

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2063006	(X3) Date Survey Completed 09/23/2022
Name of Provider or Supplier Stillwater Histology, Llc	Street Address, City, State 1201 S Adams, Stillwater, OK	
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	The recertification survey was performed on 09/23/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the administrative laboratory director and histotechnician at the conclusion of the survey.
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the procedure manual and interview with the administrative laboratory director and histotechnician, the laboratory failed to ensure written policies and procedures had been approved, signed, and dated by the current laboratory director. Findings include: (1) On 09/23/2022 at 10:15 am, the histotechnician stated the laboratory performed gross examinations of gastric and digestive tissues; (2) A review of the manual titled, "Stillwater Histology, LLC Procedure Manual" revealed no evidence the manual had been approved signed, and dated by the current laboratory director; (3) The manual was reviewed with the administrative laboratory director and histotechnician. Both stated on 09/23/2022 at 10:55 am, the manual had not been signed and dated by the current laboratory director.</p>
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate</p>

results.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the administrative laboratory director and histotechnician, the laboratory director failed to ensure that a person performing high complexity testing had the appropriate training for one of one testing person.

Findings include: (1) A review of personnel records and interview with the histotechnician on 09/23/2022 at 10:50 am revealed the histotechnician was hired to perform grossing procedures on 06/06/2022. Documentation to prove this person had been initially trained could not be located; (2) The findings were reviewed with the administrative laboratory director and histotechnician. Both stated on 09/23/2022 at 11:05 am, documentation of initial training was not available.