

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2007541	(X3) Date Survey Completed 12/12/2022
Name of Provider or Supplier Histopath Inc	Street Address, City, State 6130 Parkway Drive, Corpus Christi, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation and confirmed in interview with laboratory personnel, the laboratory failed to ensure 1 of 7 expired inks used for grossing was not available for patient use on December 12, 2022, the day of the inspection. The findings included: 1. Surveyor observation in the Pathology Frozen Room in the cabinet above the microscope on December 12, 2022 at 10:30 hours found the following expired ink was available for use in specimen grossing: Tissue Marking Dye (Violet) Lot Number: 9205 Expiration Date: 07-31-2021 (499 days past its expiration date) 2. Interview with testing personnel #2 (as listed on Form CMS 209) at 10:30 hours in the Pathology Frozen Room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services</p>
D5803	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policies, review of patient records, and confirmed in interview of laboratory personnel, the laboratory failed to follow its own policy to ensure 7 of 15 frozen section results reviewed from October</p>

2021, November 2021, and December 2022 were documented on the requisition slip. The findings included: 1. Surveyor observation on December 12, 2022 in the conference room found 8 frozen section requisitions from December 2022 that had hand written grossing results on the back of the requisitions. 2. Review of the laboratory's "Frozen Section" policy approved by the laboratory director under, "Additional Information," it stated, "...Frozen section diagnosis are made a permanent record in the surgical pathology report and it is documented on the requisition slip." 3. Random review of patient records from October 2021, November 2021, and December 2022 found no record of a frozen section requisition that had frozen section results written on the back. Further, the backs of the requisitions were not scanned electronically into the patient record. The following patient cases had no documentation of frozen section diagnoses on a requisition slip: October 2021: ST-21-03573 ST-21-03601 ST-21-03607 ST-21-03615 November 2021: ST-21-03741 ST-21-03805 ST-21-03905 4. The findings were confirmed in interview with the Practice Manager and Testing Personnel #2 (as listed on Form CMS 209) on December 12, 2022 at 13:30 hours in the conference room. Key: CMS - Centers for Medicare and Medicaid Services