

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0867957	(X3) Date Survey Completed 03/15/2021
Name of Provider or Supplier Siu Clinics Lab - Dermatology	Street Address, City, State 751 N Rutledge St, Rm 2300, Springfield, IL	
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
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, record review, and an interview with the laboratory director (LD), the laboratory failed to establish and observe safety procedures to ensure protection from chemical hazards, affecting 2 TP (TP7 and TP8). Findings: 1. On 03/15/2021 at 10:10 AM during a tour of the Mohs laboratory the surveyor observed; * 1 (one) table top Auto Stainer. * Under the autostainer in the cabinets were stored the following chemicals: Methanol, Alcohol, Xylene, Eosin, and Hematoxylin. *The laboratory failed to have a safety cabinet for flammable chemicals. 2. The histopathology staining procedures, employee files, and the material safety data sheets (MSDS) for the above chemicals were reviewed. 3. The Auto Stainer was programmed to perform Hematoxylin and Eosin (H & E) staining for tissue received from Mohs surgery patients. 4. Review of the MSDS for the chemicals used in the H&E staining procedure revealed the Eosin, Xylene, Methanol, 80-100% Alcohol are flammable liquids and produce vapors. 5. The employee files showed 2 TP (TP7 and TP8) performing the H & E staining procedures. 6. The laboratory failed to ensure the safety of 2 out of 2 TP by failing to provide proper storage of flammable liquids used to stain Histopathology slides. 7. On a Recertification survey conducted on 03/15/2021 at 2:00 PM, the LD confirmed the above findings.</p>
D5609	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease</p>

nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the laboratory director (LD), the laboratory failed to document all control procedures performed, as specified in the specialty of Histopathology for 131 patients. Findings Include: 1. The laboratory manual, Daily Work logs, and quality control (QC) sheets were reviewed. 2. The patients for Mohs procedures are documented on the Daily Work logs. The following dates were selected for QC record review: *10/08-11/2018; *02/01-05/2019; *06/11-14/2019; *11/25-26/2019; *03/02-05/2020; *07/21-27/2020; *12/21/2020; and 02/01-04/2021. 3. The QC worksheets showed the laboratory failed to document the following information on the above (finding #2) selected test dates: *The lot numbers and expiration dates of the reagents and stains used in the performance of the Hematoxylin and Eosin (H & E) tissue staining procedure; and *Record the date prepared and/or opened when reagents and stains are put into use. 4. Further review of the Daily work logs revealed the laboratory processed 131 patients' tissue during the selected dates. 5. The laboratory manual and QC worksheet failed to include a written method that would ensure the required information for its reagents and stains are documented each day of tissue processing and staining. 6. On a Recertification survey conducted on 03/15/2021 at 2:10 PM, the LD confirmed the above findings.