

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2260654	(X3) Date Survey Completed 06/18/2024
Name of Provider or Supplier Fair Winds Dermatology Llc	Street Address, City, State 2430 Nw Professional Dr, Corvallis, OR	
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 review of the laboratory's standard operating procedure (SOP) for Cryostat use, maintenance and cryostat temperature control and interview with the Laboratory Director (LD), the laboratory failed to follow their written SOP that designates the operating temperature of the cryostat maintained for Mohs dermatopathology surgery specimens from humans. Findings include: 1. Upon review of the SOP for the Cryostat maintained in the Mohs laboratory space, the SOP, titled "Maintenance Record for Cryostat", stated that the temperature for the Cryostat will be maintained at -20 to -30 degrees Celcius. 2. Also noted under Equipment Quality Control for Cryostats, in the "Maintenance Record for Cryostat", #3 states: "Corrective action is taken and documented if temperature exceeds range". 3. Review of the temperature records dated 12/5/2023 until the day of survey 06/18/2024, 45 days out of 74 days revealed the cryostat temperature was out of range (-20 - -30 degrees C), as reflected in the laboratory's SOP for the Cryostat. 4. Request for corrective action (CA) documentation for the 45 out of 74 days of temperature outliers from 12/5/2023 - 06/18/2024, the laboratory failed to produce any written evidence of CA for any of these temperature outliers. 5. Interview with the LD at 1100 confirmed that no CA had been taken for the temperature outliers dated 12/5/2023 - 06/18/2024. 6. The laboratory reports performing 1000 Mohs surgical procedures / year.</p>

D5781

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(1)

(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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory Cryostat temperature records dated 12/5/2023 until the day of survey 06/18/2024 and interview with the Laboratory Director (LD), the laboratory failed to ensure corrective action (CA) was performed and documented as reflected in the laboratory's Standard Operating procedure (SOP) for the Cryostat temperature and what protocol to follow when they are out of range. Findings include:

1. Upon request for CA documentation for the 45 out of 74 days of temperature outliers from 12/5/2023 - 06/18/2024, the laboratory failed to produce any written physical evidence of CA for any of the temperature outliers during this time.
2. Interview with the LD at 1100 on day of survey confirmed that no CA had been taken for the temperature outliers dated 12/5/2023 - 06/18/2024. (45 out of 74 days)
3. The laboratory reports performing 1000 Mohs surgical procedures / year.