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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D0947936 | (X3) Date Survey Completed 07/08/2024 |
| Name of Provider or Supplier Advanced Pathology Llp DbA | Street Address, City, State 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. | | |

| (X4) ID Prefix Tag | Summary Statement of Deficiencies |
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| D0000 | An onsite survey conducted 07/08/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories. |
| D5629 | <p>CYTOLOGY CFR(s): 493.1274(c)(5)</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) (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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory annual statistics, laboratory documents, and confirmed in interview, the laboratory failed to include the annual statistical laboratory evaluation for patient cases reported by diagnosis, including the number reported as unsatisfactory for diagnostic interpretation, for 517 non-gynecological cases evaluated in 2023. The findings included: 1. Review of the laboratory form titled "Annual Statistical Evaluation of Cases by Specimen Type" for 2023 included the following information: "Non-Gynecological Cytology Cases: 527" Surveyor asked for the statistical evaluation for non-gynecological patient cases reported by diagnosis at 12:30 hours, in the laboratory, and none was provided. 2. In an interview on 7/8/2024 at 12:45 hours, in the conference room, the laboratory director confirmed that the annual</p> |

statistic for non-gynecologic cytology patient cases reported by diagnosis, to include those unsatisfactory for diagnostic interpretation, was not evaluated for 2023.