Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2251432	04/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
B&B Bio Llc	4 Professional Dr, Ste 115, Gaithersburg, 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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: I. Based on observation and interview with the technical supervisor (TS), the laboratory failed to ensure the eyewash station solution was not expired. Findings: 1. The laboratory had an eyewash station affixed to the wall containing a bottle of solution to aid in flushing out the eyes of testing personnel should they be splashed with patient specimens, cleaning solutions, or testing reagents. 2. The expiration date listed on the bottle was 12/2022. 3. During the survey on 04/05/2023 at 12:45 PM, the TS confirmed that the eyewash solution was expired. II. Based on review of the procedure manual and personnel training records and interview with the technical supervisor (TS), the laboratory failed to ensure safety training for laboratory staff was documented as stated in the safety procedures. Findings: 1. The laboratory's "Fire Manual and Plan" (LAB.GEN.002) stated that all employees should be trained in fire safety and included a "Fire Safety Training Checklist" that recorded the name of the employee, the name of the trainer, the hire date, the training date, and a checklist of 11 fire safety knowledge items. 2. The laboratory's "Laboratory Bloodborne Pathogens Exposure Control Plan" (LAB.GEN.004) stated "The lab director shall ensure that training is provided at the time of initial assignment to tasks where occupational exposure to blood or other potentially infectious materials may occur. Training shall be repeated every 12 months, or when there are any changes or tasks or procedures affecting an employee's occupational exposure." The procedure included a "Employee Bloodborne Pathogens Training Checklist" that recorded the name of the employee, the name of the trainer, the hire date, the training date, and a checklist of 13 bloodborne pathogens knowledge items. 3. The completed "Fire Safety Training

	Checklist" and "Employee Bloodborne Pathogens Training Checklist" were missing from the training files of the testing person. 4. During the survey on 04/05/2023 at 12: 45 PM, the TS confirmed that the "Fire Safety Training Checklist" and "Employee Bloodborne Pathogens Training Checklist" were not completed for the testing person.
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 the manufacturer's instructions for use (IFU), review of the laboratory's testing procedure, and interview with the technical supervisor (TS), the laboratory failed to include instructions for interpreting and reporting patient results for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) molecular assay. Findings: 1. The laboratory tested nasal swab specimens using the LumiraDX SARS-CoV-2 RNA STAR Complete testing kit. 2. The manufacturer's IFU included instructions for acceptable batch quality control (QC) results and corrective actions to take if the QC failed. 3. The manufacturer's IFU also included instructions for how to interpret patient results based on SARS-CoV-2 and internal control detection and corrective actions to take if a result was invalid. 4. The laboratory's procedure did not include instructions for QC acceptability or interpretation of patient test results. 5. The TS explained that patient results were manually entered into the laboratory information management system (LIMS). The procedure did not include instructions for manually entering patient results into the LIMS. 6. During the survey on 04/05 /2023 at 12:45 PM, the TS confirmed that the testing procedure did not include instructions for interpreting QC and patient results and for manually entering patient results into the LIMS.
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 the procedure manual and temperature logs and interview with the technical supervisor (TS), the laboratory failed to define the acceptable room temperature and humidity ranges for performing the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) molecular assay. Findings: 1. The laboratory recorded room temperature and humidity on a single paper log. 2. Neither the procedure manual nor the log included the acceptable room temperature and humidity ranges. 3. During the survey on 04/05/2023 at 12:45 PM, the TS confirmed that the acceptable ranges for room temperature and humidity were not defined in the procedure manual or on the log.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the instrument calibration schedule and the manufacturer's operator's manual and interview with the technical supervisor (TS), the laboratory was overdue for maintenance for the biological safety cabinet (BSC) and didn't establish maintenance procedures for the frequency of testing performed. Findings: 1. The laboratory used an Air Science Purair BIO Class II, Type A2 BSC. 2. The "Instrument Calibration Schedule" (LAB. PRO. 002) stated that the BSC was to be serviced annually and the next service was due on 01/24/2023. The sticker on the BSC also stated that the next service was due on 01/24/2023. 3. The "Maintenance Schedule" (LAB. PRO. 003) included a table with columns for the "Device Name," "CHECK POINTS," "Frequency," and the date and initials for each service performed. The only device listed was for the BSC. The frequency for "CHECK POINT" of the "Dust Filter" was annually and for the "HEPA Filter" was every two years. The initial service date was listed as 01/07/2022 with no initials. There were no maintenance records showing that the dust filter was checked or replaced in 01/2023. 4. The TS stated that the laboratory had only tested about 50 specimens since 04/11/2022. 5. The manufacturer's "User Operation Manual PURAIR-BIO.V2.2021 NSF" (UOM) stated that the HEPA filter replacement depended on "the amount of cabinet usage, the cleanliness of the room air and the amount of particles generated during the procedures performed inside the cabinet" and then defined the conditions when the filter should be replaced. 6. The UOM also provided a list of weekly, monthly, and annual routine maintenance activities "necessary to maintain optimum cabinet performance" and stated that the "interval may be greater or lesser depending on cabinet use." 7. There was no procedure listing the weekly, monthly, and annual routine maintenance activities or the frequency with which they should be performed

	based on usage and testing volume. 8. During the survey on 04/05/2023 at 12:45 PM, the TS confirmed that the annual maintenance for the BSC was overdue and the laboratory did not establish the frequency of routine maintenance activities to be performed based on current usage and testing volume.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the procedure manual and laboratory records and interview with the technical supervisor (TS), the laboratory director (LD) failed to perform quality assessment activities as defined in the procedure manual. Findings: 1. The laboratory's "General Laboratory System Quality Assessment Policy" stated that the LD was "responsible for ensuring HIPAA [Health Insurance Portability and Accountability Act of 1996] compliance by performing HIPAA risk analysis (physical, technical, and administrative safeguards) initially and annually" and that the LD was also responsible for performing the "safety audit initially and annually." 2. The "Confidentiality of Patient Information" procedure included the "HIPAA Risk Analysis Form." 3. The "Laboratory Safety Manual" included the "Safety Audit Checklist." 4. The laboratory had no records of the "HIPAA Risk Analysis Form" or the "Safety Audit Checklist" that were completed by the laboratory initially or annually. 5. During the survey on 04/05/2023 at 12:45 PM, the TS confirmed that no HIPAA Risk Analyses or Safety Audits had been performed by the laboratory as stated in the procedure manual.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the procedure manual and personnel records and interview with the technical supervisor (TS), the laboratory failed to ensure that competency assessments were performed at least semiannually during the first year for testing personnel forming high complexity testing. Findings: 1. The "Analytical System Quality Assessment Policy" stated that a "Competency assessment will be done semi-annually during the first year and annually after." 2. The Laboratory Personnel Report (form CMS-209) listed a single testing person (TP). 3. Personnel records show that the TP was hired on 12/15/2021. 4. There was a single competency assessment form dated 12/16/2022 covering the period of 12/15/2021-12/15/2022. There was no competency assessment form evaluating the TP around six months after hire. 5. During the survey on 04/05/2023 at 12:45 PM, the TS confirmed that a competency assessment was not performed for the TP semiannually during the first year.