

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1099774	(X3) Date Survey Completed 08/11/2021
Name of Provider or Supplier Surgical Dermatology Associates	Street Address, City, State 4851 South I-35, Suite 101, Corinth, TX	
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
D0000	A recertification survey was conducted on 08/11/2021. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. Standard level deficiencies were cited.
D3013	<p>FACILITIES CFR(s): 493.1101(e)</p> <p>Records and, as applicable, slides, blocks, and tissues must be maintained and stored under conditions that ensure proper preservation.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of temperature/humidity logs, and in interview with staff, the laboratory failed to have a system in place to ensure slides were maintained under proper preservation conditions for 2019, 2020, and 2021. Findings included: 1. During a tour of the clinic on 08/11/2021 at 2:45 pm, filing cabinets with slides from previous Mohs cases were observed to be stored in a closed room. There was no mechanism observed to monitor storage conditions in the room. 2. Review of temperature/humidity logs from 2019 through 2021 did not include documentation of the room in which slides were stored to ensure proper preservation of those conditions. 3. During an interview on 08/11/2021 at 3:45 pm, the laboratory manager confirmed the room with slides was not monitored or documented for storage conditions.</p>
D5401	<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:

I. Based on review of the laboratory's procedure manual, cryostat preventative maintenance (PM) records, and in interview with staff, the laboratory failed to follow their own written policy for ensuring cryostat PM was performed and documented every 6 months for 2020 and 2021. Findings included: 1. Review of the laboratory's "Quality Control Policies and Documentation" stated, "Cryostat: 10. Preventative maintenance and grounding checks are done 6 months." 2. Cryostat records revealed the laboratory had documentation of PM for two (2) Leica CM1510S (serial numbers: 6198 and 6258) completed: 07/30/2020 and 07/20/2021. The laboratory did not have PM documentation for 01/2020 and 01/2021 for the cryostats (6 months), per their written policy. 3. During an interview on 08/11/2021 at 3:50 pm, the laboratory manager reviewed and confirmed the above findings. II. Based on review of the laboratory's procedure manual, Linistain Stainer reagent logs, and in interview with staff, the laboratory failed to follow their own written policy for changing reagents on the Linistain Stainer (Hematoxylin, Eosin and Xylene) for 7 of 7 months reviewed from 10/2020 through 05/2021. Findings included: 1. Review of the laboratory's "Hematoxylin and Eosin Stain" policy for reagent schedule stated, "Changed Weekly: Eosin and Xylene substitute; Change Monthly: Hematoxylin...This Protocol implemented on 08/24/2015." The "Quality Control Record for Mohs Lab: Linistain STAINER" stated, "Hematoxylin and Eosin are changed monthly...(Updated 10/19)." The laboratory protocols were not consistent with one another. 2. Review of the "Quality Control Record for Mohs Lab: Linistain STAINER" records from 10/2020 through 05/2021 revealed the following: 11/2020, 12/2020, 01/2021, 02/2021, 03/2021, 04/2021, and 05/2021 did not have documentation ("c - changed") that the Hematoxylin was changed monthly per the laboratory's protocol. The last documentation that Hematoxylin was changed was on 10/19/2020. 11/2020, 12/2020, 01/2021, 02/2021, 03/2021, 04/2021, and 05/2021 did not have documentation ("c - changed") that the Eosin and Xylene were changed weekly per the laboratory's protocol ("Hematoxylin and Eosin Stain"). The last documentation that Eosin and Xylene were changed was on 10/19/2020. 3. During an interview on 08/11/2021 at 3:50 pm, the laboratory manager reviewed the above findings and confirmed when she changed the reagents she did not indicate that on the "Quality Control Record for Mohs Lab: Linistain STAINER" form.