

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2129189	(X3) Date Survey Completed 08/02/2022
Name of Provider or Supplier Clinical Pathology Associates Name	Street Address, City, State Pathology Dept 1st Floor, 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
D0000	The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, competency records, pre-survey paperwork, and interview, the laboratory failed to ensure the competency was assessed for one of six Technical Supervisors performing histopathology and cytology microscopic interpretations. Findings follow. A. Review of the Technical Supervisor /General Supervisor policy and procedure, effective May 30, 2018, under Competency Assessments of the Technical Supervisor/General Supervisor stated, "1. Each pathologist serving as a technical supervisor and general supervisor will receive a competency assessment for the duties. 2. This assessment will be performed initially and will be performed any time that the assigned duties are changed or new duties are added. 3. The CPA Scheduling and Credentialing office will accumulate competency metrics as outlined in the SOP Professional Competency Policy for Pathologist. On an annual basis (or semiannually for new pathologists), CPA Scheduling and Credentialing will collect pathologist metrics and data from competency activities described above for review on an individual basis by the president of CPA, a board-certified pathologist, or a designated (pathologist) quality officer. A summary of competency activities is maintained by CPA Scheduling and Credentialing to be available to or distributed to Laboratory Director as required by credentialing agencies, inspection authorities, or institutional policies." B. Review of the Technical Supervisor /General Supervisor Competency Assessment, dated 06/17/2022, stated,</p>

"these individuals are authorized to perform histopathology testing to include microscopic examinations and macroscopic examination of patient specimens without supervision or need for review prior to reporting results." Technical Supervisor # 5 on the CMS form 209, was not listed. C. Review of the pre-survey paperwork, Laboratory Personnel, showed Technical Supervisor #5 was hired on 8/16/2021. D. Interview with the Clinical Support Manager on July 27, 2022 at 0940 hours in the office acknowledged Technical Supervisor #5 was not on the list.

D5631

CYTOLOGY

CFR(s): 493.1274(c)(6)

(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.

This STANDARD is not met as evidenced by:

Based on review of the personnel files and interview, the laboratory failed to provide documentation that cytostatistics were performed and reviewed for one of five pathologists interpreting abnormal cytology cases for one of one years (2021) reviewed. Review of five 2021 personnel files for the pathologists showed no CytoPathologist Summary for technical supervisor #4, as listed on the CMS form 209. The Cytopathologist Summary breaks down the number of cases reported by diagnosis classification and includes the percentage for the pathologist compared to the overall group at that location and for that pathologist compared to the overall group across all locations. Review of the generated report showed technical supervisor #4 reported 2452 cytology cases in 2021. Interview with the Clinical Support Manager on July 27, 2022 at 1115 hours confirmed the findings.