

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2140548	(X3) Date Survey Completed 12/15/2021
Name of Provider or Supplier Umhc - South Miami Dermatology	Street Address, City, State 7000 Sw 62nd Ave, Ph-A., 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 12/15/2021 found that the UMDC-SOUTH MIAMI DERMATHOLOGY clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document corrective actions when the room humidity percentage was not within the acceptable humidity ranges during 2020 and 2021. Findings include: -Review of manufacturer manual for Avantik Cryostat revealed a requirement of maximum room humidity of 60 %. - Review of Daily Humidity log for years 2020 and 2021 revealed that of 211 testing days 144 days the room humidity was out of range. -No records of corrective action found for the days the room humidity was out. During an interview on 12/15/2021 at 11:00 AM with the office manager, she confirmed that there were no corrective actions for the days the humidity was out of the acceptable range.</p>