

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2247758	<b>(X3) Date Survey Completed</b> 08/20/2024
<b>Name of Provider or Supplier</b> Panhandle Dermatology Of Summitmd	<b>Street Address, City, State</b> 1600 S Coulter St, Ste E - 703, Amarillo, 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>	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the laboratory's records, presurvey paperwork, and interview, the laboratory failed to retain the chemical name and concentration (if applicable), manufacturer, lot number, expiration date, received date, and open date of the chemicals and stains used in the laboratory for Mohs testing for two of two years reviewed. Findings follow. A. The reagent log was requested on August 20, 2024 at 1000 in the laboratory but not provided. B. Review of the CMS Form 116 showed an estimated annual volume of 470 Mohs stages. C. Interview with the Medical Assistant on August 20, 2024 at 1030 hours in the laboratory confirmed the laboratory did not have a reagent log available for review. II. Based on review of the Mohs log and interview, the laboratory failed to retain the number of slides and blocks per case for Mohs testing for 21 of 21 months reviewed. Findings follow. A. Review of the Mohs log from 09/22/2022 to 07/18/2024 (elapsed time 21 months) showed the number of slides and blocks per case was not recorded. B. Review of the CMS Form 116 showed an estimated annual volume of 470 Mohs stages. C. Interview with the Medical Assistant on August 20, 2024 at 1015 hours in the laboratory confirmed the number of slides and blocks was not recorded.</p>
<b>D5203</b>	<b>SPECIMEN IDENTIFICATION AND INTEGRITY</b>

CFR(s): 493.1232

The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, slide review, test reports, Mohs logs, and interview, the laboratory failed to ensure positive identification and optimum integrity of patient specimens from the time of collection and receipt of the specimen through completion of testing and reporting of results for two of 10 cases reviewed. Findings follow. I. A. Review of the laboratory's policies and procedures did not have a procedure for the labeling of slides. B. Review of the slide for case 01-18-23-33 showed an identifier of 1-18-19 on the slide label. Laboratory practice was the date of service was documented on the slide. C. Review of the test report and map showed the date of service was 1-18-23 for case number 33 that day. D. Interview with the Medical Assistant on August 20, 2024 at 1210 hours in the laboratory confirmed the slide was mislabeled. II. A. Review of the laboratory's policies and procedures did not have a procedure for the documentation of Mohs logs. B. Review of the Mohs log showed the wrong date of birth (03/10/1948) for the fourth name on the case list on 07-19-23. C. Review of the test report showed the date of birth was 03/30/1966. D. Interview with the Medical Assistant on August 20, 2024 at 1200 hours in the laboratory confirmed the date of birth on the Mohs log was incorrect.

**D5217**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to provide documentation of twice a year accuracy assessments of Mohs testing for two of two years reviewed. Findings follow. A. Review of the laboratory's policies and procedures did not have a procedure for accuracy assessments. B. Review of the accuracy assessments from 2022 and 2023 and to date in 2024, showed cases were sent out for review, but the laboratory never received the results of the peer review. C. Review of the CMS Form 116 showed an estimated annual volume of 470 Mohs stages. D. Interview with the Medical Assistant on August 20, 2024 at 1100 hours in the laboratory confirmed the findings. \*This is a repeat deficiency from the 09/28/2022 survey.

**D5403**

**PROCEDURE MANUAL**

CFR(s): 493.1251(b)

The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's policies and procedures, pre-survey paperwork, and interview, the laboratory failed to include accuracy assessments for Mohs testing in its procedures for two of two years reviewed. Findings follow. A. Review of the laboratory's policies and procedures did not include accuracy assessments (see D5217). B. Review of the CMS Form 116 showed an estimated annual volume of 470 Mohs stages. C. Interview with the Medical Assistant on August 20, 2024 at 1100 hours in the laboratory confirmed the findings. II. Based on review of the laboratory's policies and procedures, pre-survey paperwork, and interview, the laboratory failed to include the documentation of its reagents in its procedures for two of two years reviewed. Findings follow. A. Review of the laboratory's policies and procedures did not include the documentation of its reagents (see D3031). B. Review of the CMS Form 116 showed an estimated annual volume of 470 Mohs stages. C. Interview with the Medical Assistant on August 20, 2024 at 1030 hours in the laboratory confirmed the findings. III. Based on review of the laboratory's policies and procedures, pre-survey paperwork, and interview, the laboratory failed to include the documentation of its slides in its procedures for two of two years reviewed. Findings follow. A. Review of the laboratory's policies and procedures did not include the documentation of its slides (see D5203 I). B. Review of the CMS Form 116 showed an estimated annual volume of 470 Mohs stages. C. Interview with the Medical Assistant on August 20, 2024 at 1210 hours in the laboratory confirmed the findings. IV. Based on review of the laboratory's policies and procedures, pre-survey paperwork, and interview, the laboratory failed to include the documentation of its Mohs logs in its procedures for two of two years reviewed. tion of its Mohs log (see D5203 II). B. Review of the CMS Form 116 showed an estimated annual volume of 470 Mohs stages. C. Interview with the Medical Assistant on August 20, 2024 at 1200 hours in the laboratory confirmed the findings.

**D5473**

**CONTROL PROCEDURES**

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (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. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, quality control (QC) records, presurvey paperwork, and interview, the laboratory failed to document the reactivity of the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics for their quality control used in Mohs testing for 21 of 21 months reviewed. Findings follow. A. Review of the manufacturer's Instructions For Use titled Thermo Scientific Richard-Allan Scientific Histology and Cytology Standard Stains, 2012, under Modified Harris Hematoxylin stated, "provides traditional nuclear staining results" and Eosin-Y Alcoholic stated, "Muscle, red blood cells and connective tissue all stain various shades of red and pink...."and "...will provide a clear contrast between cytoplasm and nuclei of the cell." B. Review of the Mohs Surgery Maintenance Log from 09/22/2022 to 07/18/2024 showed Control Slide Acceptability for the stain but did not define what was considered acceptable. C. Review of the CMS Form 116 showed an estimated annual volume of 470 Mohs stages. D. Interview with the Medical Assistant on August 20, 2024 at 1035 hours in the laboratory confirmed what was considered acceptable was not on the form.