

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0880678	(X3) Date Survey Completed 11/17/2020
Name of Provider or Supplier Oncology & Radiation Associates Pa	Street Address, City, State 3659 S Miami Ave Ste 2001, Miami, 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 11/17/2020 found that the Oncology & Radiation Associates PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>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 requirement to ensure optimal operation for the Coulter Ac-T Diff 2 Analyzer for 2 out of 2 years reviewed. The findings include: An observation of laboratory during the tour on 11/17/2020 at 10:30 am, indicated that no thermometer and humid meter was located by the analyzer. A review of Coulter AcT diff2 Hematology Analyzer manual revealed a requirement for optimal operation a range of room temperature of 16 to 35 C and Humidity between 20 to 85 %. A review of temperature logs for 2019 and 2020, revealed no documentation of room humidity and temperature. During an interview on 11/17/202 at 3:30 pm Testing personnel A, confirmed that there was no documentation of the room temperature and humidity for the period of reference.</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p>

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 document calibration verification procedures of the Beckman Coulter AC T diff Analyzer at least every 6 months from 12/14/2018 to 9/25/2019. Findings include: -Review of the Beckman Coulter AC T diff Analyzer calibration records revealed that the laboratory performed calibrations on 12/4/2018, 9/25/2019, 2/12/2020, 5/12/2020. During an interview on 11/17/2020 at 2:00 p.m., the testing person A confirmed that there was no documentation to indicate the instrument calibration every 6 months in the period of 12/04/2018 to 9/25/2019.