| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D2178455 | 09/27/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Bnb Diagnostics, Llc | 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** | Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. |
| **D2009** | TESTING OF PROFICIENCY TESTING SAMPLES<br>CFR(s): 493.801(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's American Proficiency Institute (API) records for 2021, the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of the laboratory director signing two of two attestation statements in 2021. Findings include: 1. A review of the laboratory's API records from 2021 revealed the laboratory failed to have documentation of the laboratory director signing the attestation statements for the following two events: - 2021 Immunology /Immunohematology 1st Event - 2021 Immunology/Immunohematology 2nd Event 2. Further review of the above listed API attestation records revealed testing person #1's signature in the areas designated for the Laboratory Director and the Person performing test. 3. A review of the laboratory's records revealed the laboratory failed to have documentation of the laboratory director delegating the responsibility of signing proficiency testing attestation statements to testing person #1. 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 9/27/21 at 9:45 a.m. in the laboratory, after review of the records, confirmed the above findings. |
| | |

| | |
|---|---|
| **D5213** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(b)(1)<br><br>The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's American Proficiency Institute (API) proficiency testing evaluation records for 2021, and staff interview, it was revealed that the laboratory failed to have documentation of verifying the accuracy of analytes that were 'not graded' by the proficiency testing program for two of two testing events in 2021. Findings include: 1. A review of the API Proficiency Testing Performance Evaluation form revealed the following: "Laboratories should review the Performance Summary and Comparative Evaluation thoroughly for failures or 'not graded' analytes. Laboratories are responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." 2. A review of the laboratory's API proficiency testing evaluation records for the following two events in 2021 revealed the following analytes were scored as not graded and there was no documentation that the laboratory performed a self-evaluation: a) 2021 Immunology /Immunohematology 1st Event -Phadia ImmunoCAP Class (1-6)/Animal: Cockroach, German Sample ALL-01 Sample ALL-02 Sample ALL-03 Sample ALL-04 Sample ALL-05 -Phadia ImmunoCAP Class (1-6)/Tree pollens: Maple, Box Elder Sample ALL-01 Sample ALL-02 Sample ALL-03 Sample ALL-04 Sample ALL-05 -Phadia ImmunoCAP Class (1-6)/Tree pollens: Oak Sample ALL-01 Sample ALL-02 Sample ALL-03 Sample ALL-04 Sample ALL-05 -Phadia ImmunoCAP/Grass pollens: Bermuda grass Sample ALL-05 -Phadia ImmunoCAP/Molds: Alternaria Sample ALL-05 -Phadia ImmunoCAP/Tree pollens: Maple, Box elder Sample ALL-05 b) 2021 Immunology/Immunohematology 2nd Event -Phadia ImmunoCAP Class (1-6) /Animal: Honey bee venom Sample ALL-06 Sample ALL-07 Sample ALL-08 Sample ALL-09 Sample ALL-10 -Phadia ImmunoCAP Class (1-6)/Food: Cashew Sample ALL-06 Sample ALL-07 Sample ALL-08 Sample ALL-09 Sample ALL-10 -Phadia ImmunoCAP Class (1-6)/Molds: Aspergillus Sample ALL-08 -Phadia ImmunoCAP Class (1-6)/Tree pollens: Birch (silver) Sample ALL-06 Sample ALL-07 Sample ALL-08 Sample ALL-09 Sample ALL-10 -Phadia ImmunoCAP Class (1-6)/Tree pollens: Maple, Box Elder Sample ALL-06 Sample ALL-07 Sample ALL-08 Sample ALL-09 Sample ALL-10 -Phadia ImmunoCAP Class (1-6)/Weed pollens: Sheep Sorrel Sample ALL-06 Sample ALL-07 Sample ALL-08 Sample ALL-09 Sample ALL-10 -Phadia ImmunoCAP/Animal: Honey bee venom Sample ALL-06 -Phadia ImmunoCAP/Molds: Aspergillus Sample ALL-06 -Phadia ImmunoCAP/Tree pollens: Maple, Box Elder Sample ALL-06 -Phadia ImmunoCAP/Weed pollens: Sheep Sorrel Sample ALL-06 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 9/27/21 at 9:50 a.m. in the laboratory, after review of the records, confirmed the above findings. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies, the laboratory's temperature logs from 2021, and staff interview, it was revealed that the laboratory's Temperature policy failed to include the acceptable temperature ranges for four of four temperature monitoring areas of the laboratory. Findings include: 1. A review of the the laboratory's Temperature policy revealed the following: "Many testing reagents, calibrators, controls and instruments have designated temperatures for storage and use. Listed below are the temperatures required for monitoring and recording: - Room temperature - Refrigerator temperature - Freezer temperature - Reagent temperature on instrument" 2. A review of the laboratory's temperature logs for 2021 revealed the laboratory was recording the temperatures of the above listed areas each day of patient testing. 3. Further review of the temperature logs for 2021 revealed that there was no documentation of the acceptable temperature ranges for each of the four areas. 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 9/27/21 at 12: 00 p.m. in the laboratory, after review of the records, confirmed the above findings. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the Phadia Instruments Verification Protocol, the laboratory's verification records for the Thermo Scientific Phadia 250 analyzer and staff interview, it was revealed that the laboratory failed to have documentation of performing one of four required verification studies on the Thermo Scientific Phadia 250 analyzer in 2020. Findings include: 1. A review of the Phadia Instruments Verification Protocol revealed the following: "Laboratories may start with the manufacturer's stated reference range but the laboratory is required to monitor this range and make adjustments as necessary." 2. A review of the laboratory's verification records for the |

| | |
|---|---|
| | Thermo Scientific Phadia 250 analyzer performed in May 2020 revealed the laboratory failed to have documentation of performing a normal patient range study. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 9/27/21 at 10:18 a.m. in the laboratory, after review of the records, confirmed the above findings. |
| **D5441** | CONTROL PROCEDURES<br>CFR(s): 493.1256(a)(b)(c)(g)<br><br>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's quality control (QC) records for August 2021 and September 2021, and staff interview, it was revealed that the laboratory failed to have a method in place to monitoring quality control values over time for six of six lots of QC material run on the Thermo Scientific Phadia 250 analyzer. Findings included: 1. A review of the laboratory's quality control records for August 2021 and September 2021 revealed the laboratory ran the following six lots of QC material once a day, each day of patient testing: ImmunoCAP Specific IgE Control L Lot number: CZ4B6 ImmunoCAP Specific IgE Control M Lot number: CZ1AV ImmunoCAP Specific IgE Control H Lot number: CYYB3 ImmunoCAP Total IgE Control L Lot number: BMLD4 ImmunoCAP Total IgE Control M Lot number: BMMD5 ImmunoCAP Total IgE Control H Lot number: BMND3 2. Further review of the laboratory's QC records for August 2021 and September 2021 revealed the laboratory failed to have documentation of monitoring quality control values over time to detect shifts and trends. 3. An interview with testing person #1 (as indicated on the CMS 209 form) on 9/27/21 at 10:55 a.m. in the laboratory revealed the laboratory only assessed quality control values each day and did not monitor or evaluate values over time for shifts or trends. This confirmed the above findings. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the laboratory's policies, the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of the technical consultant performing a competency assessment, at least semiannually during the first year of testing, for one |

| | |
|---|---|
| | of one testing personnel. Findings include: 1. A review of the laboratory's policy titled 'Personnel Competency Assessment' revealed the following: "Evaluation will be performed at 6 months after the techs start date and 1 year after the start date. Evaluation will be performed annually from then on." 2. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 9/24/21) revealed the laboratory identified one testing person performing moderate complexity testing. 3. A review of the laboratory's personnel records revealed the following one testing person, their hire date, and documentation of the competency assessments performed: a) Testing person #1 Hire date: 5/26/20 Competency assessment: 5/25/21 Based on the hire date, testing person #1 should have had at least 2 competency assessments performed prior to 5/2021. 4. An interview with testing person #1 (as indicated on the CMS 209 form) on 9/27/21 at 9:25 a.m. in the laboratory, after review of the records, confirmed the above findings. |