

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0279428	(X3) Date Survey Completed 05/11/2018
Name of Provider or Supplier Oncology & Radiation Associates Pa	Street Address, City, State 1321 Nw 14th St Ste 601, 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
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 interview, laboratory failed to check and monitor room temperature and humidity from June 2016 to May 11, 2018. The findings include: On 5/11/18 at 1:00 PM, surveyor did not observe humidity check/ room temperature monitoring device in the laboratory. Instrument maintenance records from June 2016 to May 11, 2018 did not show records of humidity check and room temperature for the laboratory. During an interview on 5/11/18 at 1:30 PM, testing person confirmed that the laboratory did not monitor the room temperature or humidity from June 2016 to May 11, 2018 and there was no humidity check/ room temperature monitoring device in the laboratory.</p>