Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0675687	09/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lufkin Pathology Associates	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An onsite survey conducted 09/20/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of laboratory policy, laboratory documents, the Centers for Medicaid and Medicare (CMS) form 116, and confirmed in an interview, the laboratory failed to have a policy that included step-by-step instructions for the determination of acceptable quality control (QC) stain characteristics for eight of eight stains used in histopathology and cytology since it was put into place in 1999. The

	findings include: 1. Review of the laboratory document titled "Technical Quality Review" had the letter 'G' listed in a column under the title 'Pathology, H&E Quality". In the front of the binder, written in sharpie on the plastic pocket, had the following key: "G = good A = adequate U = unsatisfactory" A review of the laboratory policy titled "Special Stains", revised in 1999, listed the following stains with their control tissues: Stains Control Tissue 1. Mucicarmine Small Intestine 2. GMS Histoplasmosis 3. Acid Fast Lungs 4. PAS Kidneys 5. Alcian Blue Mesothelium 6. Trichrome Uterus 7. Giemsa Stomach/Bone Marrow Surveyor queried the laboratory director for policy for the determination of acceptable QC stain characteristics for the above stains, and none was provided. 2. Review of the CMS form 116, section VII "Non-Waived Testing" had the annual test volume for the specialty "Pathology" as 1,000. 3. In an interview on 9/20/2022 at 11:20, in the laboratory director's office, the laboratory director confirmed that the laboratory policy did not include information for the determination of acceptable QC stain characteristics.