

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D2138121	<b>(X3) Date Survey Completed</b> 01/10/2023
<b>Name of Provider or Supplier</b> Levy Dermatology, Pc	<b>Street Address, City, State</b> 1125 Schilling Blvd East Suite 105, Collierville, TN	
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>D5217</b>	<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> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory records and patient test records, and interview with the office manager/histotech the laboratory failed to verify the accuracy of its' histopathology procedures twice a year 2022. The findings include: 1. Observation of the laboratory on 01/10/23 at 8:30 am revealed equipment in use for performing processing and staining of tissue removed during Mohs surgery, as well a microscope used by the dermatologist for interpretation of histopathology slides. 2. Review of laboratory records revealed verification of accuracy was not performed twice per year in 2022. 3. Review of patient records revealed testing for histopathology performed on patient case #M22-016 performed on 01/25/22 and patient case #M22-151 performed on 09/02/22. Patient accessioning logs revealed that approximately 181 patients had histopathology procedures performed in 2022. 4. Interview with the office manager/histotech on 01/10/23 at 11:45 am confirmed the laboratory did not perform twice a year verification of histopathology procedures in 2022 with patient testing performed.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p>

This STANDARD is not met as evidenced by:  
Based on review of the laboratory procedure manual, the laboratory reagent log, and interview with the office manager/histotech, the laboratory failed to follow the procedure for recording stain reactivity when opening new reagents in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory procedure titled "Histopathology - Mohs Surgery" revealed the following under section 4.2.3: Stains, reagent and dyes are logged and the stain reaction is recorded. 2. Review of the laboratory reagent log revealed no documentation of stain reaction/acceptability when reagents were opened from 08/16/21 until the date of the survey on 01/05/23. 3. Interview with the office manager/histotech on 01/10/23 at 11:45 am confirmed the laboratory failed to follow its' own procedure for recording stain reactivity when new reagents/stains were opened in 2021, 2022 and 2023.

**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 observation of the laboratory, review of the manufacturer's operating manuals, environmental records, annual test volumes and interview with the office manager/histotech, the laboratory failed to monitor room humidity for the Avantik QS12 cryostat and the Linistat automated stainer in 2020, 2021, and 2022. The findings include: 1. Observation of the laboratory on 01/10/23 at 8:30 am revealed the Advantik QS12 cryostat (serial #S16099837) and the Thermo Scientific Linistat automated stainer (serial #LS5167A1704) in use for processing tissues removed during Mohs surgical procedure in preparation for histopathology procedures. 2. Review of the manufacturer's operating manuals revealed the following: Avantik QS 12 cryostat environmental conditions require a maximum relative humidity of 60%. Linistat automated stainer environmental conditions require a maximum relative humidity of 80% 3. Review of the laboratory's environmental records for the months of 07/2020, 02/2021, 09/2021, 01/2022, 09/2022, and 01/2023 revealed no monitoring of room humidity. 4. Review of the laboratory annual test volume estimates revealed approximately 500 patients tissues were processed during the period the humidity was not being monitored. 5. Interview with the office manager/histotech on 01/10/23 at 11: 45 am confirmed the laboratory did not monitor room humidity for the use of the cryostat and Linistat automated stainer in 2020, 2021, 2022 and 2023.