Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0244133	12/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dilworth Dermatology	719 East Boulevard, Charlotte, NC	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of 2024 personnel competency records, and review of 2024 patient testing logs 12/03/24, the laboratory failed to follow policy for competency assessment of testing personnel (TP) whom perform Potassium Hydroxide (KOH) testing, 7 patients were tested from 03/25/24 until date of survey 12 /03/24. Findings: Review of laboratory policy "Proficiency Testing Competency and CLIA competency assessment" revealed "CLIA guidelines require assessment of personnel competency during the first year of test performance for Moderate or High Complexity testing. Thereafter, evaluation will be performed at new start up, additionally after first 3 months, 6 months then annually....Personnel competency must be assessed by the Laboratory Director or Technical Consultant and will be an on-going process at this facility bi-annually.". Review of 2024 TP competency records for TP #2 revealed no documentation of an assessment of competency for the KOH testing performed. Review of 2024 patient testing logs for the KOH testing revealed 7 patients were tested from 03/25/24 until date of survey 12/03/24.
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 laboratory policy, absence of verification of accuracy records for the KOH testing performed and interview with HT 12/03/24, the laboratory failed to enroll in proficiency testing (PT) or perform a verification of accuracy for KOH since testing began 03/25/24, a period of approximately 9 months. Findings: Review of laboratory policies "Mycology" revealed "This lab has joined a proficiency testing program with The American Proficiency Testing Institute. Membership receipt attached. This lab will have reviews done at least bi-annually. Results will be documented in manuals....Diagnosis for fungus or dermatophytosis can be made with several different laboratory tests. 1. KOH prepared slide....". Review of laboratory records revealed no documentation the laboratory had either enrolled in a PT program or performed an alternative verification of accuracy for KOH since testing began 03/25 /24. Interview with HT at approximately 11:45 a.m. confirmed there was no documentation of enroll in a PT program or the performance of a verification of accuracy for KOH.
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: Based on review of laboratory procedures and interview with HT 12/03/24, the laboratory procedures for KOH and Mohs testing are incomplete. 1. The laboratory procedure for KOH fails to state what elements of the KOH are reported and how the elements are quantified. Findings: Review of laboratory procedure "KOH examination" revealed the procedure fails to include what elements of the KOH examination are reported (For example: yeast, parasites, fungus). The procedure also fails to include how the elements reported are quantified. (For example: few, many, present or absent). Interview with HT at approximately 1:30 p.m. confirmed the procedure failed to include what elements of the KOH examination are reported and how the elements reported are quantified. 2. The laboratory procedure "Frozen Section Procedure", for the Mohs testing performed, fails to include the mechanism used to enter results into the patients medical record. Review of laboratory procedure "Frozen Section Procedure" revealed "11. The surgeon will then read the slide and generate a pathology report.". The procedure fails to include the mechanism used to

	"generate a pathology report" and how the pathology report is entered into the patients medical record. Interview with HT at approximately 1:30 p.m. confirmed the procedure failed to include the mechanism used to enter the results into the patients medical record.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of operator's manual for the Avantik cryostat, review of laboratory policy, review of 2024 Mohs patient testing logs, review of 2024 room temperature and humidity logs, and review of 2024 Cryostat temperature logs 12/03/24, the laboratory failed to document the room temperature and humidity 4 of 50 days in which patient testing was performed. The laboratory also failed to document the temperature of the Avantik cryostat microtome/chamber for 4 of 50 days in which patient testing was performed. 1. The laboratory failed to document the room temperature and humidity 4 of 50 days in which patient testing was performed. Findings: Review of operator's manual for the Avantik cryostat revealed room temperature operating limits of 59F to 86F and a relative humidity of 60% or less. Review of laboratory policy "LABORATORY DAILY MAINTENANCE" revealed " 7. Temperature charts and logs are checked daily or whenever in use". Review of 2024 Mohs patient testing logs revealed patients were tested on 50 days from 3/25/24 until time of survey 12/03/24. Review of 2024 laboratory temperature and humidity logs revealed the following 4 days in which the temperature and humidity was not documented and patient testing was performed; 04/29/24, 05/06/24, 11/04/24, and 11 /13/24. 2. The laboratory failed to document the temperature of the Avantik cryostat microtome/chamber 4 of 50 days in which patient testing was performed. Findings: Review of operator's manual for the Avantik cryostat revealed on Page 36 "Microtome / Chamber Temperature The microtome/chamber is actively cooled and the user can adjust the temperature independently.". Review of laboratory policy "Quality Control Policies and Documentation" revealed "Cryostat:...Temperature range is -21 Celsius (C) to -30 C.". Review of 2024 Mohs patient testing logs revealed patients were tested on 50 days from 3/25/24 until time of survey 12/03/24. Review of 2024 Cryostat temperature logs revealed the following 4 days in which the temperature of the Avantik cryostat microtome/chamber was not documented and patient testing was performed; 04/29/24, 05/06/24, 11/04/24, and 11/13/24.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each

	special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory procedures, review of 2024 Mohs patient testing logs, and review of 2024 laboratory Hematoxylin and Eosin (H&E) quality control (QC) records 12/03/24, the laboratory failed to document QC of the H&E stain 10 of 50 days in which patient testing occurred. Findings: Review of laboratory procedure "Quality Assurance for Routine Stains" revealed "1. A quality control slide will be run each day the lab operates. 2. The QC (quality control) slide will be for Hematoxylin and Eosin...The lab director will determine whether the stain is acceptable for the day. Each QC will be logged on the stain QC chart....". Review of 2024 Mohs patient testing logs revealed patients were tested on 50 days from 3/25/24 until time of survey 12/03/24. Review of 2024 H&E QC records revealed no documentation of QC for the H&E stain on 10 on the following days in which patients were tested: 03/24/24, 04/22/24, 05/06/24, 06/24/24, 08/12/24, 09/09/24, 10/21/24, 11/04/24, 11/13/24, and 11/18/24.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on deficiencies cited at time of survey, review of laboratory policy, absence of quality assessment (QA) records, and phone interview with laboratory director (LD) 12/03/24, the LD failed to ensure a QA policy was established and maintained to identify failures in quality as they occur. Findings: The following deficiencies in quality were cited at time of survey: 1. Testing personnel competency assessments - (See D5209). 2. Proficiency Testing - (see D5217). 3. Temperature and humidity documentation - (See D5413). 4. Quality control documentation - (See D5601). Review of laboratory policy "QUALITY ASSURANCE" revealed "Monthly the nurse or tech will check off the Monthly Quality Assurance Checklist. This will cover the quality assessment program for procedures used in this office. This checklist is used to evaluate General Laboratory Systems, Pre-analytic Systems, Analytic Systems, and Post-analytic Systems.". The policy fails to include what specific quality assessments are performed. Review of laboratory records revealed no documentation of a "Monthly Quality Assurance Checklist" either performed or a blank copy. During exit interview phone call at approximately 3:00 p.m., the LD confirmed the QA policy was not established and/or maintained to identify failures in quality as they occur.