

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 37D2254947	<b>(X3) Date Survey Completed</b> 04/25/2025
<b>Name of Provider or Supplier</b> Anatomical Pathology Associates-Cp Lab	<b>Street Address, City, State</b> 417 N Monte Vista, Ada, OK	
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>	The recertification survey was performed on 04/22,23,24/2025. The laboratory was found in compliance with a standard-level deficiency cited. The findings were reviewed with the laboratory director and technical consultants #1 and #2, at the conclusion of the survey.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> CFR(s): 493.15(e)</p> <p>493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of manufacturer's package insert, and interview with technical consultant #1, the laboratory failed to ensure test kits were stored following the manufacturer's instructions for one of one area observed. Findings include: (1) On 04/22/2025 at 11:00 am, technical consultant #1 stated Hemoglobin A1c testing was performed using the Siemens DCA Vantage analyzer; (2) Observation of the storage closet (adjacent to the laboratory) on 04/22/2025 at 11:00 am identified six boxes of DCA Systems Hemoglobin A1c reagent cartridges being stored at room temperature: (i) Six boxes of lot #0866025, which had not been dated when received or placed at room temperature; (3) Review of the manufacturer's package insert under the heading "Storage and Use" stated, "Store reagent cartridges refrigerated at 2-8 C. Alternately, the cartridges can be kept for up to three months at room temperature any time before the expiration date"; (4) The findings were reviewed with technical consultant #1 who stated on 04/22/2025 at 11:00 am, the boxes had not been dated with the three month room temperature expiration date or date of receipt.</p>