Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2196263	11/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
New Discovery Laboratories	701 E Pratt Street, 5005, Baltimore, MD	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the validation procedure and laboratory records and interview with the general supervisor (GS) and technical supervisor (TS), the laboratory failed to verify the accuracy of its reverse transcription polymerase chain reaction (RT-PCR) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing at least twice annually. Findings: 1. The laboratory performed SARS-CoV-2 testing using RT-PCR. 2. As part of the SARS-CoV-2 assay validation, the laboratory performed comparison studies in 12/2020 using four samples that were previously tested at another laboratory and four samples freshly collected from volunteer patients who had previous results determined by other laboratories. All validation results matched the known results. 3. As of 11/01/2021, the laboratory was not enrolled in an approved proficiency testing (PT) program for SARS-CoV-2 testing and had not performed any additional studies to verify the accuracy of the RT-PCR SARS-CoV-2 testing. 4. During the survey on 11/01/2021 at 2:00 PM, the GS and TS confirmed that the laboratory was not enrolled in an approved PT program for RT-PCR SARS-CoV-2 testing to verify the assay's accuracy at least twice annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if

	applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on procedure and record review and interview with the general supervisor (GS) and technical supervisor (TS), the laboratory failed to define acceptable ranges for room temperature and humidity. Findings: 1. The laboratory used a "Temperature Log" to record refrigerator, freezer and room temperature as well as room humidity. 2. Neither the procedure manual nor the "Temperature Log" defined the acceptable ranges for room temperature and humidity to ensure proper reagent storage and equipment operation. 3. During the survey on 11/01/2021 at 2:00 PM, the GS and TS confirmed that the acceptable ranges for room temperature and humidity were not defined.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of validation documentation and interview with the general supervisor (GS) and technical supervisor (TS), the laboratory failed to verify the precision of the reverse transcription polymerase chain reaction (RT-PCR) severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) assay. Findings: 1. The laboratory's validation procedure stated that the validation included "Repeatability (intra-assay precision)", "Accuracy", and "Limit of Detection." 2. The data reported in the procedure was from three separate test batches. One batch tested samples that were previously tested at another laboratory performing SARS-CoV-2 RT-PCR testing to verify accuracy of the assay. The second batch tested freshly collected samples from volunteer patients who had previous results determined by other laboratories to also verify accuracy of the assay. The third batch tested 21 unknown samples. 3. There was no additional data showing that the laboratory verified the precision of the test system by assessing day-to-day, run-to-run, and within-run variation within defined acceptable criteria. 4. During the survey on 11/01/2021 at 2:00 PM, the GS and TS confirmed that the validation did not include verification of precision for the RT-PCR SARS-CoV-2 assay.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

	This STANDARD is not met as evidenced by: Based on review of personnel qualifications and interview with the general supervisor (GS) and technical supervisor (TS), the laboratory director failed to ensure that all testing personnel (TP) had documentation of educational qualifications. Findings: 1. The laboratory listed three TP on the Laboratory Personnel Report (form CMS-209). 2. Personnel records for TP#2 did not include a copy of TP#2's diploma or transcripts. 3. During the survey on 11/01/2021 at 2:00 PM, the GS and TP confirmed that TP#2 received a bachelor of science (BS) from a university in Nigeria, but the laboratory did not have documentation of the diploma, transcripts or an evaluation of foreign credentials from a credentialing agency. 4. In an email received on 11/03/2021 at 7:06 PM, the GS confirmed that TP#2 received a BS from the University of Lagos and was working with the university to obtain a copy of the diploma.