

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2129190	(X3) Date Survey Completed 08/04/2022
Name of Provider or Supplier Clinical Pathology Associates	Street Address, City, State Pathology Dept 1st Floor, Round Rock, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5631	<p>CYTOLOGY CFR(s): 493.1274(c)(6)</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) (6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken.</p> <p>This STANDARD is not met as evidenced by: Based on review of the personnel files and interview, the laboratory failed to provide documentation that cytology discrepancies were reviewed for three of three pathologists interpreting abnormal cytology cases for one of one years (2021) reviewed. A. Review of three 2021 personnel files for the pathologists showed no Cytology Pathologist Competency for technical supervisors #6, #8 & #9, as listed on the CMS form 209. The Cytology Pathologist Competency lists the number of randomly reviewed reports and those which disagree, and the number of corrected reports per pathologist. B. Review of the generated Cytopathologist Summary report showed technical supervisor #6 reported 288, technical supervisor #8 reported 158 and technical supervisor #9 reported 63 cytology cases in 2021. C. Interview with the Clinical Support Manager on July 27, 2022 at 1115 hours confirmed the findings.</p>