

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2052455	(X3) Date Survey Completed 09/07/2018
Name of Provider or Supplier Clinical Pathology Associates	Street Address, City, State 1500 Red River Pathology Dept Lower Level, Austin, 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
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 policies and procedures, annual cytology statistics documentation, and interview with facility personnel, the laboratory failed to establish an annual statistical laboratory evaluation of the number of Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison and Gynecologic cases where cytology and histology are discrepant for 2017. The findings included: 1. Based on the laboratory's policy " Gynecologic Case Statistical Data " effective 5/31/2018, the laboratory had established a procedure to evaluate annually the statistics for cytology to detect errors in the performance of cytology examinations and the reporting of results. The policy stated the following: "POLICY PURPOSE: This policy establishes guidelines for the collection and review of GYN statistical data for this location. POLICY STATEMENT: CPA pathologists perform cytology examination on slides processed</p>

and stained at {Other Lab Name Redacted} retains all statistical data for each testing location. Statistical Data Collection and Review Procedure 1. {Other Lab Name Redacted} Cytology pulls statistical information by location on an annual basis. 2. The data sets include the following information: a. Cases examined b. Specimens processed for the location by type c. Number of cases reported by diagnosis including any unsatisfactory for diagnostic interpretation d. Number of HSIL, adenocarcinoma, or other malignancy cases for which histology results were available for comparison. e. Number of cases where cytology and histology were discrepant f. Major Diagnostic Discrepancies: cases where the rescreen of normal or negative specimen results in a reclassification as low-grade squamous intraepithelial lesion, HSIL, adenocarcinoma, or other malignant lesions." 2. Based on review of the documentation on-site during the inspection, the annual statistics for cytology, provided by the laboratory failed to address number of Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison and Gynecologic cases where cytology and histology are discrepant for 2017. Additional documentation was provided at 13:30 hours on 9/6/2018 via email. The documentation was titled "HIGH GRADE CORRELATION SUMMARY 2017". In an email response at 13:56 hours on 9/6/2018 via email, the Clinical Pathology Support Manager stated "Also...to clarify, this is not by location, it is for the practice as a whole." 3. In a phone interview at 10:08 hours on 9/7/2018, the Clinical Pathology Support Manager confirmed the statistics had been evaluated practice-wide, and not for this specific laboratory.