

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0211849	(X3) Date Survey Completed 05/21/2026
Name of Provider or Supplier Sona Dermatology	Street Address, City, State 6500 Rock Spring Dr Ste 105, Bethesda, MD	
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
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 humidity log record review and interview with the histotechnician (HT), the laboratory failed to document corrective action when room humidity was out of acceptable range. Findings: 1. The laboratory documents room humidity readings on the "Room Temperature and Humidity Log" (humidity log). The log states that the acceptable humidity range is "Maximum 60%". 2. A review of humidity logs from 2025 and 2026 showed that room humidity was out of range four out of 11 days recorded in June 2025, four out of 12 days recorded in July 2025, and three out of 15 days recorded between 05/01/2026 and 05/21/2026. 3. Record review showed that there were no corrective actions documented for the out of range humidity readings. 4. During an interview on 05/21/2026 at 11:30 AM, the HT confirmed that room humidity was out of range and that no corrective actions had been documented.</p>
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an</p>

ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:

Based on procedure manual and record review and interview with the histotechnician (HT), the laboratory failed to follow written policies and procedures for performing postanalytic quality assurance (QA) reviews. Findings: 1. The procedure, "Mohs Surgery and Frozen Section, Quality Assessment; Histopathology Quality Control" states, "At the end of each month the facility logs will be provided to the Laboratory Director for review and signature", "Comments or events documented on the facility logs will be investigated" and "Corrective actions will be documented." 2. A review of "Room Temperature and Humidity Logs" (humidity logs) from 2025 and 2026 showed that laboratory humidity was out of acceptable range with no corrective actions documented (cross-refer to D5781). 3. The humidity log has space at the bottom of the log labeled "LD" with room for the laboratory director (LD) to sign off that they have performed the monthly review. Record review showed that the LD did not review and sign the humidity logs for 16 out of 16 months between January 2025 and April 2026 and did not document that humidity readings were out of range with no corrective action. 4. During an interview on 05/21/2026 at 11:30 AM, the HT confirmed that the laboratory failed to follow written policies for performing QA reviews.