

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0482320	(X3) Date Survey Completed 11/30/2021
Name of Provider or Supplier Pathology Services Of Texarkana	Street Address, City, State 1002 Texas Blvd Suite 500, Texarkana, 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 of facility personnel, the laboratory failed to ensure expired items were not available for testing. The findings included: 1. Surveyor observation made on November 30, 2021 at 09:30 hours during the initial tour of the laboratory found the following expired items: a. Hema-Diff Xanthene (1 bottle) Lot 098285 Expiration date: 10-31-2021 b. Isopropyl Alcohol (4 gallons) Lot 088926 Expiration date: 09-03-2021 c. Isopropyl Alcohol (1 gallon) Lot 067176 Expiration date: 06-30-2021 d. Methanol (3 gallons) Lot 54887 Expiration date: 10-31-2021 2. An interview with cytotechnologist 1 (as listed on Form CMS-209) on November 30, 2021 at 10:20 hours in the laboratory confirmed the findings. She agreed the items were expired and said most of them were not in use.</p>
D5601	<p>HISTOPATHOLOGY CFR(s): 493.1273(a)(f)</p> <p>(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory quality control records, review of patient reports, and confirmed in interview, the laboratory failed to document the stain quality of known positive and negative reactivity with each patient slide or group of patient slides when assessing the professional component of ten of ten immunohistochemical stains (IHC) reviewed: Ki-67 CKC S-100 SOX-10 CK7 P53 P504s P16 P63 CK 5/6 The findings included: 1. Random review of patient records from November 2021 found four of eleven reports with professional interpretation for the following special immunohistochemical stains (IHC): Ki-67 CKC S-100 SOX-10 CK7 P53 P504s P16 P63 CK 5/6 2. Review of the quality control records from November 1, 2021 to November 30, 2021 found no documentation of the stain quality of known negative reactivity of the above stains. 3. An interview with histotechnologist 1 (as listed on Form CMS-209) on November 30, 2021 at 11:15 hours in the office confirmed the findings. She confirmed that the laboratory only documents the positive control.