

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2179501	(X3) Date Survey Completed 10/19/2022
Name of Provider or Supplier Harpeth Valley Dermatology	Street Address, City, State 990 Elliston Way Suite 101, Thompsons Station, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of procedure manual, review of testing personnel records, and interviews with the histotech and the lab director, the laboratory failed to follow its' own competency assessment policy in 2021 and 2022. The findings include: 1. Observation of the laboratory on 10/19/22 at 8 am revealed the sole histotech performing mapping and inking of tissue removed during a MOHS surgical procedure. 2. Review of the laboratory procedure manual revealed the following statement in the competency assessment policy: "All personnel will be initially evaluated within a 90 day time period of start day using the Employee Performance Review (see back of QA section). A follow up performance evaluation will be performed at 6 months, 1 year, and then yearly thereafter." 3. Review of personnel records revealed no documentation of training or competency assessment for the histotech. 4. Interview with the histotech on 10/19/22 at 10:00 am revealed that the histotech began testing approximately August 2021. 5. Interview with the lab director on 10/19/22 at 11:15 am confirmed the laboratory failed to follow its' own policy for assessing testing personnel competency in 2021 and 2022 when it did not have documentation of competency assessments for the histotech.</p>
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>

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, record review, and interview with the histotech, the laboratory failed to verify the accuracy of its' histopathology procedures twice a year in 2020 and 2021. The findings include: 1. Observation of the laboratory on 10/19/22 at 8:00 am revealed the laboratory performs patient testing for histopathology on tissue removed during MOHS surgical procedure. 2. Review of records for peer comparison used for verification of accuracy for histopathology procedures revealed the records did not include twice a year verification of accuracy in 2020 or 2021. 3. Interview with the histotech on 10/19/22 at 10:30 am confirmed the laboratory failed to verify the accuracy of its' histopathology procedures twice a year in 2020 and 2021.

D5291

GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:
Based on review of the laboratory procedure manual, lack of documentation and interview with the lab director, the laboratory failed to follow its' own quality assessment procedures in 2020, 2021 and 2022. The findings include: 1. Review of the laboratory's quality assessment procedure revealed that the laboratory would perform quarterly quality assessments. 2. No documentation of quarterly quality assessment activities was available for surveyor review. 3. Interview with the lab director on 10/19/22 at 11:00 am confirmed the laboratory failed to follow its' own quality assessment procedures in 2020, 2021, and 2022.

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 environmental records and interview with the lab director, the laboratory failed to define criteria for temperature and humidity in 2020, 2021, and 2022. The findings include: 1. Review of the laboratory environmental records revealed the laboratory monitors room temperature and humidity. The acceptable range for room temperature and humidity were not defined on the monitoring log or in the procedure manual. 2. Interview with the lab director on 10/19/22 at 11:00 confirmed the laboratory failed to define the criteria for acceptable ranges for

	<p>temperature and humidity for storage of reagents and patient slides in 2020, 2021, and 2022.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the histotech, the laboratory failed to ensure the laboratory did not use expired tissue dye in 2022. The findings include: 1. Observation of the laboratory on 10/19/22 at 8:00 am revealed tissue dyes on the counter used for performing inking of tissue removed during MOHS surgical procedures. All five of the dyes were expired. The dates of expiration ranged from 02/28/22 to 05/31/22. 2. Interview with the histotech on 10/19/22 at 8:30 am confirmed five of five dyes used for performing inking of tissue were expired on the date of the survey (10/19/22).</p>
<p>D5609</p>	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, lack of documentation, review of patient records, and interview with the lab director, the laboratory failed to maintain quality control records that included lot numbers, date opened, expiration dates, and quality assessment when new reagents were opened in 2020, 2021, and 2022. 1. Observation of the laboratory on 10/19/22 at 8 am revealed multiple reagents, chemicals, stains and dyes in use for performing patient tissue processing, staining and inking on tissue removed during MOHS surgical procedure. 2. There was no historic documentation to include reagent logs for chemical, reagent, stains or dyes or documentation of quality control/quality assessment when new reagents were opened. 3. Review of patient accessioning logs revealed the first patient procedure was performed on 09/16/20-- case number = TS20-001. 4. Interview with the histotech 10/19/22 at 8:30 am confirmed the laboratory failed to keep records of reagent lot numbers and documentation of quality control/quality assessment when new reagents were opened in 2020, 2021 and 2022.</p>