

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2172693	<b>(X3) Date Survey Completed</b>  09/09/2025
<b>Name of Provider or Supplier</b>  Framingham Dermatology	<b>Street Address, City, State</b>  761 Worcester Road, Framingham, MA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A CLIA recertification survey was conducted for the Framingham Dermatology laboratory on 09/09/2025 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D5219</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>(c)(2) Any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory does not have a procedure to verify the accuracy of testing at least twice annually. Findings include: 1. Review of the laboratory procedure manual revealed there is no policy for peer review of MOHS cases by another surgeon at least twice annually. 2. Interview with the Histotechnician on 09/09/2025 at 11:00 AM confirmed the above finding. 3. The laboratory has performed 15 MOHS surgeries from July 28, 2025 to September 8, 2025.</p>
<b>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the Laboratory Procedure Manual was not approved, signed, and dated by the new Laboratory Director (LD). Findings include: 1. A review of the laboratory procedure manual revealed no documentation that the</p>

LD had reviewed, approved, and signed the procedure manual. 2. Interview with the Histotechnician on 09/09/2025 at 11:00 AM revealed the current LD started in his role in July of 2025 and the LD did not review and approve the Procedure Manual. 3. The laboratory has perform 15 cases between July 28, 2025 to September 9, 2025.

**D5821**

**TEST REPORT**  
CFR(s): 493.1291(k)

(k)When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:  
Based on record review and interview with the Histotechnician (HT) and Physician Assistant (PA) the laboratory does not have a policy for corrective action when errors are found in patient records. Findings include: 1. A chart review of 6 MOHS cases revealed a transcription error in 1 of 6 cases. 2. Review of the test order, Visit Note, and MOHS Micrographic Surgery Operative Record (MOHS Map) for specimen number MOHS25-357 revealed: a. The Visit Note Pre-op biopsy size is recorded as 0.5 x 0.5 cm. b. The MOHS Map Pre-op biopsy size is recorded as .5 x .5 mm. 3. Review of the laboratory procedures revealed there was no policy for corrective reports that was signed and accepted by the Laboratory Director. 4. Interview with the HT and PA on 09/09/2025 at 1:00 PM confirmed the above findings. 5. The laboratory has performed 15 MOHS cases from July 28, 2025 to September 8, 2025.