

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2261384	(X3) Date Survey Completed 04/26/2024
Name of Provider or Supplier Concierge Dermatology	Street Address, City, State 7100 Oakmont Blvd Suite 101, Fort Worth, 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
D0000	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instruction manual, and confirmed in staff interview, the laboratory failed to follow manufacturer's instructions for ensuring 1 of 1 microscope was covered with a dust cover when not in use. Findings included: 1. During a tour of the laboratory on 04/26/2024 at 11:10 am, the surveyor observed the Olympus BX41 microscope (Serial #7C25648) uncovered. The microscope was not in use the day of inspection. 2. Review of Olympus BX41 microscope instruction manual revealed: "Maintenance and Storage ... 5. When the microscope is not in use, be sure to set the main switch to "O" (OFF). After checking that the lamp housing had been cooled down, place the dust-prevention cover on the microscope for storage." 3. During an interview on 04/26/2024 at 11:23 am, the Histotechnician confirmed the laboratory failed to follow manufacturer's instructions for ensuring the microscope was covered with a dust cover when not in use.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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</p>

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 laboratory's procedure manual, Quality Control (QC) logs and confirmed in interview, the laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 11 of 11 days in 2023 (10/2023, 11/2023) and 9 of 9 days in 2024 (01/2024 through 04/2024). Findings included: 1. Review of the "HEMATOXYLIN AND EOSIN STAIN" procedure revealed: "Principle ... Staining carried out on microscopic sections includes routine staining, which does little more than differentiate between the nucleus and cytoplasm and special staining, which involves a multiple of special techniques to demonstrate one particular element to the exclusion of all others. The simplest staining is nuclear staining, and the stain most frequently used is hematoxylin. Eosin is the most widely used counterstaining the routine staining of sections. Used properly, at least three shades of pink can be obtained with eosin alone, erythrocytes, collagen, and the cytoplasm of muscle or epithelial cells should stain with different shades of intensities of pink ... Quality Control: Frozen sections have an internal control. There is a QC sheet that will be filled out daily ... RESULTS Nuclei Blue RESULTS Erythrocytes and eosinophilic granules Bright pink to red RESULTS Cytoplasm and other tissue elements Various shades of pink" 2. A random review in 2023 (10/2023-11/2023) and 2024 (01/2024-04/2024) of the "Hematoxylin and Eosin/Section Quality - Microscope Maintenance" log revealed the following: The log had a column for "H&E Quality," each day stain quality was documented as "good" in the column and initialed by the physician. The laboratory failed to specify the meaning of the term "good". The following dates were observed to be documented with "good": October 2023: 2, 9, 16, 23, 27, 30 November 2023: 2, 6, 13, 20, 27 January 2024: 12, 22 February 2024: 5, 19 March 2024: 4, 18 April 2024: 1, 15, 22 The laboratory failed to document the intended reactivity to ensure predictable H&E characteristics; and did not define "good." 3. The following patients were tested and reported in 2023 (10/2023-11/2023) and 2024 (01/2024-04/2024) when the laboratory failed to document the intended reactivity for the H&E stain: 10/02/2023 Mohs Case #: 066, 067, 068, 069 10/09/2023 Mohs Case #: 070, 071, 072, 073 10/16/2023 Mohs Case #: 074, 075 10/23/23 Mohs Case #: 076, 077 10/27/2023 Mohs Case #: 078 10/30/2023 Mohs Case #: 079, 080 11/02/2023 Mohs Case #: 081 11/06/2023 Mohs Case #: 082 11/13/2023 Mohs Case #: 083, 084, 085, 086, 087, 088 11/20/2023 Mohs Case #: 089, 090, 091, 092 11/27/2023 Mohs Case #: 093, 094 01/12/2024 Mohs Case #: 001 01/22/2024 Mohs Case #: 002, 003, 004, 005 02/05/2024 Mohs Case #: 006, 007, 008, 009, 010 02/19/2024 Mohs Case #: 011, 012, 013 03/04/2024 Mohs Case #: 014, 015 03/18/2024 Mohs Case #: 016, 017, 018, 019, 020, 021 04/01/2024 Mohs Case #: 022, 023, 024, 025, 026, 027 04/15/2024 Mohs Case #: 028, 029, 030, 031 04/22/2024 Mohs Case #: 032, 033, 034, 035 3. During an interview at 10:11 am, the histotechnician confirmed the laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin stain.