Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2170325	01/22/2021
Name of Provider or Supplier	**Street Address, City, State**	
Next Bio-Research Services Llc	15225 Shady Grove Road #210, Rockville, 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
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: I. Based on review of completed sample tracking worksheets, review of the procedure manual and interview with the testing person (TP), the procedure manual failed to include instructions on how to assign a run name for each batch of samples tested on the Applied Biosystems 7500 real-time polymerase chain reaction (PCR) instrument. Findings: 1. Review of the worksheets titled "Sample Tracking Sheet" (CLN-00020 ATT 1 and CLN-00023 ATT 2) showed that the "Run Name" was the date, month, and year of testing followed by the assay gene target. 2. During the survey on 01/22 /2021 at 2:00 PM, the TP confirmed that the procedure manual did not include written

	instructions on what format to use when assigning a run name to a batch of samples being run on the Applied Biosystems 7500 real-time PCR system. II. Based on review of the procedure manual, worksheets and interview with the TP, the laboratory's procedure manual did not include instructions for documenting the deoxyribonucleic acid (DNA) concentration of the patient specimen once it was processed and tested on the Qubit fluorometer. Findings: 1. Review of the "CLN-00002-ATT1 Sample Tracking Form" dated "30July2020 1:45pm" showed that three digit values were being recorded along the side of the column labeled "Sample Name." 2. When interviewed, the TP stated that the values being recorded were the DNA concentration of each patient sample analyzed on the Qubit fluorometer prior to the next step of testing. 3. During the survey on 01/22/2021 at 2:00 PM, the TP confirmed that the worksheet did not provide a section to record the DNA concentration of each patient and the procedure manual did not include written instructions for documenting the DNA concentration of each patient specimen on the "CLN-00002-ATT1 Sample Tracking Form." III. Based on review of the sample tracking form, review of the procedure manual and interview with the TP and quality assurance (QA) manager, the laboratory's procedure manual failed to define limits of acceptability for the Qubit fluorometer calibration standards, corrective actions to take when the results were unacceptable and requirements for recording and retaining the results of the Qubit fluorometer calibration standards. Findings: 1. The laboratory used a Qubit fluorometer to measure the DNA concentration of extracted patient specimens. Prior to analyzing a batch of extracted specimens, a set of two calibration standards were run through the Qubit fluorometer to set up the calibration curve to which the patient specimen DNA concentrations were determined from. 2. The sample tracking form (CLN-00002-ATT1), where the individual specimen DNA concentrations were recorded, did not contain a section to record the results of the calibration standards run prior to each batch of patient specimens. 3. The procedure, CLN-00009-SOP, contained a four page attachment (CLN-00009 ATT 1) which included sections to record the preparation of the calibration standards and the date and time each standard was measured with the Qubit fluorometer, but based on record review, this attachment was not used for patient testing. 4. The procedure did not include the limits of acceptability for the two calibration standards nor the corrective actions to take if the results were unacceptable. 5. During the initial survey on 01/22/2021 at 2:00 PM, the TP and QA manager confirmed that the results of the calibration standards run on the Qubit fluorometer were not recorded and maintained and the procedure did not include limits of acceptability for the calibration standards and what corrective actions to take if the results were unacceptable. IV. Based on review of the procedure manual and interview with the TP, the laboratory's procedure manual did not include instructions for transferring data from the Applied Biosystems 7500 real-time PCR instrument to the laboratory information system (LIS). Findings: During the survey on 01/22/2021 at 11:15 AM, the TP confirmed that once the testing is completed on the Applied Biosystems 7500 real-time PCR system, the data is downloaded to a thumb drive and then uploaded into the LIS to be analyzed and incorporated into the patient's final report. The testing person confirmed that there were no written instructions for the transfer of the data.
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 review of facility logs, review of the procedure manual and interview with the quality assurance (QA) manager, the laboratory failed to define the acceptable temperature and humidity ranges for reliable test system operation. Findings: 1. The laboratory had three rooms were testing occurred: an extraction room where the extraction reagents were stored, a water bath was utilized, and a Qubit fluorometer was operated; a polymerase chain reaction (PCR) set-up room; and an amplification room where the Applied Biosystems 7500 real-time PCR instrument was operated. 2. Ambient temperature and humidity logs were only available for the extraction room and did not define the acceptable ranges for temperature and humidity to ensure that values did not fall outside the manufacturer's requirements for reagent storage and instrument operation. 3. The water bath procedure and temperature log did not define the acceptable ranges for the testing procedure requirements. 4. During the survey on 01/22/2021 at 2:00 PM, the QA manager confirmed that neither the procedure manual nor the temperature and humidity logs defined the acceptable ranges for reliable test system operation.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the final test report and interview with the quality assurance (QA) manager, the laboratory failed to identify the laboratory location where each assay was performed. Findings: 1. The laboratory is currently running 3 assays out of a panel of multiple assays. The remaining assays on the testing panel are performed within the same company, but at a different laboratory location. 2. The final report lists the name and address of both laboratories performing the testing, but does not indicate which tests were performed at which location. 3. During the survey on 01/22 /2021 at 2:00 PM, the QA manager confirmed that the final report did not indicate which assay was performed at which laboratory location.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

	This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the testing person (TP), the technical supervisor failed to perform direct observations, as part of competency assessments, at the location where testing was performed. Findings: 1. Records of competency assessments of the TP were reviewed. The TP stated that all assessments were performed at the same company, but at a different laboratory location. 2. The observation of routine patient handling, preparation, and testing and instrument maintenance and function checks was not performed at the laboratory location being surveyed. 3. During the initial survey on 01/22/2021 at 11:30 AM, the TP confirmed that competency assessments were performed at a different laboratory location.