

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2247758	(X3) Date Survey Completed 09/28/2022
Name of Provider or Supplier Panhandle Dermatology Of Summitmd	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Review of the laboratory's policies and procedures, test records and staff interview of facility personnel found the laboratory failed to have documentation of performing twice annual accuracy assessment for histopathology in 2022. Findings included: 1. A review of the laboratory's policy and procedure manual found no written policy for performing twice annual accuracy assessment of histopathology. 2. Review of patient test records found the laboratory had tested 202 patient specimens on 10 days between March 13, 2022 and September 23, 2022 without twice annual accuracy assessment. 3. The PA confirmed that the twice annual accuracy assessment had not been performed during the interview conducted on September 28, 2022 at 9:48 AM.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of policies and procedures and interview of facility personnel, the laboratory failed to have a written policy for the step by step procedure for performing Mohs micrographic surgical procedures and interpretations to include specimen</p>

collection, preparation, interpretation and reporting of results. The Findings included: 1. Review of procedures found no written procedure for performing Mohs micrographic surgery to include step by step instructions for specimen collection , preparation interpretation and reporting of results. 2. During interview conducted on September 28, 2022 at 11:00 AM, the medical assistant confirmed there were no written policies available for review. The PA stated they just bought the CLIA Manual for Dermatology, but it had not been approved as the procedure by the laboratory director.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on observations and interview of facility personnel, the laboratory failed to label four of four secondary containers (used for Hematoxylin and Eosin) to identify the contents, storage, preparation and expiration dates and other pertinent information. The findings included: 1. Observations made in the laboratory found four unlabeled screw top containers with Orange lids (containing small amounts of dark liquids) in a tray below the sink with the Hematoxylin and Eosin stains and reagent grade alcohol 100%. 2. During the interview of the medical assistant and Pa conducted September 28, 2022 at 9:54 AM, the medical assistant stated they were stains used to stain specimens. The PA went on to say they had ordered a flammables cabinet but it had not yet arrived.