

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2021404	<b>(X3) Date Survey Completed</b> 02/07/2023
<b>Name of Provider or Supplier</b> Clinical Pathology Associates	<b>Street Address, City, State</b> 1201 W 38th St, Austin, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
<b>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, case lists, pre-survey paperwork, accuracy assessments and interview, the laboratory failed to verify the accuracy of its interpretation of its hematopathology cases for two of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Pathologists' Competency Assessments, effective 05/29/2018, stated, "2. Where applicable, pathologists participate in quality assurance activities as required by institutional policies (i.e., hospital practices, outpatient laboratory, others) to assure competency. These may include but are not limited to: - Random prospective case review - Retrospective case review - Frozen section -permanent correlation - Intradepartmental consultation correlation - Extradepartmental consultation correlation Refer to institutional specific quality specific assurance policies for further details." B. Review of the case lists and patient test reports showed the lab was reporting out bone marrow hematopathology reports, not represented on the CMS form 116. The form was updated by the Laboratory Director and Clinical Support Manager. C. Review of the CMS form 116 showed an annual test volume of 7 cases in the specialty of hematopathology. D. Review of the Intradepartmental Consultation peer reviews showed one case for 2021 and 2022. E. Interview with the Laboratory Director on January 26, 2023, at 1540 hours acknowledged he was not sure if they did any random reviews for hematopathology, and they had been reporting</p>

hematopathology cases as long as they've had the CLIA certificate. Email with the Clinical Support Manager on January 27, 2023, at 1217 hours confirmed there was only one peer review each year in hematopathology.