

|  |   |   |
|--|---|---|
| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>37D2023407          | <b>(X3) Date Survey Completed</b><br><br>09/27/2021 |
| <b>Name of Provider or Supplier</b><br><br>Ssm Health Dermatology  | <b>Street Address, City, State</b><br><br>330 South 5th Street, Suite 400, Enid, OK |   |
| 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>D0000</b>              | The recertification survey was performed on 09/27/2021. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the Mohs technician at the conclusion of the survey.  |
| <b>D5429</b>              | <p>MAINTENANCE AND FUNCTION CHECKS<br/>CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:<br/>Based on a review of records, manufacturer's instructions, and interview with the Mohs technician, the laboratory failed to perform maintenance procedures as required by the manufacturer of the cryostat for 20 of 20 months. Findings include: (1) On 09/27/2021 at 11:00 am, the Mohs technician stated to the surveyor Mohs surgical specimens and skin biopsies were processed using the Avantik QS 11 Cryostat ; (2) The surveyor reviewed the manufacturer's maintenance instructions contained in the operator's manual for the cryostat in section 5-1 titled, "Shutting-Off for Cleaning" which stated, "Cleaning, care and decontamination of the cryostat depends on how frequently the instrument is used. However, it is recommended to shut the instrument off every 6 - 8 weeks". (3) Maintenance records were reviewed by the surveyor for 20 months (January 2020 through August 2021). The shutting-off maintenance had not been documented as performed during the review period; (4) The surveyor reviewed the records with the Mohs technician who stated on 09/27/2021 at 12:00 pm there was no evidence the above maintenance had been performed as required.</p> |