

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0482320	<b>(X3) Date Survey Completed</b> 10/25/2022
<b>Name of Provider or Supplier</b> Pathology Services Of Texarkana	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite survey conducted 10/25/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5621</b>	<p><b>CYTOLOGY</b> CFR(s): 493.1274(c)(1)</p> <p>(c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c) (1) A review of slides from at least 10 percent of the gynecologic cases interpreted by individuals qualified under 493.1469 or 493.1483, to be negative for epithelial cell abnormalities and other malignant neoplasms (as defined in paragraph (e)(1) of this section). (c)(1)(i) The review must be performed by an individual who meets one of the following qualifications: (c)(1)(i)(A) A technical supervisor qualified under 493.1449(b) or (k). (c)(1)(i)(B) A cytology general supervisor qualified under 493.1469. (c)(1)(i)(C) A cytotechnologist qualified under 493.1483 who has the experience specified in 493.1469(b)(2). (c)(1)(ii) Cases must be randomly selected from the total caseload and include negatives and those from patients or groups of patients that are identified as having a higher than average probability of developing cervical cancer based on available patient information. (c)(1)(iii) The review of those cases selected must be completed before reporting patient results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS) personnel form 209, laboratory workload reports, laboratory documents, and confirmed in interview, the laboratory failed to include a 10% negative rescreen for one of two cytotechnologists performing gynecologic cytology interpretations from April to September 2022. The findings include: 1. Review of the CMS personnel form 209 had the following testing persons (TP) qualified to perform gynecologic cytology (CT) screenings: CT/TP 1 CT/TP 2 2. Review of the laboratory policy titled "Quality</p>

Control Negative Case Review Procedure" stated the following: "Upon completion of a batch cases, the cytotechnologist will have a minimum of 10% of negative cases pulled." 3. Review of laboratory documents from April to September 2022 did not include a 10% negative review, before patient test results are released, for CT/TP 2. Surveyor queried on 10/25/2022 at 10:50 in the laboratory office for documentation of a negative rescreen review for CT/TP 2, and none was provided. 4. Review of workload reports for CT/TP 2 had the following 124 total negative cases read from April to September 2022: Month : Negative Cases April: 26 May: 15 June: 14 July: 42 August: 21 September: 6 5. In an interview on 10/25/2022 at 11:00, in the office, the laboratory manager and CT/TP1 confirmed that a 10% negative rescreen for CT/TP 2 had not been performed.