

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2178455	(X3) Date Survey Completed 04/24/2025
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	A proficiency testing desk review survey was performed on 04/24/2025. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The CONDITIONS NOT MET were: D2016 - 42 C. F.R. 493.803 Condition: Successful participation [proficiency testing] D6076 - 42 C. F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute</p>

	<p>(API) records, the laboratory failed to achieve successful performance in two of three consecutive testing events in 2024 and 2025, resulting in an initial unsuccessful performance for the specialties Bacteriology and Virology. Refer to D2028 and D2064.</p>
<p>D2028</p>	<p>BACTERIOLOGY CFR(s): 493.823(e)</p> <p>(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) records from 2024 and 2025, the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for two of three consecutive testing events for the specialty of Bacteriology. Two out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings included: 1. A review of the CASPER Report 155 listed the following scores for the PT specialty of Bacteriology: API 2024 Event 2: 0% API 2025 Event 1: 0% 2. A desk review of API proficiency testing records confirmed that the laboratory received the above scores for Bacteriology for 2024 Event 2 and 2025 Event 1.</p>
<p>D2064</p>	<p>VIROLOGY CFR(s): 493.831(e)</p> <p>(e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) records from 2024 and 2025, the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for two of three consecutive testing events for the specialty of Virology. Two out of three overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. Findings included: 1. A review of the CASPER Report 155 listed the following scores for the PT specialty of Virology: API 2024 Event 2: 0% API 2025 Event 1: 0% 2. A desk review of API proficiency testing records confirmed that the laboratory received the above scores for Virology for 2024 Event 2 and 2025 Event 1.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p>

This CONDITION is not met as evidenced by:
Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for the specialties of Bacteriology and Virology for two of three consecutive events reviewed in 2024 and 2025. Refer to D6089.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

This STANDARD is not met as evidenced by:
Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) records, the laboratory director failed to ensure successful performance in two of three consecutive testing events in 2024 and 2025, resulting in an initial unsuccessful performance two of two laboratory's specialties, Bacteriology and Virology. Refer to D2028 and D2064.