

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0675687	<b>(X3) Date Survey Completed</b> 10/25/2021
<b>Name of Provider or Supplier</b> Lufkin Pathology Associates	<b>Street Address, City, State</b> 700 Gaslight Blvd, Lufkin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5417</b>	<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: Observations made during the tour of the facility, and review of manufacturer's instructions, found that the laboratory failed to ensure that 33 of 33 expired formalin vials were not available for use in patient testing. The findings included: 1. Observations made during the tour of the laboratory conducted October 25, 2021 at 1410 hours found expired formalin containers on the cabinet, and on the floor of the laboratory's grossing area. 2. Review of the manufacturer's instructions on the package labeling found the following Formalin solutions were expired: BioReference Laboratory Formalin container Lot 2105 expiration 05/20216; 9 vials. StatLab Medical Products Formalin Solution 10% Neutral Buffered pH 7.0, Lot 41700-00 expiration 02/2009; 24 vials. 3. During an interview of the Laboratory Director conducted on October 25, 2021 at 1450 hours in her office, it was stated, "They rarely give out formalin to offices that need some, but not those since they are expired." When asked where the non-expired formalin was kept it was stated that she didn't know.</p>
<b>D6127</b>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.</p>

This STANDARD is not met as evidenced by:  
Based on review of testing personnel files, and interview of facility personnel, the Technical Supervisor failed to evaluate and document personnel competency for the individuals responsible for high complexity testing in 2019 and 2020 for two of two testing personnel (TP) performing histopathology and cytology procedures. The findings included: 1. Review of personnel files found no records of competency assessment performed for TP2, and TP3 who were performing high complexity histopathology and cytology procedures during 2019 and 2020. 2. Interview of the Technical Supervisor conducted on October 25, 2021 at 1458 hours, confirmed there were no competency assessments available for review and that she 'was always told that MD's don't need to have one.'. Key: MD's - Medical Doctors