

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2281413	<b>(X3) Date Survey Completed</b> 10/22/2025
<b>Name of Provider or Supplier</b> Summitmd Dermatology	<b>Street Address, City, State</b> 3257 Buffalo Gap Rd, Abilene, TX	
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>	An onsite recertification survey was conducted on 10/22/2025. The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures, Centers for Medicare &amp; Medicaid Services (CMS) 209 form, personnel records, and confirmed in interview, the laboratory failed to establish written procedures to ensure competency assessment for 1 of 1 Clinical Consultant (CC)/Technical Supervisor (TS)/General Supervisor (GS) in 2024 who provided oversight of dermatopathology slide interpretations. Findings included: 1. Review of the laboratory's written procedures did not include a procedure for competency assessments for individuals designated as the clinical consultant, technical supervisor, and general supervisor, as required. The clinical consultant and supervisors provided oversight of dermatopathology slide interpretations. 2. Review of the CMS 209 form and personnel records for CC/TS/GS - 1 did not include competency assessments performed and documented based on position responsibilities as defined in Subpart M (493.1351) in 2024. 3. During an interview on 10/22/2025 at 2:00 p.m., the laboratory representative confirmed written procedures did not include performing and documenting competency assessments for the technical supervisor, general supervisor, and clinical consultant.</p>
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p>

(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, laboratory quality control (QC) records, patient records, and confirmed in staff interview, the laboratory failed to define test staining materials for intended reactivity to ensure the predictable staining characteristics each day of use for one of one stain (Hematoxylin and Eosin (H & E)), and failed to test and document QC for H & E staining on each day of patient testing for five of five days from August 2024 to October 2024. Findings included: 1. Review of laboratory policy "MOHS SECTION PROCEDURE" stated: "PROCEDURE ... Once the slide is stained, coverslip applied, check the quality under the microscope and deliver to Dr. [XX] for review." The procedure failed to define the staining characteristics for intended reactivity of the H&E stain. 2. Review of the "Daily Maintenance Record" revealed the following: "Technician Instructions ... 2) Indicate acceptability of Control Slides" The log had a column for "Control Slide Acceptability Yes/No" each day stain quality was documented as "Yes", "check mark" or "Y" in the column and initialed by the laboratory director. A legend at the bottom of the log for stain documentation revealed: "Yes = Meets H/E Standards (No actions Needed) No = Changes Needed See Corrective Action Worksheet" The log did not specify if the "checkmark" was indicated for H&E intended reactivity to ensure predictable staining characteristics. The following dates were observed to be documented with a "checkmark": 08/07/2024 08/19/2024 09/04/2024 09/16/2025 10/08/2024 The laboratory failed to document the intended reactivity to ensure predictable H&E characteristics for the above dates. 3. Review of patient records identified the following patients who were tested and reported when the laboratory failed to document the intended reactivity to ensure predictable H&E characteristics: 08/07/2024 Patient IDs: 080724-01, 080724-02, 080724-03, 080724-04, 080724-05, 080724-06, 080724-07, 080724-08, 080724-09, 080724-10, 080724-11, 080724-12, 080724-13, 080724-14, 080724-15, 080724-16, 080724-17, 080724-18, 080724-19, 080724-20, 080724-21, 080724-22, 080724-23, 080724-24, 080724-25, 080724-26, 080724-27, 080724-28 08/19/2024 Patient IDs: 081924-01, 081924-02, 081924-03, 081924-04, 081924-05, 081924-06, 081924-07, 081924-08, 081924-09, 081924-10, 081924-11, 081924-12, 081924-13, 081924-14, 081924-15, 081924-16, 081924-17, 081924-18, 081924-19, 081924-20, 081924-21, 081924-22, 081924-23, 081924-24, 081924-25, 081924-26, 081924-27 09/04/2025 Patient IDs: 090424-01, 090424-02, 090424-03, 090424-04, 090424-05, 090424-06, 090424-07, 090424-08, 090424-09, 090424-10, 090424-11, 090424-12 09/16/2025 Patient IDs; 091624-01, 091624-02, 091624-03, 091624-04, 091624-05, 091624-06, 091624-07, 091624-08, 091624-09, 091624-10, 091624-11, 091624-12, 091624-13, 091624-14, 091624-15, 091624-16, 091624-17, 091624-18, 091624-19, 091624-20, 091624-21 10/08/2024 Patient IDs: 1008724-01, 1008724-02, 1008724-03, 1008724-04, 1008724-05, 1008724-06, 1008724-07, 1008724-08, 1008724-09, 1008724-10, 1008724-11, 1008724-12, 1008724-13, 1008724-14, 1008724-15, 1008724-16, 1008724-17, 1008724-18, 1008724-19, 1008724-20, 1008724-21, 1008724-22, 1008724-23, 1008724-24, 1008724-25, 1008724-26 4. During an interview on 10/22/2025 at 2:00 p.m., the laboratory representative, after a review of the records confirmed the laboratory failed to define test staining materials for intended reactivity to ensure the predictable staining characteristics each day of use for one of one stain (Hematoxylin and Eosin (H & E)), and failed to test and document QC for H & E staining on each day of

patient testing for five of five days from August 2024 to October 2024.

**D5805**

TEST REPORT  
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

I. Based on review of patient Mohs maps and confirmed in interview, the laboratory failed to include the testing facility address on the Moh's maps for 12 of 12 patients in 2024 (random review December) and 12 of 12 patients in 2025 (random review October). Findings included: 1. A random review of patient Mohs maps from December 2024 and October 2025 revealed the following 24 patient Mohs maps which did not include the testing facility address: 12/04/2024 Patient IDs: M120424-01, M120424-02, M120424-03, M120424-04, M120424-05, M120424-06, M120424-07, M120424-08, M120424-09, M120424-10, M120424-11, M120424-12 10/07/2025 Patient IDs: M100725-01, M100725-02, M100725-03, M100725-04, M100725-05, M100725-06, M100725-07, M100725-08, M100725-09, M100725-10, M100725-11, M100725-12 2. During an interview on 10/22/2025 at 2:29 p.m., the laboratory representative, after a review of records, confirmed the above findings. II. Based on review of the laboratory policies, Mohs maps, and confirmed in interview, the laboratory failed to include the key on the Mohs map for the symbols indicating the marking dyes on the sections used on 24 of 24 Mohs maps reviewed in 2024 and 2025. Findings included: 1. Review of the laboratory's policy "MOHS SECTION PROCEDURE" stated: "Mapping and Tissue Preparation KEEP ORIENTATION OF THE SPECIMEN THE SAME AS RECEIVED Draw out map on the patient card, making sure to take note of the niche made by the physician Bisect or leave specimen whole (physician preference) Ink the specimen according to physician preference, and annotate the coloring on patient card as well" The policy failed to define the symbols drawn on the Mohs maps indicating the marking dyes on the sections used on the Mohs map. 2. Random review of 24 patient Mohs maps from 12/04/2024 and 10/07/2025 showed symbols for the marking dyes used, but there was no key on the map to show what colors the symbols were, as listed by date of service and patient ID number: Date of service: 12/04/2024 Patient IDs: M120424-01, M120424-02, M120424-03, M120424-04, M120424-05, M120424-06, M120424-07, M120424-08, M120424-09, M120424-10, M120424-11, M120424-12 Date of service: 10/07/2025 Patient IDs: M100725-01, M100725-02, M100725-03, M100725-04, M100725-05, M100725-06, M100725-07, M100725-08, M100725-09, M100725-10, M100725-11, M100725-12 3. During an interview on 10/22/2025 at 2:13 p.m., the laboratory representative, after a review of records, confirmed the laboratory failed to include the key on the Mohs map for the symbols indicating the marking dyes on the sections used on 24 of 24 Mohs maps reviewed in 2024 and 2025.