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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 06D2003038 | (X3) Date Survey Completed 02/21/2019 |
| Name of Provider or Supplier Ameripath/Colorado Pathology Consultants | Street Address, City, State 200 Exempla Circle, Lafayette, CO | |
| 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 |
|---------------------------|---|
| 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 procedures, laboratory records, and interview it was determined that the laboratory failed to follow written procedure to maintain two of three required annual statistics for nongynecologic cytology in 2017 and 2018. Findings include: 1. The procedure titled "RECORDING AND EVALUATION OF CYTOLOGY LABORATORY ANNUAL STATISTICS" stated the following: "6. LOCAL ADDENDUM. Non-Gyn volume per CLIA site will be calculated Quarterly and Annually. This will include the specimens reviewed by specimen type. Cases will be reported by diagnosis inclusive of Unsatisfactory." 2. The Survey Team requested and the laboratory failed to provide records of the following two annual statistics for nongynecologic cytology in 2017 and 2018. - The number of specimens processed by specimen type. - The number of patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation). a. The Survey Team reviewed the "CYTOLOGY LABORATORY ANNUAL STATISTICAL</p> |

SUMMARY" records for 2017 and 2018. These records did not include the number of nongynecologic cytology specimens processed by specimen type and the number of cases reported by diagnosis. 3. These findings were confirmed by the Laboratory Director during an interview on 2/20/19 at 3:48 PM.

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