Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1103293	(X3) Date Survey Completed 09/25/2019
Name of Provider or Supplier Oncology And Radiation Associates	**Street Address, City, State** 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	A recertification survey conducted on 9/25/19 found that the Oncology & Radiation Associates clinical laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document initial and semiannual competencies assessment for 3 out of 4 testing personnel (TP) (# A, B, C and D) for 2018 and 2019 Findings include: - A review of CMS-209 laboratory personnel signed and dated on 9/25/2019 by laboratory director (LD) revealed that the laboratory had 4 TP. LD is TP # A - Review of employee records revealed: TP # B started on November 2018, TP # C started on February 2019, TP # D started on 12 /2018; no initial and 6 months assessment were documented. During an interview on 9 /25/19 at 9:30am, testing personnel # B, confirmed there was no documentation of competencies assessment for the 3 TP of above-reference.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to document room humidity and temperature requirements to ensure optimal operation for the Coulter Ac-T Diff 2 Analyzer during 2 out of 2 years reviewed. The findings include: During observation of the laboratory, it was noted that no thermometer and humid meter was located by the analyzer. A review of Coulter Ac-T Diff 2 Hematology Analyzer manual revealed a requirement for optimal operation to include a range of room temperature of 16 to 35 degrees C., and Humidity between 20 to 85 %. A review of temperature logs for 2018 and 2019, revealed no documentation of room humidity and temperature during this two year period. During an interview at 9: 30 am, on 9/25/19, TP # B confirmed that there was no documentation of the room temperature and humidity for the period of above-reference.