

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D2033989	(X3) Date Survey Completed 06/07/2023
Name of Provider or Supplier Pathology Services For Jefferson Regional Mc	Street Address, City, State 1600 West 40th Avenue, Pine Bluff, AR	
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
D5619	<p>CYTOLOGY CFR(s): 493.1274(b)(3)</p> <p>(b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, observation and interviews, the laboratory failed to establish written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining in 2021, 2022 and to the date of the survey in 2023. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for identifying nongynecologic specimens with a high potential for cross-contamination and staining them separately from other nongynecologic specimens and filtering or changing the stains following staining. 2. During an observation of nongynecologic specimen staining on June 6, 2023 at 3:00 PM the Cytology Supervisor stated there were separate staining containers inserted into the automated stainer specifically for nongynecologic specimens but there was no procedure or method used to prevent cross-contamination between these specimens which were stained together. 3. During an interview on June 7, 2023 at 11:10 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor #1.</p>
D5655	<p>CYTOLOGY CFR(s): 493.1274(e)(4)</p> <p>(e) Slide examination and reporting. The laboratory must establish and follow written</p>

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 and interview with the Laboratory Director/Technical Supervisor #1, the laboratory failed to establish written policies and procedures to ensure unsatisfactory 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 specifying criteria that ensured unsatisfactory slide preparations were identified and reported as unsatisfactory for evaluation. 2. During an interview on June 7, 2023 at 11:10 AM, these findings were confirmed with the Laboratory Director/Technical Supervisor #1.

D6115

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(2)

The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

This STANDARD is not met as evidenced by:

Based on microscopic review of 357 negative gynecologic cytology cases/slides from January 5, 2023 through February 21, 2023 and confirmation by Technical Supervisor #2 on June 6 and 7, 2023 the Technical Supervisor failed to verify the accuracy of three gynecologic cytology tests. 1. G-23-00143 1/23/2023 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR #2 DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion 2. G-23-00402 2/16/2023 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Atypical Glandular Cells TECHNICAL SUPERVISOR #2 DIAGNOSIS: Atypical Glandular Cells 3. G-23-00438 2/21/2023 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion or Malignancy SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion TECHNICAL SUPERVISOR #2 DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion

D9999

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