

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2104154	(X3) Date Survey Completed 01/16/2026
Name of Provider or Supplier Next Bio Research Services, Llc	Street Address, City, State 11601 Iron Bridge Road - Suite 101, Chester, VA	
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	<p>An unannounced, off-site CLIA proficiency testing (PT) desk review was conducted for Next Bio Research Services, LLC on January 15, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The survey concluded with an interview and review of records on 1/16/26. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The following deficiencies are a result of the PT desk review of scores obtained from the national database and verified with the proficiency testing company. The following CONDITION LEVEL DEFICIENCIES were found to be out of compliance: D2016 - 42 CFR. 493.803 Condition: Successful Participation, D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director.</p>
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>

This CONDITION is not met as evidenced by:
Based on a review of the Center for Medicaid and Medicare Services CASPER 0155 report, the laboratory's proficiency testing (PT) records and interview, the laboratory failed to successfully participate in the hematology specialty for analyte Red Blood Cell Count (RBC). The laboratory had unsatisfactory RBC scores for the first and third PT events of calendar year 2025. Refer to D2130.

D2130

HEMATOLOGY
CFR(s): 493.851(f)

(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on an off-site desk review of the Center for Medicaid and Medicare Services (CMS) Certification and Survey Provider Enhanced Reporting CASPER 0155 report, the laboratory's proficiency testing (PT) records, and interviews, the laboratory failed to attain a score of at least eighty percent (80%) of acceptable responses for Red Blood Cell (RBC) counts on two of three Complete Blood Count (CBC) hematology testing events in calendar year 2025 resulting in an unsuccessful PT performance. Findings include: 1. Review of the CMS CASPER 0155 report revealed: Hematology 2025 1st Event - laboratory received an unsatisfactory score of 60% for analyte 0775 RBC; Hematology 2025 3rd Event - laboratory received an unsatisfactory score of 0% for analyte 0775 RBC. 2. Desk review of the laboratory's American Proficiency Institute (API) PT records revealed RBC scores of less than 80% for the following two 2025 hematology CBC events: 2025 API Event 1: RBC scored 60% (challenge sample DXH-02 reported as 2.20 with acceptable range 2.22-2.42, challenge sample DXH-05 reported as 2.20 with acceptable range 2.23-2.43); 2025 API Event 3: RBC scored 0% (challenge sample DXH-11 reported as 4.80 with acceptable range 5.00-5.43, challenge sample DXH-12 reported as 4.37 with acceptable range 4.53-4.93, challenge sample DXH-13 reported as 4.43 with acceptable range 5.52-4.91, challenge sample DXH-14 reported as 4.94 with acceptable range 4.98-5.40, challenge sample DXH-15 reported as 2.21 with acceptable range 2.27-2.46); resulting in an unsuccessful PT performance. 3. Virtual interviews with the laboratory President and Director of Clinical Laboratory Operations on 1/16/26 at 12:30 PM confirmed the above findings.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:
Based on a review of the Center for Medicaid and Medicare Services (CMS) Certification and Survey Provider Enhanced Reporting CASPER 0155 report, proficiency testing records, and interview, the laboratory director failed to provide overall direction and management of the laboratory services. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(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 review of the Center for Medicaid and Medicare Services Certification and Survey Provider Enhanced Reporting CASPER 0155 report, proficiency testing (PT) records, and interview, the laboratory director failed to ensure successful participation in the laboratory's Health and Human Services PT program. Refer to D2130.