

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0483901	(X3) Date Survey Completed 10/28/2021
Name of Provider or Supplier Malladi & Reddy Lab	Street Address, City, State 319 Gaslight Boulevard, Lufkin, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory test list and staff interview, it was revealed the laboratory failed to have documentation of verifying the accuracy of all stains used at least twice annually in 2019 and 2020. The findings included: 1. A review of the laboratory test list revealed the laboratory performed the following stains in 2019: a) Giemsa stain b) PAS stain- Periodic acid-Schiff 2. A review of the laboratory test list revealed the laboratory performed the following stains in 2020: a) Giemsa stain 3. The laboratory was asked to provide documentation of performing the twice annual accuracy assessments for each of the special stains in 2019 and 2020. No documentation was provided. 4. An interview with the technical supervisor and histotechnologist on 10-28-2021 in the laboratory confirmed the findings.</p>
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 that expired items were not available for patient testing. The findings included: 1. Surveyor observation made on October 28, 2021 at 09:10</p>

hours in the laboratory found the following expired items: Black Tissue Marking Lot #066828 Expiration date: 05-2020 Black Tissue marking Lot #066597 Expiration date: 05-2020 2. Interview with the Laboratory Director and Histotechnologist on October 28, 2021 at 09:13 hours in the laboratory confirmed the findings. They agreed the items were expired.