Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2165905	03/17/2026
Name of Provider or Supplier	**Street Address, City, State**	
Next Oncology	2829 Babcock Road, Suite 300, San Antonio, 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
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's maintenance records for the EasyRA chemistry analyzer from October 2025 to February 2026, and staff interview, the laboratory failed to have documentation of performing monthly maintenance for 3 of 5 months. The findings included: 1. A review of the EasyRA chemistry analyzer maintenance records from October 2025 to February 2026 determined the following maintenance was to be performed monthly: Bleach diluent bottle Bleach waste bottle Clean wash cap w/alc pad Clean ISE sample cup w/cotton tip 2. Further review of the records determined the laboratory failed to have documentation of performing monthly maintenance for the following 3 months: October 2025 January 2025 February 2026 3. Technical consultant number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 03/17/2026 at 1300 hours in the office. 44278 II. Based on review of laboratory's maintenance records for the STA Compact Max coagulation analyzer from August 2025 to December 2025, and staff interview, the laboratory failed to have documentation of performing weekly maintenance for 11 of 20 weeks in 2025. Findings included: 1. Review of STA Compact Max coagulation analyzer maintenance records from August 2025 to December 2025 determined the following maintenance was to be performed monthly: Clean wash wells Clean drawers and measurement plate-warm Clean measurement and incubation wells Clean and inspect suction tip Perform needle purge Data backup Shut down analyzer Clean touch screen Decontaminate stir bars as per package insert Further review of maintenance records in 2025, revealed the following weeks the laboratory failed to document the above maintenance: a. August 2025 Week 3 and Week 4 b. September 2025 Week 2, Week 3 and Week 4 c. October 2025 Week 3 and Week 4 d. November 2025 Week 1, Week

	2, Week 3 and Week 4 The laboratory was asked to provide the above weekly maintenance documentation in 2025. No documentation was provided. 2. In an interview on 03/17/2026 at 1430 hours in the laboratory office, Technical Consultant 1 (TC-1) confirmed the laboratory failed to have documentation of performing weekly maintenance for 11 of 20 weeks in 2025.
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 the manufacturer's instructions for ISE testing performed on the Dimension EXL, review of the laboratory's records from 2024 and 2025, and staff interview, the laboratory failed to have documentation of performing calibration verification for sodium, potassium and chloride 4 of 4 times in 2024 and 2025. The findings included: 1. A review of the manufacturer's instructions for ISE testing on the Dimension EXL identified the assay required 1 level for calibration and two levels of quality control tested each day. Thus, calibration verification was required. 2. A review of the laboratory's records from 2024 and 2025 determined the laboratory failed to perform calibration 4 of 4 times in 2024 and 2025. 3. Technical consultant number 1 (as listed on Form CMS 209) confirmed calibration verification was not performing in 2024 and 2025 in an interview conducted on 03/17/2026 at 1540 hours in the office.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (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.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's records from October 2025 to February 2026, and staff interview, the laboratory failed to have documentation of monitoring quality control values over time for 4 of 4 assays tested on the TOSOH AIA 360 over 5 of 5 months. The findings included: 1. A review of the laboratory's test menu identified the following tests performed on the TOSOH AIA 360 analyzer: Free T3 Free T4 Thyroid Stimulating Hormone cTnI2 2. A review of the laboratory's quality control records from October 2025 to February 2026 determined the laboratory failed to have documentation of monitoring quantitative quality control values over time for 5 of 5 months. 3. Technical consultant number 1 (as listed on Form CMS 209) stated the laboratory had been trying to program its LIS to monitor quality control over time, but, as of the survey, this has not been completed. This confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from August 2025, review of patient test records from August 2025, and staff interview, the laboratory failed to ensure quality control values were acceptable prior to reporting out patient results on 3 of 3 days. The findings included: 1. A review of the laboratory's Dimension EXL quality control values from June 2025 and August 2025 identified the following days when quality control results failed to meet manufacturer's criteria for acceptability: a) Date: 8/4/2025 Analyte: Thyroid Stimulating Hormone QC Level 1 value: 0.823 Acceptable Range: 0.56 - 0.82 b) Date: 8/5/2025 Analyte: Beta hCG QC Level 3 value: 399 Acceptable Range: 460 - 607 c) Date: 8/11/2025 Analyte: Triglycerides QC Level 1 value: 91 QC Level 1 value: 158 QC Level 1 value: 90 Acceptable Range: 70.1 - 89.6 2. A review of patient test records from 8/4/2025, 8/5/2025, and 8/11/205 identified the following results which were reported on the days with failed quality control: a) Date: 08/04/2025 Sample ID: 20473219 Thyroid Stimulating Hormone value: 5.380 b) Date: 08/05/2025 Sample ID: 20474359 Beta hCG value: 3 c) Date: 08 /11/2025 Sample ID: 20478008 Triglycerides value: 92 3. Technical consultant number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 03/17/2026 at 1405 hours in the office.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the

	reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on laboratory policy, quality control records in December 2025, and confirmed in interview, the laboratory failed to document corrective actions when test systems performed outside acceptable parameters for 4 of 31 days randomly reviewed in December 2025. Findings included: 1. Review of laboratory policy, "Quality Control" (Approved by the laboratory director on 01/20/2026) revealed the following: "...8. When controls are out of range: a. If a run is made and the controls are out of range, the following should be followed: i. If it is an initial control run and not accompanied with patient specimens, repeat control. If the results are still out, resort to appropriate in-house trouble shooting and documentation prior to outside service call." 2. Review of coagulation quality control (QC) records in December 2025 revealed the following days quality control performed outside acceptable parameters: D-Dimer Lot Number: 271648 QC Level Abnormal a. 12/11/2025 Flag- outside acceptable range b. 12/15 /2025 Flag- outside acceptable range c. 12/29/2025 Flag- outside acceptable range d. 12/31/2025 Flag- outside acceptable range The laboratory was asked to provide corrective action documentation for the above days QC fell outside acceptable parameters. No documentation was provided. 3. In an interview on 03/17/2026 at 1330 hours in the laboratory office, Technical Consultant 1 (TC-1) confirmed the laboratory failed to document corrective actions when test systems performed outside acceptable parameters for 4 of 31 days randomly reviewed in December 2025.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's Triglycerides quality control records from June 2025, review of patient test records, and staff interview, the laboratory failed to have documentation of remediating 2 of 2 patients tested the day prior to quality control failure. The finding included: 1. A review of the laboratory's Triglycerides quality control records from June 2025 identified quality control failed 5 times on 06/11/2025 and the system required calibration in order the control to be acceptable. The quality control results and corrective actions performed were: Multiqual level 1 a) run 1 Value: 67 Acceptable range: 70.1 - 89.6 Corrective action: will repeat b) run 2 Value: 68 Acceptable range: 70.1 - 89.6 Corrective action: will repeat c) run 3 Value: 66 Acceptable range: 70.1 - 89.6 Corrective action: will repeat with new flex d) run 4 Value: 65 Acceptable range: 70.1 - 89.6 Corrective action: will repeat with new flex e) run 5 Value: 66 Acceptable range: 70.1 - 89.6 Corrective action: post calibration - will repeat f) run 6 Value: 86 Acceptable range: 70.1 - 89.6 2. A review of patient test records from 6/10/2025 identified the following two patients which required

	remediation: a) Sample ID: 20447055 b) Sample ID: 20447084 3. Technical consultant number 1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 03/17/2026 at 1405 hours in the office.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, and staff interview, the laboratory director failed to ensure a quality control plan was developed and followed to ensure accurate and reliable results. The findings included: 1. The laboratory director failed to ensure quality control values were monitored over time (refer to D5441). 2. The laboratory director failed to ensure quality control values were acceptable prior to reporting patient results (refer to D5481). 3. The laboratory director failed to ensure corrective actions were documented when quality control values were outside acceptable range (refer to D5781). 4. The laboratory director failed to ensure patient remediation was performed on patient results after quality control failure (refer to D5783).