

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  51D0692280	<b>(X3) Date Survey Completed</b>  12/13/2018
<b>Name of Provider or Supplier</b>  Ganzer-Hahn Dermatology Associates PLLC	<b>Street Address, City, State</b>  300 Wharton Circle Suite 180, Triadelphia, WV	
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>D3001</b>	<p><b>FACILITIES</b> CFR(s): 493.1101(a)(1)</p> <p>The laboratory must be constructed, arranged, and maintained to ensure the space, ventilation, and utilities necessary for conducting all phases of the testing process.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance records and observation and interview with testing personnel, the laboratory failed to document certification and maintenance of the fume hood in the histology lab for 2017 and 2018. Findings: 1. There was no evidence found of inspection and certification of the fume hood in the histology lab. 2. There was no sticker or other evidence of service, maintenance, or certification of the histology hood. 3. On 12/13/18 at approximately 2:20 PM, TP1 confirmed that certification and maintenance of the histology hood had not been performed.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's temperature records for 2017 and 2018 and</p>

interview with testing personnel, the laboratory failed to verify calibration of the thermometers in the histology lab and in the Cryostat instrument. Findings: 1. Review of the laboratory's maintenance records identified no documentation of thermometer calibration. 2. On 12/13/18 at approximately 2:30 PM, Testing Personnel #1 (TP1) confirmed that the thermometers are not certified. TP1 also stated that the thermometer in the Cryostat was supplied by the manufacturer or distributor without evidence of calibration.

**D5433**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's maintenance records for 2017 and 2018, observation and interview with testing personnel, the laboratory failed to document preventive maintenance records for the histology microscope. Findings: 1. No documentation of microscope service or maintenance (preventive or unscheduled) was found for the histology microscope. 2. The histology microscope did not have a sticker documenting the last maintenance performed. 3. On 12/13/18 at approximately 11:45 AM, TP1 confirmed that the laboratory did not have documentation of microscope service or maintenance contracts.

**D5435**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(b)(2)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's procedure manual and maintenance records for 2017 and 2018, observation and interview with testing personnel, the laboratory failed to properly monitor the temperatures in the Mohs surgery testing laboratory. Findings: 1. During the laboratory tour, there was no thermometer present in the Mohs laboratory. 2. There was no policy found for monitoring the room or cryostat instrument temperature in the Mohs laboratory. 3. On 12/13/18 at approximately 2:30 PM, Testing Personnel #2 (TP2) confirmed that there is no external thermometer in the Mohs lab, and stated that the wall thermostat was used to monitor the temperature in the room.

**D6108**

**LABORATORY TECHNICAL SUPERVISOR**

CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's personnel records and interview with testing personnel, the laboratory failed to produce sufficient evidence of meeting the qualifications for high complexity technical supervisor based on the standard 493.1449. Findings: 1. The laboratory failed to provide the necessary documentation to prove the technical supervisor designated on the 209 Form is qualified to be the technical supervisor, based on 42 CFR 493.1449. 2. On 12/13/18 at approximately 1:30 PM, TP1 was unable to locate proof of board certification for the listed technical supervisor. 3. On 12/13/18 at approximately 1:40 PM, a phone call was made to the laboratory director by TP1, who confirmed that the listed technical supervisor does not possess a board certification or proof of board eligibility.