

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0675687	(X3) Date Survey Completed 01/10/2024
Name of Provider or Supplier Lufkin Pathology Associates	Street Address, City, State 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of competency assessment records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish and follow written policies and procedures to assess the competency of the Technical Supervisor. The laboratory failed to assess the competency for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the process to assess the competency of the Technical Supervisor. 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for one of one Technical Supervisors in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Technical Supervisors include: - The Laboratory Director/Technical Supervisor 3. During an interview on January 8, 2024 at 3:30 PM these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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</p>

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 review of seven laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's step-by-step process for reporting final non-gynecologic test results. 2. During an interview on January 10, 2024 at 10:00 AM, these findings were confirmed by the Laboratory Director/Technical Supervisor.

D5407

PROCEDURE MANUAL
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:
Based on review of seven laboratory policies and procedures and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to ensure that seven of seven written procedures were approved, signed and dated by the Laboratory Director. Findings include: 1. The Laboratory Director failed to sign and date seven of seven laboratory procedures. Procedures include: - SPECIMEN RECEIVING - SPECIMEN HANDLING - MONITORING OF EXPIRED REAGENTS - PROCEDURE FOR ASSESSING ADEQUACY OF STAINS - PERSONNEL POLICIES - JOB DESCRIPTIONS - QUALITY ASSURANCE 2. During an interview on January 8, 2024 at 3:30 PM, these findings were confirmed by the Laboratory Director/Technical Supervisor.

D5655

CYTOLOGY
CFR(s): 493.1274(e)(4)

(e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, non-gynecologic cytology slide preparations, corresponding final test reports and interview with the Laboratory

	<p>Director/Technical Supervisor, the laboratory failed to establish and follow written policies and procedures to ensure unsatisfactory non-gynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory non-gynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. During an interview on January 8, 2024 at 3:30 PM these findings were confirmed by the Laboratory Director/Technical Supervisor.</p>
D9999	<p>By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.</p>