

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2155259	(X3) Date Survey Completed 08/15/2024
Name of Provider or Supplier Ganzer-Hahn Dermatology Associates	Street Address, City, State 4100 Johnson Road, Suite 201, Steubenville, OH	
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
D5217	<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 record review and interviews with Testing Personnel (TP) #1, the laboratory failed to conduct blind test accuracy verification (TAV) activities, at least twice annually, for the high complexity tissue biopsy gross testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 250 out of 250 tissue biopsy blocks grossed between 02/24/2023 through 12/31/2023. Findings Include: 1. Review of the laboratory's "Proficiency Testing" policy and procedure, approved by the Laboratory Director on 06/19/2024 and provided on the date of the inspection, found the following statement: "Once every 6 months 4 slides will be sent to an outside dermatopathologist for proficiency testing." 2. Review of proficiency testing records for 2023 found one shipment of four cases sent 02/23/2023 to an outside dermatopathologist for blind TAV. 3. The Inspector requested the laboratory's 2023 documentation of twice annual blind TAV for the tissue gross test procedures performed from TP #1. TP #1 confirmed the laboratory did not follow the laboratory's policy and procedure for blind TAV activities at least twice annually for the high complexity tissue biopsy gross testing procedures performed and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 08/15/2024 at 11:25 a.m.</p>