

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2261384	<b>(X3) Date Survey Completed</b> 03/03/2026
<b>Name of Provider or Supplier</b> Concierge Dermatology	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite recertification survey was conducted on 03/03/2026. The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. 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. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on direct observation and confirmed in staff interview, the laboratory failed to retain the operator's manual for one of one cryostat and one of one microscope used in dermatopathology slide interpretations (Mohs). Findings included: 1. During a tour of the laboratory on 03/03/2026 at 12:15 p.m. the surveyor observed the following: one Microm HM550 cryostat, Serial Number: 26768 one Olympus BX417, Model: BX41TF, Serial Number: 7C25648 The laboratory was asked to provide the operator's manual for the cryostat and microscope, and none were provided. 2. During an interview in the laboratory on 03/03/2026 at 12:26 p.m., the histotechnician stated she could not find the operator's manuals for the cryostat and microscope. This confirmed the laboratory failed to retain the operator's manual for one of one cryostat and one of one microscope used in dermatopathology slide interpretations (Mohs).</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks</p>

may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

I. Based on review of laboratory policy, patient slides, and confirmed in interview, the laboratory failed to follow their own policy for labeling Mohs dermatopathology patient slides for 158 of 158 slides randomly reviewed in 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026). Findings included: 1. Review of the laboratory policy titled "Embedding and Cutting Frozen Sections", approved by the laboratory director on 01/2021 stated: "Procedure ... 2. Take two blank slides (one for embedding and one for your cut sections) and place the patients name, mohs case number, stage, number of tissue, and Slide [sic] number ... Mohs case number starts with location then M for mohs (FW-Fort Worth C-Cleburne), then the year, then the case number." 3. Random review of Mohs dermatopathology patient slides from 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026) revealed the laboratory failed to follow their own policy for labeling slides as follows: 04/07/2025 slides were not labeled with the complete location name: Patient ID: FM25-036 (4 of 4 slides) FM25-037 (2 of 2 slides) FM25-038 (4 of 4 slides) 04/10/2025 slides were not labeled with the complete location name: Patient ID: FM25-039 (4 of 4 slides) 06/02/2025 slides were not labeled with the complete location name: Patient ID: FM25-049 (3 of 3 slides) FM25-050 (3 of 3 slides) FM25-051 (6 of 6 slides) FM25-052 (8 of 8 slides) 06/09/2025 slides were not labeled with the complete location name: Patient ID: FM25-053 (10 of 10 slides) FM25-054 (18 of 18 slides) 06/12/2025 slides were not labeled with the complete location name: Patient ID: FM25-055 (4 of 4 slides) FM25-056 (3 of 3 slides) 06/30/2025 slides were not labeled with the complete location name: Patient ID: FM25-057 (9 of 9 slides) FM25-058 (6 of 6 slides) FM25-059 (6 of 6 slides) 08/11/2025 slides were not labeled with the complete location name: Patient ID: FM25-065 (3 of 3 slides) FM25-066 (3 of 3 slides) FM25-067 (5 of 5 slides) FM25-068 (3 of 3 slides) FM25-069 (5 of 5 slides) 08/18/2025 slides were not labeled with the complete location name: Patient ID: FM25-070 (2 of 2 slides) FM25-071 (7 of 7 slides) FM25-072 (4 of 4 slides) FM25-073 (2 of 2 slides) FM25-074 (3 of 3 slides) FM25-075 (2 of 2 slides) 01/08/2026 slides were not labeled with the "M" for Mohs: Patient ID: FW26-001 (3 of 3 slides) 01/19/2026 slides were not labeled with the "M" for Mohs: Patient ID: FW26-002 (2 of 2 slides) 01/19/2026 slides were not labeled with the complete location name: Patient ID: FM26-003 (3 of 3 slides) FM26-004 (1 of 1 slide) 02/02/2026 slides were not labeled with the complete location name: Patient ID: FM26-005 (2 of 2 slides) FM26-006 (4 of 4 slides) FM26-007 (1 of 1 slide) 02/09/2026 slides were not labeled with the complete location name: Patient ID: FM26-008 (4 of 4 slides) FM26-009 (4 of 4 slides) 02/16/2026 slides were not labeled with the complete location name: Patient ID: FM26-010 (1 of 1 slide) FM26-011 (1 of 1 slide) FM26-012 (2 of 2 slides) The laboratory failed to follow their own written policy for labeling Mohs slides with complete location name or the "M" for Mohs. 4. During an interview in the laboratory on 03/03/2026 at 11:04 a.m., the histotechnician confirmed the laboratory failed to follow their own policy for labeling Mohs dermatopathology patient slides for 158 of 158 slides randomly reviewed in 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026). II. Based on review of laboratory policies, Mohs accession logs, and confirmed in interview, the laboratory failed to follow their own written policy for documenting Mohs case numbers correctly on the accessioning log for 42 of 42 patients randomly reviewed in 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026). Findings included: 1. Review of the laboratory policy titled "ACCESSIONING /MOHS MAPPING", approved by the laboratory director on 01/2021 stated: "Principle: The laboratory shall maintain a record of the daily accession of cases and

the appropriate system for identification of each ... MOHS When the tissue comes into the lab do the following: 1. Give the case the next number A: Mohs case numbers will be location, then M [sic] then the year, then the case number example: FWM23-1234" 2. Random review of the laboratory's Mohs accession logs form 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026) revealed the laboratory failed to accession patient case numbers correctly as stated in the policy. The case numbers failed to have the location, the letter "M" and the year. The following is a sampling of patients reviewed that were NOT labeled according to the laboratory's written policy: 04/07/2025 Mohs Case #: 036, 037, 038 04/10/2025 Mohs Case #: 039 04/24/2025 Mohs Case #: 044 04/28/2025 Mohs Case #: 045 06/02/2025 Mohs Case #: 049, 050, 051, 052 06/09/2025 Mohs Case #: 053, 054 06/12/2025 Mohs Case #: 055, 056 06/30/2025 Mohs Case #: 057, 058, 059 08/11/2025 Mohs Case #: 065, 066, 067, 068, 069 08/18/2025 Mohs Case #: 070, 071, 072, 073, 074, 075 08/25/2025 Mohs Case #: 076, 077 01/08/2026 Mohs Case #: 001 01/19/2026 Mohs Case #: 002, 003, 004 02/02/2026 Mohs Case #: 005, 006, 007 02/09/2026 Mohs Case #: 008, 009 02/16/2026 Mohs Case #: 010, 011, 012 3. During an interview in the laboratory on 03/03/2026 at 10:0 a.m., the histotechnician confirmed the laboratory failed to follow their own written policy for documenting Mohs case numbers correctly on the accessioning log for 42 of 42 patients randomly reviewed in 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026). III. Based on review of laboratory policy, Mohs accession logs, and confirmed in staff interview, the laboratory failed to follow their own written policy to ensure documentation was transcribed onto the Mohs accession log for one of eleven patients reviewed from June 2025. Findings included: 1. Review of the laboratory's policy titled "ACCESSIONING/MOHS MAPPING", approved by the laboratory director on 01/2021 stated: "Principle: The laboratory shall maintain a record of the daily accession of cases and the appropriate system for identification of each ... MOHS ... After the case is clear 6. Write how many stages ... 9. Write how many slides per case" 2. Review of the laboratory's Mohs accession logs for June 2025, revealed the following: 06/09/2025 Accession Number- FM25-054 Mohs accession log number of stages: blank number of slides: blank The laboratory failed to ensure the number of stages and slides were documented on the Mohs accession logs for the patient identified above. 2. During an interview in the laboratory on 03/03/2026 at 11:20 a.m., the histotechnician, after a review of records, confirmed the laboratory failed to follow their own written policy to ensure documentation was transcribed onto the Mohs accession log for one of eleven patients reviewed from June 2025.

**D5473**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(e)(2)(g)

(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 the laboratory's policy manual, Quality Control (QC) logs, patient reports, 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 12 days in 2025 (04/2025-08/2025) and five of five days in 2026 (01/2026-02/2026). Findings included: 1. Review of the "HEMATOXYLIN AND EOSIN STAIN" laboratory policy, approved by the laboratory director in 11/2021, stated: "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" 2. A random review in 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026) 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", a "checkmark", or not documented in the column and initialed by the physician. The laboratory failed to specify the meaning of the term "good" or the "checkmark". The following dates were observed to be documented with "good": August 2025: 11, 18 January 2026: 8, 19 (these dates were not initialed by the physician) February 2026: 2, 9 The following dates were observed to be documented with a "checkmark": April 2025: 10 June 2025: 2, 9, 12, 30 Quality control was NOT documented on the following dates: April 2025: 7, 24, 28 August 2025: 25 February 2026: 16 The laboratory failed to document the intended reactivity to ensure predictable H&E characteristics; and did not define "good" or "checkmark". 3. The following patients were tested and reported in 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026) when the laboratory failed to document the intended reactivity for the H&E stain: 04/07/2025 Mohs Case #: 036, 037, 038 04/10/2025 Mohs Case #: 039 04/24/2025 Mohs Case #: 044 04/28/2025 Mohs Case #: 045 06/02/2025 Mohs Case #: 049, 050, 051, 052 06/09/2025 Mohs Case #: 053, 054 06/12/2025 Mohs Case #: 055, 056 06/30/2025 Mohs Case #: 057, 058, 059 08/11/2025 Mohs Case #: 065, 066, 067, 068, 069 08/18/2025 Mohs Case #: 070, 071, 072, 073, 074, 075 08/25/2025 Mohs Case #: 076, 077 01/08/2026 Mohs Case #: 001 01/19/2026 Mohs Case #: 002, 003, 004 02/02/2026 Mohs Case #: 005, 006, 007 02/09/2026 Mohs Case #: 008, 009 02/16/2026 Mohs Case #: 010, 011, 012 4. During an interview in the laboratory on 03/03/2026 at 10:00 a.m., 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. This is a repeat deficiency from a certification survey conducted on 4/26/2024.

**D5791**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's Quality Assurance (QA) policy, environmental logs, H&E stain quality control logs, maintenance logs, patient slides, Mohs accession logs, and staff interview, it was revealed the laboratory failed to follow its written policies to assess, monitor, and correct problems in analytic systems for four of four months in 2024 (random review September -December) four of four months in 2025 (random review September -December) and one of one month in 2026 (January). Findings included: 1. Review of the laboratory's QA policy titled "PROFICIENCY TESTING QUALITY ASSUARANCE", approved by the laboratory director on 01/2021, stated: "Purpose: The QA Program/Proficiency Testing assures the accurate,

reliable and prompt reporting of test results and provides methods to evaluate the effectiveness of its policies and procedures, to identify and correct problems, and to assess the adequacy and competency of the staff. Principal: It is the policy of this laboratory to apply the principles of this QA Program to all activities of this laboratory, including preanalytic, analytic and postanalytic [sic] activities ... The Laboratory Director reviews all quality control charts and logs on at least a monthly basis. All out-of-control situations not resolved by a simple repeat analysis will be reviewed by the laboratory director as soon as practical after the event." Random review of laboratory environmental records, H&E Stain Quality Control Chart, Cryostat Maintenance logs, Hematoxylin and Eosin/Section Quality Microscope Maintenance logs revealed that no QA was performed monthly from September through December 2024, September through December 2025 and January 2026. 2. The laboratory failed to have a mechanism in place to monitor, assess, and when indicated, correct problems identified in analytic systems, as follows: a. The laboratory failed to follow their own policy for labeling Mohs dermatopathology patient slides for 158 of 158 slides randomly reviewed in 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026). Refer to D5401-I. b. The laboratory failed to follow their own written policy for documenting Mohs case numbers correctly on the accessioning log for 42 of 42 patients randomly reviewed in 2025 (04/2025-08/2025) and 2026 (01/2026-02/2026). Refer to D5401-II. c. The laboratory failed to follow their own written policy to ensure documentation was transcribed onto the Mohs accession log for one of eleven patients reviewed from June 2025. Refer to D5401-III. d. 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 12 days in 2025 (04/2025-08/2025) and five of five days in 2026 (01/2026-02/2026). Refer to D5473. 3. During the exit interview in the laboratory on 03/03/2026 at 1:00 p.m., the histotechnician, after a review of records, confirmed the above findings. Word Key: H&E- hematoxylin and eosin

**D5801**

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

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:  
Based on review of Mohs accession logs, Mohs maps, patient final reports, and confirmed in staff interview, the laboratory failed to ensure dermatopathology slide interpretation documentation was accurately transcribed into the electronic medical record for one of eleven patients reviewed from June 2025 and one of four patients reviewed from January 2026. Findings included: 1. Review of the laboratory's Mohs accession logs, Mohs maps and corresponding patient final reports revealed the following: 06/02/2025 Accession Number- FM25-051 Mohs accession log- number of stages: "1" Mohs Map- 1 stage Patient final report- Summary: "2 stages" 01/08/2026 Accession Number- FM25-001 Mohs accession log- number of stages: "2" Mohs Map- 2 stages Patient final report- Summary: "1 stage" The laboratory failed to

accurately transcribe the number of stages to the final reports for patients identified above. 2. During an interview in the laboratory on 03/03/2026 at 11:20 a.m., the histotechnician, after a review of records, confirmed the laboratory failed to ensure dermatopathology slide interpretation documentation was accurately transcribed into the electronic medical record for one of eleven patients reviewed from June 2025 and one of four patients reviewed from January 2026.

**D5803**

TEST REPORT  
CFR(s): 493.1291(b)

(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:  
Based on review of patient electronic records and confirmed in staff interview, the laboratory failed to ensure three of three patient results were available in the patient's chart from 02/02/2026. Findings included: 1. Review of patient electronic records from 02/02/2026, revealed the laboratory failed to ensure the documentation of the Mohs Operative Report was available in the patient chart for the following three patients: Accession Numbers: FW26-001, FW26-002, FW26-003 2. During an interview in the laboratory on 03/03/2026 at 12:11 p.m., the histotechnician, after a review of records, confirmed the laboratory failed to ensure three of three patient results were available in the patient's chart from 02/02/2026.