Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2104154	03/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
Next Bio Research Services, Llc	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	An announced CLIA recertification survey was conducted at Next Bio Research Services, LLC on March 17, 2026 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Next Bio Research Services, LLC was not in compliance with applicable Standards and Conditions under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and include the Conditions: D2000 - 42 CFR. 493.801 Enrollment and Testing of Samples D5200 - 42 CFR 493.1230 General Laboratory Systems D5400 - 42 CFR 493.1250 Analytic Systems D6000 - 42 CFR 493.1403 Laboratory Director
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: A. Based on a pre-survey review of the Centers for Medicare and Medicaid Services Application for Certification (CMS 116) form and CMS CLIA Application and Survey Summary Report (CASPER 96), a tour, review of analyzer validation records, proficiency testing (PT) records, patient test logs, lack of documentation, and interviews, the laboratory failed to enroll in a PT program for Complete Blood Count (CBC) for 12 of 12 months in calendar year 2024 while reporting 1,247 CBC panel test results. Findings: 1. During pre-survey workload, a review of the laboratory's

submitted CMS 116 form revealed that the laboratory director (LD) identified non waived CBC testing by Beckman Coulter DxH560 and a review of CMS CASPER 96 report revealed regulated analytes under speciality 0760 HEMATOLOGY were recorded for 2025 PT Events 1-3. 2. During a tour of the laboratory at 12:30 PM on 3 /17/26, the inspector noted one DxH560 hematology analyzer serial number (SN) BG030189 in use for CBC testing. Review of the DxH560 validation records revealed that the analyzer was installed by Beckman Coulter field service on 12/19/23 with validation and procedures approved by the LD on 1/5/24. 3. Review of the laboratory's American Proficiency Institute (API) PT records, a total of four events (2025 Events 1-3, 2026 Event 1) for timeframe of April 2024 to the date of the recertification, 3/17/26, revealed that the laboratory failed to participate in PT for CBC regulated analytes: White Blood Cell, Red Blood Cell, Hematocrit, Hemoglobin, Platelet Count, and WBC Differential -Automated in calendar year 2024. The inspector requested to review hematology PT documentation for calendar year 2024. No records were available for review. 4. Review of test log records revealed that patient CBC testing started on 4/8/2024. The inspector noted that 1,247 CBC panels were reported by the laboratory during the timeframe of 4/8/24 to 12/31/24 while failing to enroll in PT modules during 2024. 5. Interviews with the facility's President and the Director of Clinical Laboratory Operations at 5 PM on 3/17/26 confirmed the above findings. B. Based on a review of the CMS 116 form, CASPER 96 report, tour, analyzer validation records, PT records, patient test logs, lack of documentation, and interviews, the laboratory failed to enroll in a PT program for 24 of 26 regulated chemistry analytes in calendar year 2024 and for one of 26 regulated chemistry analytes in calendar years 2024, 2025, and year to date (YTD) 2026 assayed by Beckman Coulter AU480 while reporting 5,063 test results. Findings: 1. Review of the submitted CMS 116 form revealed that the LD identified non waived chemistry testing for the following 26 regulated analytes by AU480 instrument: Albumin (ALB), Alkaline Phosphatase (ALP), Alanine Aminotransferase (ALT), Aspartate Aminotransferase (AST), Blood Urea Nitrogen (BUN), Calcium (CA), Carbon Dioxide (CO2), Chloride (CL) Cholesterol (CHOL), Creatinine (CREA), Creatine Kinase (CK), Glucose (GLU), High Density Lipoprotein (HDL), Hemoglobin A1C, Iron, Low Density Lipoprotein (LDL), Magnesium (MG), Phosphorus (PHOS), Potassium (K), Sodium (NA), Total Bilirubin (TBILI), Total Protein (TP), Triglycerides (TRIG), Uric Acid (UA), Valproic Acid, and Vancomycin (VANC). 2. Review of CMS CASPER 96 report revealed results for 24 of the 26 regulated analytes outlined above under speciality 0245 ROUTINE CHEMISTRY and 0605 TOXICOLOGY in calendar year 2025 (Events 1-3). The inspector noted during the CASPER 96 review that CMS had no results for regulated CK analyte. 3. During a tour at 12:40 PM on 3/17/26, the inspector noted one Beckman Coulter AU480 analyzer SN 2023070734 in use for chemistry testing. Review of the AU480 validation records revealed that the analyzer verification and procedures were approved by the LD on 1/5/24. 4. Review of the laboratory's available API PT records for timeframe of April 2024 to 3/17/26 revealed four events (2025 Events 1-3, 2026 Event 1). The inspector noted no documentation for: Calendar year 2024: no PT records for ALB, ALP, ALT, AST, BUN, CA, CO2, CL, CHOL, CREA, GLU, HDL, A1C, Iron, LDL, MG, PHOS, K, NA, TBILI, TP, TRIG, UA, Valproic Acid, and VANC;. Calendar year 2024, 2025, YTD 2026: no PT documentation for CK. The inspector requested to review missing PT for the AU480 regulated chemistry analyte testing outlined above. No additional documentation was available. 5. Review of test log records revealed that patient chemistry testing by AU480 went live on 4/8/2024. The inspector noted that the laboratory reported 5,063 chemistry tests during the timeframe of 4/8/24 to 12/31/24 while failing to enroll in PT as outlined above in 2024 -2026. 6. Interviews with the facility's President and the Director of Clinical

	Laboratory Operations at 5 PM on 3/17/26 confirmed the above findings. C. Based on a review of the CMS 116 form, CASPER 96 report, tour, analyzer validation records, PT records, patient test logs, lack of documentation, and interviews, the laboratory failed to enroll in a PT program for seven of nine regulated analytes assayed by Beckman Coulter Access 2 immunoassay instrument in calendar year 2024 and two of nine in calendar year 2024, 2025, and year to date (YTD) 2026 while reporting 1,569 test results. Findings: 1. Review of the submitted CMS 116 form revealed that the LD identified non waived chemistry testing for the following regulated analytes by Access 2 immunoassay instrument: Carcinoembryonic Antigen (CEA), Digoxin, Folate, Thyroid Stimulating Hormone (TSH), Free Thyroxine (FT4), B-Natriuretic Peptide (BNP), Prostate Specific Antigen (PSA), Parathyroid Hormone (PTH), and Vitamin B12. 2. Review of CMS CASPER 96 report revealed results for the following seven regulated analytes under specialities 0245 Routine Chemistry, 0525 Endocrinology, and 0605 Toxicology for calendar year 2025 (Events 1-3): Digoxin, Folate, TSH, FT4, PSA, PTH, and Vitamin B12. The inspector noted that the laboratory's CASPER 96 report did not include results for CEA or BNP. 3. During a tour at 12:40 PM on 3/17/26, the inspector noted one Beckman Coulter Access 2 immunoassay instrument SN 574715 in use for chemistry/endocrinology testing. Review of the Access 2 validation records revealed that the analyzer verification and procedures were approved by the LD on 1/5/24. 4. Review of the laboratory's available API PT records for timeframe April 2024 to 3/17/26 revealed a total of four events (2025 Events 1-3, 2026 Event 1). The inspector noted no PT records for the following: Calendar year 2024: no PT documentation for Digoxin, Folate, TSH, FT4, PSA, PTH, and Vitamin B12; Calendar year 2024, 2025, YTD 2026: no PT documentation for CEA and BNP. The inspector requested to review missing PT for the Access 2 chemistry/endocrinology testing outlined above. No additional documentation was available. 5. Review of test log records revealed that patient chemistry testing by Access 2 went live on 4/8/2024. The inspector noted that the laboratory reported 1,569 tests by Access 2 during the timeframe of 4/8/24 to 3/17/26 while failing to enroll in PT as outlined above in 2024 -2026. 6. Interviews with the facility's President and the Director of Clinical Laboratory Operations at 5 PM on 3/17 /26 confirmed the above findings.
D2116	TOXICOLOGY CFR(s): 493.845(e) (e)(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of CMS CLIA Application and Survey Summary Report (CASPER 96), proficiency testing (PT) records, procedures, lack of documentation, and interviews, the laboratory failed to document evaluation/remedial action taken for five of five unacceptable Vancomycin results on 2025 American Proficiency Institute (API) PT Event 2. Findings include: 1. During pre-survey preparation, a review of CMS CASPER 96 report revealed that 2025 PT Event 2 Speciality 0605 Toxicology was recorded as unsatisfactory (Score 66%) with analyte Vancomycin scored as

	unsatisfactory (Score 0%). 2. Review of the laboratory's available API PT records (2025 Events 1-3, 2026 Event 1), a total of four events, revealed no evidence of remedial action for the following unacceptable Vancomycin challenge scores: 2025 Event 2 Chemistry/Toxicology Module: CH-06 reported as 8.3 (expected result 1.3-5.4), CH-07 reported as 49.9 (expected result 27.9-37.9), CH-08 reported as 20.8 (expected result 11.8 - 16.0), CH-09 reported as 35.9 (expected result 20.8-28.3), CH-10 reported as 82.5 (expected result 38.6-52.3); resulting in unsatisfactory performance for Vancomycin - scored as 0 %. 3. Review of the laboratory's procedures revealed a Proficiency Testing policy that stated: "Results that do not fall within the expected expected range will be investigated and documented on PT Exception Summary report form. Result discrepancies are researched and resolved by the laboratory manager in consultation with the supervisor. Document on PT Exception Summary Report form." 4. Review of the laboratory's PT corrective action forms revealed no evaluation action documentation for the unacceptable Vancomycin analyte scores outlined above. The inspector noted that the API Performance Review and Corrective Action page for the event outlined above was signed as reviewed on 6 /18/25 with no mention of remedial action for Vancomycin. 5. Interviews with the facility's President and the Director of Clinical Laboratory Operations at 5 PM on 3/17 /26 confirmed the above findings.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of proficiency testing records, procedures, manufacturer's instructions, Centers for Medicare and Medicaid Services Application for Certification form, tour, review of analyzer validation records, patient test logs, lack of documentation, and interviews, the laboratory failed to: 1. evaluate non-graded analyte challenges resulted on four of four PT events reviewed for calendar year 2025 and up to the date of the inspection on 3/17/26 - Refer to D5215; 2. verify the accuracy of chemistry analyte Ammonia twice annually for 24 of 24 months reviewed (March 29, 2024 to March 17, 2026) - Refer to D5217; 3. document evaluation taken for two unacceptable chemistry/endocrinology analyte proficiency testing results on American Proficiency Institute 2025 Event 1 - Refer to D5221.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

	This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, procedures, manufacturer's instructions, lack of documentation, and interviews, the laboratory failed to evaluate eight chemistry/immunoassay and nine microbiology non-graded analyte challenges resulted on four of four PT events reviewed for calendar year 2025 and up to the date of the inspection on 3/17/26. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) PT results (2025 Events 1-3, 2026 Event 1), a total of four events, revealed that API released non-graded analyte responses for: Total Bilirubin (T Bili) due to variance on the following three events: API 2025 Event 2 - T Bili challenges CH-07, CH-09, CH-10 API 2025 Event 3 - T Bili challenges CH-12, CH-15 API 2026 Event 1 - T Bili challenge CH-05; Folate due to variance on the following event: API 2025 Event 2 - Folate challenges IA-07, IA-09 --a total of eight non-graded chemistry/immunoassay challenge samples were reported by API; Urine Culture MIC/Zone Value on the following three events with instructions to review Summary Data: API 2025 Event 1 - challenges UR-01 and UR-02; API 2025 Event 2 - challenges UR-06 and UR-07; API 2025 Event 3 - challenges UR-11 and UR-12; --a total of six non-graded microbiology urine culture MIC/Zone value challenge samples were reported by API. Urine Culture Susceptibility on the following two events with instructions to review Summary Data: API 2025 Event 1 - Susceptibility UR-02; API 2025 Event 3 - Susceptibility UR-11 and UR-12; --a total of three non-graded microbiology urine culture susceptibility challenge samples were reported by API; 2. Review of the laboratory's PT review documentation revealed no evaluation /verification of accuracy recorded for the non-graded challenge sample results outlined above. The inspector requested to review evaluation documentation for the non-graded challenges. Documentation was not available. 3. Review of the laboratory's procedures revealed a policy (title: Proficiency Testing Policy) that stated, "When PT results are not graded due to no consensus the laboratory will document comparison of results to the most common result on the peer report form. Ungraded survey samples due to lack of consensus, etc. will have discrepancies reviewed." 4. Review of API PT Performance Evaluation form instructions revealed guideline, "The American Proficiency Institute evaluation reports consist of four parts: Report Cover, Performance Summary, Comparative Evaluation, and Participant Data Summary. 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 and must perform a self evaluation using statistics presented on the Participant Data Summary for samples that have not been graded." 4. Interviews with the facility's President and the Director of Clinical Laboratory Operations at 5 PM on 3/17/26 confirmed the above findings.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services Application for Certification (CMS 116) form, tour, review of analyzer validation records, proficiency testing (PT) records, patient test logs, lack of documentation, and interviews, the laboratory failed to verify the accuracy of Beckman Coulter AU480 chemistry analyte Ammonia twice annually for 24 of 24 months reviewed (March 29, 2024 to March 17, 2026) while reporting 51 test results. Findings include: 1. During pre-survey

	preparation, a review of the submitted CMS 116 form revealed that the laboratory director (LD)identified non waived chemistry testing by Beckman Coulter AU480 for Ammonia. 2. During a tour at 12:40 PM on 3/17/26, the inspector noted a Beckman Coulter AU480 analyzer Serial Number (SN)2023070734 in use for chemistry testing. Review of the AU480 test menu and verification records revealed that the analyzer's Ammonia validation and procedure was approved by the LD on 1/5/24. 3. Review of the laboratory's available PT and accuracy verification documentation revealed the laboratory utilizes American Proficiency Institute (API) to verify the AU480 analyzer accuracy. A review of the laboratory's available API reports, a total of four (2025 Events 1-3, 2026 Event 1) revealed the laboratory failed to enroll for Ammonia in calendar years 2024, 2025, and year to date 2026. The inspector inquired regarding twice annual accuracy documentation for Ammonia. No records were available for review. 4. Review of test log records revealed that AU480 patient testing started on 4/8 /2024. The inspector noted that 51 Ammonia results were reported during the timeframe of 4/8/24 to 3/17/26 while failing to to verify the accuracy. 5. Interviews with the facility's President and the Director of Clinical Laboratory Operations at 5 PM on 3/17/26 confirmed the above 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: Based on a review of proficiency testing (PT) records, policy and procedures, lack of documentation, and interviews, the laboratory failed to document evaluation taken for two unacceptable chemistry/endocrinology analyte results on American Proficiency Institute (API) 2025 Event 1. Findings include: 1. Review of the laboratory's available API records (2025 Events 1-3, 2026 Event 1), a total of four events, revealed no evidence of remedial action for the following unacceptable scores reported on 2025 API Event 1 Chemistry/Endocrinology Module: Free Thyroxine challenge sample #CH-03 reported as 1.6 (expected result 1.7- 2.3); T3 Uptake challenge sample # CH-03 reported as 54.8 (expected result 37.9- 54.7). 2. Review of the laboratory's procedures revealed a Proficiency Testing policy that stated: "Results that do not fall within the expected expected range will be investigated and documented on PT Exception Summary report form. Result discrepancies are researched and resolved by the laboratory manager in consultation with the supervisor. Document on PT Exception Summary Report form." 3. Review of the laboratory's PT corrective action forms revealed no evaluation action documentation for the unacceptable analyte scores listed above. 4. Interviews with the facility's President and the Director of Clinical Laboratory Operations at 5 PM on 3/17/26 confirmed the above findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on a tour, review of hematology and chemistry calibration records, manufacturer's user guide, analyzer test menu and calibrator materials, calibration verification records, lack of documentation, and interviews, the laboratory failed to: 1. document calibration procedures every six months for Complete Blood Count testing according to manufacturer instructions and laboratory protocols for 12 of 24 months reviewed - Refer to D5437; 2. substantiate/verify the reportable range accuracy of 23 of 23 Beckman Coulter AU480 analytes every six months to include at least a minimal (or zero) value, a mid-point value, and a maximum value for one of two years reviewed- Refer to D5439.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a tour, review of hematology calibration records, manufacturer's user guide, lack of documentation, and interviews, the laboratory failed to document calibration procedures every six months for Complete Blood Count (CBC) testing according to manufacturer instructions and laboratory protocols for 12 of 24 months reviewed. Findings include: 1. During a tour of the laboratory at 12:30 PM on 3/17/26, the inspector noted one DxH560 hematology analyzer serial number (SN) BG030189 in use for CBC testing. Review of the DxH560 validation records revealed that the analyzer was installed by Beckman Coulter field service on 12/19/23 with validation and procedures approved by the LD on 1/5/24. 2. Review of the laboratory's DxH 560 hematology analyzer calibration documentation for the 24 months of review (timeframe 3/29/24 to the date of the recertification inspection, 3/17/26) revealed the following calibration records: 7/11/24, 7/23/25, 1/29/26. The inspector inquired regarding the laboratory's policy for DxH 560 calibration frequency. The Director of Clinical Laboratory Operations stated at 4 PM on 3/17/26, "calibrations should be performed every six months." 3. A review DxH560 user guide revealed instructions, "calibration every 6 months, upon reagent lot changes, or when quality control (QC) values shift significantly". The inspector requested to review additional calibration records for the DxH560 analyzer during the 12 months of 7/11/24 to 7/23/25. No additional calibration documentation was available for review. 4. Interviews with the facility's President and the Director of Clinical Laboratory Operations at 5 PM on 3/17/26 confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of chemistry analyzer test menu and calibrator material, calibration verification records, lack of documentation, and interviews, the laboratory failed to substantiate/verify the reportable range accuracy of 23 of 23 Beckman Coulter AU480 analytes every six months to include at least a minimal (or zero) value, a mid-point value, and a maximum value for one of two years reviewed. Findings include: 1. Review of the AU480 (serial number 2023070734) test menu analytes' calibration materials revealed the following 23 analytes with two or less routine calibrators: Albumin - Beckman Coulter Chemistry Calibrator Level 2 Ammonia - Infinity Ammonia Standard Level 1 Amylase - water blank Carbon Dioxide (CO2) - AU Bicarbonate calibrator Cal 1, Cal 2 Creatine Kinase - water blank Direct Bilirubin - Beckman Coulter Chemistry Calibrator Level 1 Total Bilirubin - Beckman Coulter Chemistry Calibrator Level 1 Blood Urea Nitrogen (BUN) - Beckman Coulter Chemistry Calibrator Level 2 Calcium - Beckman Coulter Chemistry Calibrator Level 1 and 2 Chloride - ISE Serum Standards Low and High Cholesterol - Beckman Coulter Chemistry Calibrator Level 2 Creatinine - Beckman Coulter Chemistry Calibrator Level 1 and 2 Glucose - Beckman Coulter Chemistry Calibrator Level 2 Cholesterol, High Density Lipoprotein (HDL) - HDL Cholesterol Calibrator Level 1 Iron - Beckman Coulter Chemistry Calibrator Level 1 Cholesterol, Low Density Lipoprotein (LDL) - LDL Cholesterol Calibrator Level 1 Magnesium - Beckman Coulter Chemistry Calibrator Level 2 Phosphorus - Beckman Coulter Chemistry Calibrator Level 2 Potassium - ISE Serum Standards Low and High Sodium - ISE Serum Standards Low and High Total Protein - Beckman Coulter Chemistry Calibrator Level 2 Triglycerides - Beckman Coulter Chemistry Calibrator Level 2 Uric Acid - Beckman Coulter Chemistry Calibrator Level 2 2. Review of the AU480 chemistry analyzer calibration verification records for calendar years 2024 and 2025 revealed the following documentation: 1/5/24: calibration verification included in validation and performed by field service using VeriChem linearity materials, accepted by lab director; 7/27/24, 8/2/24: calibration verification performed by testing personnel using Audit linearity materials 3. The inspector requested to review documentation of calibration verification performed in calendar year 2025 for the 23 analytes outlined above. The documentation was not available for review. 4. Interviews with the facility's President and the Director of Clinical Laboratory Operations at 5 PM on 3/17/26 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 laboratory records, procedures, hematology and chemistry calibration records, manufacturer's guidelines, calibrator material, calibration verification records, lack of documentation, and interviews, the laboratory director failed to: 1. ensure proficiency testing enrollment for regulated analytes assayed on Beckman Coulter DxH560 hematology, AU480 chemistry, and Access 2 immunoassay instruments in calendar years 2024, 2025 and year to date 2026 - Refer to D6015; 2. ensure that evaluation/remedial action was taken for unsatisfactory and unacceptable proficiency testing scores received on American Proficiency Institute's 2025 Event 1 and 2 - Refer to D6019; 3. ensure that all analytical performance quality assurance policies were maintained during the 24 months of review March 2024 through the date of the survey on March 17, 2026 - Refer to D6023.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on a review of laboratory records, lack of documentation, and interviews, the laboratory director failed to ensure proficiency testing enrollment for the Beckman Coulter DxH560 hematology, AU480 chemistry, and Access 2 immunoassay instruments in calendar years 2024, 2025 and year to date 2026. Refer to D2000
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on a review of laboratory records, procedures, lack of documentation, and interviews, the laboratory director failed to ensure that evaluation/remedial action was taken per protocols for unsatisfactory and unacceptable proficiency testing scores received on American Proficiency Institute's 2025 Event 1 and 2. Refer to D2116, D5221
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

	This STANDARD is not met as evidenced by: Based on review of procedures, hematology and chemistry calibration records, manufacturer's guide, calibrator material, calibration verification records, lack of documentation, and interviews, the Laboratory Director (LD) failed to ensure that all analytical performance quality assurance (QA) policies were maintained during the 24 months of review, March 2024 through the date of the survey on March 17, 2026. Findings include: 1. Review of the laboratory's policies and procedures revealed a QA policy that included the LD to review quality assurance corrective action measures to monitor analytical phases of patient testing. 2. Review of the laboratory's DxH 560 hematology analyzer calibration documentation revealed that the laboratory failed to document calibration procedures every six months for Complete Blood Count testing according to manufacturer instructions and laboratory protocols for 12 of 24 months reviewed. Refer to D5437 3. Review of chemistry calibration verification records revealed that the laboratory failed to substantiate/verify the reportable range accuracy for Beckman Coulter AU480 analytes every six months for 12 of 24 months reviewed. Refer to D5439 4. Interviews with the facility's President and the Director of Clinical Laboratory Operations at 5 PM on 3/17/26 confirmed the above findings.