Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2252291	10/28/2025
Name of Provider or Supplier	**Street Address, City, State**	
Access Dermatology Clinic, Llc	1630 Nashville Pike, Suite 200, Gallatin, TN	

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
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on observation of the laboratory, a review of patient final test reports, a review of the laboratory policy and procedure manual, and staff interviews, the laboratory failed to ensure that the laboratory policies and procedures for Mohs micrographic surgical procedures were approved by the laboratory director before patient testing began on 08/07/25. The findings include: 1. Observation of the laboratory on 10/28/25 at 09:00 a.m. revealed a Leica CM1850 Cryostat (Fabr Nr. 1563/03.2000), and a Rushabh Histopro 414 Linear Stainer (SN BAL-0061347) that used Hematoxylin Stain Solution (Lot 2512301, Expiration 05/15/27) and Eosin Y Stain Solution (Lot 2508729, Expiration 04/04/27) for processing and staining tissue samples removed from patients during Mohs micrographic surgical procedures. 2. A review of patient final test reports revealed that Mohs micrographic surgical patient testing began on 08 /07/25. 3. A review of the laboratory policy and procedure manual revealed that the laboratory director failed to approve and sign the manual before patient testing began. 4. The laboratory practice manager and the Mohs technician confirmed the survey findings during an interview on 10/28/25 at 11:30 a.m. .
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 laboratory observation, a review of the manufacturer's operator's manuals, patient test reports, the laboratory environmental records, and staff interviews, the laboratory failed to document temperature and humidity readings for one of three days reviewed in August, September, and October 2025. The findings include: 1. Observation of the laboratory on 10/28/25 at 09:00 a.m. revealed a Leica CM1850 Cryostat (Fabr Nr. 1563/03.2000), and a Rushabh Histopro 414 Linear Stainer (SN BAL-0061347) that used Hematoxylin Stain Solution (Lot 2512301, Expiration 05/15 /27) and Eosin Y Stain Solution (Lot 2508729, Expiration 04/04/27) for processing and staining tissue samples from patients during Mohs micrographic surgical procedures. 2. A review of the manufacturer's operator's manuals and environmental specifications revealed the following requirements: - Leica CM1850 Cryostat, room temperature maximum 35C. Air humidity must not exceed 60%. - Rushabh Histopro 414 Linear Stainer, room temperature range: 15C to 30C. Relative humidity: 20% to 80%, non-condensing. 3. A review of the laboratory's 2025 environmental records revealed no temperature or humidity readings recorded for 09/04/25. 4. A review of randomly selected test records revealed that patient test case number M25-019 was performed on 09/04/25. 5. The laboratory practice manager and the Mohs technician confirmed the survey findings during an interview on 10/28/25 at 11:30 a.m. .
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 laboratory observation, a review of patient test records, quality control (QC) records, and staff interview, the laboratory failed to document daily Hematoxylin and Eosin (H&E) staining QC for one of three testing days reviewed in 2025. The findings include: 1. Observation of the laboratory on 10/28/25 at 09:00 a.m. revealed a Rushabh Histopro 414 Linear Stainer (SN BAL-0061347) that used Hematoxylin Stain Solution (Lot 2512301, Expiration 05/15/27) and Eosin Y Stain Solution (Lot 2508729, Expiration 04/04/27) for staining tissue samples removed from patients during Mohs micrographic surgical procedures. 2. A review of randomly selected patient test records revealed that the laboratory performed H&E staining on tissues obtained during a Mohs procedure for case number M25-019 on 09/04/25. 3. A review of the daily H&E QC log revealed no documented QC results recorded for 09 /04/25. 4. The laboratory practice manager and the Mohs technician confirmed the survey findings during an interview on 10/28/25 at 11:30 a.m. .
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 a review of the laboratory Quality Assurance (QA) policy, a lack of documentation, and staff interviews, the laboratory failed to ensure their analytic systems quality assessment program identified problems with documentation of temperature, humidity and Hematoxylin and Eosin (H&E) stain quality control (QC) for one of three months reviewed in 2025. The findings include: 1. A review of the laboratory's QA policy revealed a checklist titled "Monthly Quality Assurance Checklist", with the following review requirements. - All required temperatures were taken and recorded - All quality control/calibrations were performed and were within acceptable limits before test results were reported. 2. A review of the laboratory's QA documentation for August, September, and October revealed that the laboratory failed to document any QA review in September 2025. 3. The laboratory practice manager and the Mohs technician confirmed the survey findings during an interview on 10/28 /25 at 11:30 a.m.