Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2178455	**(X3) Date Survey Completed** 08/25/2023
Name of Provider or Supplier Bnb Diagnostics, Llc	**Street Address, City, State** 350 Nursery Rd Ste 3102, Spring, TX	

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
D0000	An announced survey of the laboratory was conducted on 08/25/2023. The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records for 2021 through 2023, laboratory's policies and staff interview, the laboratory failed to ensure PT attestations were signed for 2 of 4 PT events reviewed. Findings included: 1. Review of the laboratory's American Proficiency Institute PT records for 2021 through 2023 revealed the following PT events did not have documentation of attestation of routine integration of the samples into the patient workload: 2022 Immunology /Immunohematology - 1st Event Received on 03/31/2022 Had no attestation by

	laboratory director or testing personnel 2022 Immunology/Immunohematology - 2nd Event Received on 08/05/2023 Had no attestation by testing personnel 2. Review of laboratory's "Proficiency Testing Policy" (signed off by laboratory director on 07/20 /2020) revealed: "Be sure to print and sign the Attestation Form." 3. In an interview on 08/25/2023 at 1050 hours in the laboratory, the Testing Person number 2, and the General Supervisor (as indicated on submitted form CMS-209), after review of the data, confirmed the findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) records for 2021 through 2023, laboratory's policies and staff interview, the laboratory failed to ensure all PT documents were retained for 2 of 4 PT events reviewed. Findings included: 1. Review of the laboratory's American Proficiency Institute (API) PT records for 2021 through 2023 revealed the laboratory did not retain the following: For 2022 Immunology /Immunohematology - 1st Event: - Documentation of evaluation of results - API evluation report For 2022 Immunology/Immunohematology - 2nd Event: - Test results /instrument printouts/LIS (laboratory information system) reports - API evaluation report 2. Review of laboratory's "Proficiency Testing Policy" (signed off by laboratory director on 07/20/2020) revealed: "Make and retain copies of the LIS reports and the proficiency testing answer forms." And, "All paper work(sic) will be placed in the Proficiency Testing agency notebook and retained for at least 2 years." 3. In an interview on 08/25/2023 at 1050 hours in the laboratory, the Testing Person number 2, and the General Supervisor (as indicated on submitted form CMS-209), after review of the data, confirmed the findings.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: A. Based on review of the laboratory's proficiency testing (PT) records for 2021 through 2023, laboratory's policies and staff interview, the laboratory failed to ensure PT evaluation was documented for 1 of 4 PT events reviewed. Findings included: 1. Review of the laboratory's American Proficiency Institute (API) PT records for 2021 through 2023 revealed the laboratory did not have evaluation of PT for the following Event: 2022 Immunology/Immunohematology - 1st Event: Received 03/31/2022 2.

	Review of laboratory's "Proficiency Testing Policy" (signed off by laboratory director on 07/20/2020) revealed: "When proficiency testing results are returned, these will be evaluated." 3. In an interview on 08/25/2023 at 1050 hours in the laboratory, the Testing Person number 2, and the General Supervisor (as indicated on submitted form CMS-209), after review of the data, confirmed the findings. --- B. Based on review of the laboratory's proficiency testing (PT) records for 2021 through 2023, laboratory's policies and staff interview, the laboratory failed to document corrective action activities for unacceptable performance results for 1 of 4 PT events reviewed. Findings included: 1. Review of the API PT Performance Evaluation document revealed the following instructions to the laboratories: "Laboratories are responsible for documenting and performing corrective action for failures..." 2. Review of the laboratory's American Proficiency Institute (API) PT records for 2021 through 2023 revealed the following PT samples had unacceptable performance: For 2022 Immunology/Immunohematology - 3rd Event, received 03/31/2022 Test: Allergen Specific IgE (quan), Phadia Immuno CAP Analyte: Sample: Performance: Food: Milk ALL-13 Unacceptable Food: Peanut ALL-11 Unacceptable Food: Peanut ALL-13 Unacceptable Mold: Aspergillus ALL-11 Unacceptable Mold: Aspergillus ALL-13 Unacceptable Mold: Aspergillus ALL-14 Unacceptable Tree pollens:Maple ALL-12 Unacceptable No corrective action was documented for any of the unacceptable results. 3. Review of laboratory's "Proficiency Testing Policy" (signed off by laboratory director on 07/20/2020) revealed: "If failures occur, these will be investigated and corrective action taken." 4. In an interview on 08/25/2023 at 1050 hours in the laboratory, the Testing Person number 2, and the General Supervisor (as indicated on submitted form CMS-209), after review of the data, confirmed the findings. --- C. Based on review of the laboratory's proficiency testing (PT) records for 2021 through 2023, laboratory's policies and staff interview, the laboratory failed to document self evaluation for "Not Graded" performance results for 1 of 4 PT events reviewed. Findings included: 1. Review of the API PT Performance Evaluation document revealed the following instructions to the laboratories: "Laboratories are responsible for documenting and performing corrective action for failures and must perform self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. Review of the laboratory's American Proficiency Institute (API) PT records for 2021 through 2023 revealed the following PT samples had "Not Graded" performance: For 2022 Immunology /Immunohematology - 3rd Event, received 03/31/2022 Test: Allergen Specific IgE (quan), Phadia Immuno CAP Analyte: Sample: Performance: Mold: Aspergillus ALL-15 Not Graded Tree pollens:Maple ALL-15 Not Graded & Box Elder Weed Pollens: ALL-15 Not Graded Sheep Sorrel Self-evaluation was not documented for any of the "Not Graded" results. 3. Review of laboratory's "Proficiency Testing Policy" (signed off by laboratory director on 07/20/2020) revealed the policy did not address "Not Graded" PT agency's evaluation results. 4. In an interview on 08/25/2023 at 1050 hours in the laboratory, the Testing Person number 2, and the General Supervisor (as indicated on submitted form CMS-209), after review of the data, confirmed the 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 review of laboratory's test establishment studies, policies/procedures and staff interview, the laboratory failed to define QC frequency and corrective action protocols for 7 of 7 laboratory's test procedures. Findings included: 1. Review of the laboratory's test establishment studies revealed the laboratory used the following test panels: Novaplex UTI Panel 1 Novaplex UTI Panel 2 Novaplex UTI Panel 3 Novaplex Respiratory 1A Novaplex Respiratory 2 Novaplex Respiratory 3 Novaplex Pneumobacter Assay Novaplex Antibiotic Resistance 2. Review of laboratory's policies/procedures revealed the policies/procedures did not define frequency of QC, or what corrective actions must be taken when failures or instrument flags occur. 3. In an interview on 08/25/2023 at 1500 hours in the laboratory, the Testing Person number 2 (as indicated on submitted form CMS-209), after review of the data, confirmed the findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, random laboratory instrument results, corresponding patient test reports and staff interview, the laboratory failed to follow manufacturer's instructions for "Invalid" test results for 1 of 20 samples' instrument results reviewed. Findings included: 1. Review of manufacturer instructions for use for the Seegene Novaplex Panels (10/2021 V1.01) revealed: "Interpretation ... Invalid** - Weak or negative IC (internal control) signal suggests inadequate sample collection, processing or presence of inhibitors. - Repeat the test from the nucleic acid extraction using anther aliquot of the original sample. - If the same result is shown in the re-extracted nucleic acid, please dilute (1/3~1/10) the sample in saline solution and repeat test from the extraction." 2. Review of random laboratory instrument results revealed the following sample analysis was resulted as "Invalid": Sample: 1740 Collected: 05/17/2023 Tested: 05/18/2023 Test: Respiratory Panels, Antimicrobial Resistance (AR) Panel Instrument Results: All pathogens and Antimicrobial Resistance Genes were designated as "-" (negative) Internal Control (IC): designated "-" Auto Interpretation: "Invalid" There was no record of repeat

	testing for this sample on the instrument. No other corrective action was documented. 3. Review of corresponding patient report revealed the report was issued on 05/18 /2023 with the overall summary of results as "Negative". All 36 pathogens and AR genes were reported as "Not Detected". 4. In an interview on 08/25/2023 at 1500 hours in the laboratory, the Testing Person number 2 (as indicated on submitted form CMS-209) stated that the laboratory's technical supervisor reviews the graphs and data for this kind of issues, determines result acceptability and actions to be taken. She confirmed that no corrective action or review was documented for this sample.
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 laboratory's personnel records, policies/procedures and staff interview the laboratory's Technical Supervisor failed to document his evaluation of competency for one of two testing personnel, Testing Person number 2 (TP2), during the first year of TP2 employment. Findings included: 1. Review of laboratory's personnel records revealed TP2 started work in October 2022. Semiannual competency assessment for TP2 was performed on 05/02/2023 and was signed by the General Supervisor (GS). 2. Review of laboratory's policies/procedures revealed competency assessment policy did not address delegation of competency evaluation to the GS. 3. In an interview on 08/25/2023 at 1010 hours in the laboratory, the TP2 and the GS (as indicated on submitted form CMS-209), after review of the data, confirmed the findings.