

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1103293	(X3) Date Survey Completed 05/16/2023
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 05/16/2023 found the ONCOLOGY AND RADIATION ASSOCIATES clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have all testing personnel (TP) rotate through the testing of Proficiency Testing (PT) for the Hematology specialty in five out of five events reviewed. Findings included: Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 04/20/2023 revealed the laboratory had six TP listed (TP#A, TP# B, TP#C TP#D, TP#E and TP#F). Review of American Proficiency Institute (API) PT records for 2021 (third event), 2022 (first, second and third event) and 2023 (first event), revealed that TP#A and TP#B performed all five events, TP#C, TP#D, TP#E and TP#F had no records of performing PT. During an interview on 05/16/2023 at 11:30 AM, TP#A confirmed that TP#C, TP#D, TP#E and TP#F failed to perform PT for the period of reference.</p>