

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0947936	<b>(X3) Date Survey Completed</b>  03/29/2023
<b>Name of Provider or Supplier</b>  Advanced Pathology Llp DbA	<b>Street Address, City, State</b>  801 Clarksville Street, Suite C, Paris, 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>D5625</b>	<p>CYTOLOGY CFR(s): 493.1274(c)(3)</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) (3) For each patient with a current HSIL, adenocarcinoma, or other malignant neoplasm, laboratory review of all normal or negative gynecologic specimens received within the previous 5 years, if available in the laboratory (either on-site or in storage). If significant discrepancies are found that will affect current patient care, the laboratory must notify the patient's physician and issue an amended report.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, microscopic review of gynecologic specimen slides, corresponding laboratory records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to follow written policies and procedures to identify one of seven previous negative gynecologic cases as having a more significant lesion. Findings include: 1. The laboratory failed to follow the procedure titled GYNECOLOGIC RETROSPECTIVE SLIDE REVIEW which stated: "When a pap smear or a gyn histology is diagnosed as being HSIL, AIS, adenocarcinoma, or other malignant neoplasm, the laboratory will review all previous negative paps available in the laboratory within the previous 5 years." 2. The Survey Team reviewed seven previous negative gynecologic cases from six current cases of High Grade Squamous Intraepithelial Lesion (HSIL) from July 2021 through August 2022. a. On March 28, 2023 the Survey Team identified and the Laboratory Director /Technical Supervisor confirmed that the laboratory failed to identify one of seven prior negative gynecologic cases as having a more significant lesion than was originally reported. Prior negative case includes: - GC20-1419 3. During an interview on March 28, 2023 at 10:50 AM, the Laboratory Director/Technical Supervisor confirmed these findings.</p>

**D5629**

**CYTOLOGY**

CFR(s): 493.1274(c)(5)

(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) (5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, statistical records and interview with the Laboratory Director/Technical Supervisor, the laboratory failed to follow written policies and procedures for the evaluation and comparison of one of six statistics. The laboratory failed to document one of six required annual statistics for 2021 and 2022. Findings include: 1. The laboratory failed to follow the written procedure ANNUAL STATISTICAL REPORT which stated: "An annual statistical report will be prepared to include the following information: - Number of non-gyn cases reported by collection method and body site." 2. The Survey Team requested and the laboratory failed to provide one of six required annual statistics for 2021 and 2022. Annual statistic includes: - Specimens processed by specimen type. 3. During an interview on March 28, 2023 at 10:50 AM, the Laboratory Director/Technical Supervisor confirmed these findings.

**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 the microscopic review of 310/312 random negative gynecologic cases /slides and the corresponding final test reports from January and February 2023 and confirmation by the Technical Supervisor on March 29, 2023, the Technical Supervisor failed to verify the accuracy of two gynecologic cytology tests. Cases include: 1. GC23-00164 1/30/2023 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation due to Obscuring Inflammation TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory/Inflammation 2, GC23-00169 1/30/2023 ThinPrep Pap Test LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion SURVEY TEAM DIAGNOSIS: Unsatisfactory for Evaluation due to Limited Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory

**D9999**

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