Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1103293	06/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Oncology And Radiation Associates	7150 W 20th Ave Ste 214, Hialeah, FL	

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	STANDARD: An announced CLIA recertification survey was conducted at ONCOLOGY AND RADIATION ASSOCIATES from June 11, 2025 to June 17, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory failed to retain copies for maintenance as specified by the manufacturer for the Hematology Analyzer for 7 out of 12 months reviewed (from June of 2024 to May 2025) . Findings included: 1- Review of the Beckman Coulter DxH520 maintenance records revealed that monthly bleaching records were not available from June 2024 to December of 2024. 2- Review of the CMS 209 form submitted by the laboratory revealed there are four testing personnel TP1, TP2, TP3 and TP4. 3- Review of the instrument manual PN C41838AA Table 12.1 Matrix of Frequency for Cleaning Procedures stated that the "frequency for Performing a Bleaching Cycle as Every 1,000 cycles or monthly, whichever comes first." 4- Interview on 06/11/2025 at 2:43 PM with TP2 admitted that the laboratory did not have bleaching records for months prior to January 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 record review and staff interview, the laboratory failed to ensure that the Hematology Analyzer was calibrated at a minimum every 6 months for one year (2024) out of two years reviewed (2024 to 2025). Findings Included: 1- Review of the CMS 209 form submitted by the laboratory revealed there are four testing personnel TP1, TP2, TP3 and TP4. 2- Review of the Beckman Coulter DxH520 analyzer calibration records revealed that calibration was performed on 05/21/2024 and 02/20 /2025. 3- Review of the instrument manual PN C41838AA CHAPTER 11 When to Verify Calibration states "You should verify the calibration of your instruments: As dictated by your laboratory procedures and local or national regulations." 4- Interview on 06/11/2025 at 2:43 PM with TP2 confirmed only one calibration was performed in 2024.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of Patient reports and staff interview, the Laboratory failed to include the name of the laboratory that performed the Hematology testing on 4 out of 4 (Patients #1, #2, #3, and #4) reports reviewed. Findings included: 1- Review of random patient final reports pulled 08/21/20023 (#1), 02/05/2025 (#2), 10/15/2024 (#3), and 05/27/2025 (#4) revealed that all four reports failed to spell out the laboratory that performed the Hematology testing. 2- During a phone interview on 06 /17/2025 at approximately 10:00 AM, the Office Manager confirmed that the Laboratory name was not spelled out on the final Laboratory reports.