Test" procedure to detect amplification contamination. Staff #1 state that they have Ultraviolet lights in the hoods and decontamination procedures for surfaces, but do not check for possible amplification contamination on equipment, doors, etc. 4. The contamination procedures provided showed the laboratory failed to include a procedure to check for amplification contamination. 5. The decontamination logs for five of five dates reviewed failed to include a test for amplification contamination. 6. 1653 patients' test were performed during the time period reviewed. 7. The laboratory director and staff on July 13, 2022 at 11:25 AM, confirmed the above findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to follow established written procedures to assess four of four employees performing three of three different Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) Assays on three of three different PCR analyzers, affecting 83,702 patients' tests. Findings include: 1. On July 12, 2022 at 2:10 PM during a tour of the laboratory, the surveyor observed the following instruments: *One CWBIO machine (for the CWE3200 Automated Nucleic Acid Extraction System) *One BioRad CFX384-C1000 Touch (S/N-CT060113) RT-PCR analyzer *Five MIC qPCR analyzers and *One Applied Biosystems - ABI-7500 Fast Real-Time (S/N-275010635) RT-PCR analyzer. 2. The laboratory's procedures manual, competency policy and procedures, the Laboratory Personnel Report (CMS-209), test records, the test volume worksheet, and employee files were reviewed. 3. The laboratory used the extractor and PCR analyzers listed in findings #1 to perform RT-PCR assays to detect and identify SARS-CoV-2 virus. 4. The CMS 209 listed four testing personnel (TP1, TP2, TP3 and TP4) performing the SARS-Cov-2 RT-PCR assays. 5. The test records and procedures manual revealed the following: *The laboratory used the BIOGX (with extraction), the BioGX Xfree COVID-19 Direct RT-PCR and the Bio-Speedy Direct RT-qPCR SARS-CoV-2 assays for RT-PCR testing. *Four of four TP used these assays to test patients. 6. The laboratory competency policy included a step-by-step procedure to assess the competency of its TP and stated training and assessment

	are to be completed prior to testing patients. 7. The employee files did not include any documentation of training or competency for the four TP that used the three different assays performed by the laboratory. 8. 83,702 patients were tested during July 2021 to July 2022 by the four TP. 9. The laboratory director and staff on July 13, 2022 at 11: 25 AM, confirmed the above findings.
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 record review and interview, the laboratory failed to establish procedures to report positive and negative SARS-CoV-2 Nucleic Acid Amplification Test (NAAT) results to the Health Department as required, affecting 1563 patients results. Findings include: 1. The Nova Diagnostic Laboratory's State reporting lists for 07/13/2022, 05 /25/2022, 02/04/2022, 12/21/2021, and 10/12/2021 and the laboratory's procedures manual were reviewed. 2. The laboratory failed to report 1563 positive and negative SARS-CoV-2 results as required when using the NAAT system. 3. The procedures manual revealed that the laboratory failed to include a step-by-step process for reporting SARS-Cov-2 results to the Health department and confirming their receipt as required by federal mandate. 4. Staff #1 confirmed the above findings on July 13, 2022 at 11:25 AM.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on direct observation, record review, lack of documentation, and interview, the laboratory failed to perform and document maintenance for five of five Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) analyzers used to detect and

	identify SARS-CoV-2 virus. Findings Include: 1. On July 12, 2022 at 2:10 PM during a tour of the laboratory, the surveyor observed the following PCR analyzers: *Five MIC qPCR analyzers - marked MIC M0004745, MIC M0004737, MIC M0004343, MIC M0004319, and MIC M0004139. 2. The laboratory's procedures manuals, instrument operators manuals, and maintenance documentation were reviewed. 3. The procedures, operator's manuals, and maintenance records revealed the following: *Each manufacturer has maintenance requirements for their analyzers. *The laboratory failed to have an available copy of the MIC qPCR analyzer operator's manual. *The laboratory's procedures manual failed to include the manufacturer's maintenance requirements for five of five MIC qPCR analyzers. *No documentation was provided as evidence the laboratory performed any maintenance on these five analyzers. 4. The laboratory director and staff on July 13, 2022 at 11:25 AM, confirmed the above findings.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, lack of documentation, and interview, the laboratory failed to document each lot number of the Real Time Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) kits, when opened, for two of two RT-PCR assays used to perform SARS-CoV-2 RT-PCR testing, affecting 83,702 patients' tests. Findings include: 1. The laboratory's procedures manual, test records, and the test volume worksheet were reviewed. 2. The laboratory performed RT-PCR assays to detect and identify SARS-CoV-2 virus. 3. The test records and procedures manual revealed the laboratory used the BioGX Xfree COVID-19 Direct RT-PCR and the Bio-Speedy Direct RE-qPCR SARS-CoV-2 assays kits for their RT-PCR testing. 4. Further review of these documents showed the laboratory failed to establish and include procedures for documenting the lot numbers and expiration dates of the kits and reagents used to perform the RT-PCR assays. 5. 83,702 patient specimens were tested during the period of July 2021 through July 2022. 6. The laboratory director and staff on July 13, 2022 at 11:25 AM, confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review, the Laboratory Personnel Report (CMS-209), the American Proficiency Institute (API) proficiency testing (PT) program documents, and

	interview, the laboratory director (LD) failed to ensure PT samples are tested as required by the PT program for two of two events (D6089); failed to ensure four of four testing personnel have the appropriate training and competency assessment prior to testing patients (D6102); and failed to ensure two of two new Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures were reviewed and approved prior to implementation (D6106) to ensure accurate and reliable testing.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure proficiency testing (PT) samples are tested for two of two PT events as required by the proficiency testing program during the year of 2022. Findings include: 1. The American Proficiency Institute (API) PT program events #1 and #2 and the procedures manual were reviewed. 2. The laboratory enrolled in the API-PT program as the method to verify the accuracy of its Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) assay for SARS-CoV-2 detection. 3. API-PT event #1 revealed PT samples COV-1 and COV-2 were tested in triplicate; the attestation was not signed by the LD or technical supervisor, showed no documented evidence that the results were reviewed. 4. API-PT event #2 revealed PT samples 03 and 04 were tested in duplicate; API-PT programs documents (attestation statement, instructions, completion forms, etc.) had not been saved for two years as required. 5. The LD failed to establish a PT policy and procedure that includes the PT program and Clinical Laboratory Improvement Amendments (CLIA) requirements. 6. The laboratory director and staff on July 13, 2022 at 11:25 AM, confirmed the above findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure prior to testing patients' specimens, four of four testing personnel (TP) had the appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate results impacting 83,702 patients tests. Findings include: 1. The laboratory's procedures manual, competency policy and procedures, the Laboratory Personnel Report (CMS-209), test records, the test volume worksheet, and employee files were reviewed. 2. The laboratory failed to provide and document the training and competency assessment of four of four TP performing SARS-CoV-2 virus detection and identification via Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) procedures. See D5209. 3. The LD failed to ensure the technical supervisor followed policies and procedure to train and assess the

	competency of all TP prior to testing patients' specimens. 4. The laboratory director and staff on July 13, 2022 at 11:25 AM, confirmed the above findings.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director (LD) failed to ensure that an approved procedure manual is available to five of five laboratory personnel responsible for any aspect of the Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) testing process. Findings: 1. The procedures manual, the Laboratory Personnel Report (CMS-209), and employee records were reviewed. 2. The CMS-209 listed four testing personnel, one technical supervisor and one general supervisor performing tests in the laboratory. 3. The laboratory implemented two different RT-PCR procedures assays in the year of 2022. The previous procedure was signed by the LD on June 01, 2021. 4. LD failed to ensure the two new RT-PCR procedures implemented for use by the laboratory were reviewed and approved prior to testing patients. 5. The laboratory director and staff on July 13, 2022 at 11:25 AM, confirmed the above findings.