

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2265213	(X3) Date Survey Completed 12/21/2022
Name of Provider or Supplier Ganzer-Hahn Dermatology Associates	Street Address, City, State 2994 Maple Avenue, Zanesville, 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
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record reviews and an interview with the Laboratory Manager (LM), the laboratory failed to perform and document stain quality control (QC) for the intended reactivity to ensure predictable staining characteristics each day of use. This deficient practice had the potential to affect 54 out of 54 hematoxylin and eosin stained patient specimens tested from 11/01/2022 to 12/21/2022 in the subspecialty of Histopathology. Findings Include: 1. Review of the laboratory's "Quality Assurance for Routine Stains" found the following statement: "A quality control slide will be run each day the lab operates. The QC (quality control) slide will be for Hematoxylin and Eosin and/or Toliudine blue. Whichever is used in the lab. The QC for the H&E will be of normal skin,have a crisp blue nuclei and counter stain with light pink cytoplasm. The T-blue will again be with normal skin, crisp blue nuclei and light blue to purple counter stain. The lab director will determine whether the stain is acceptable for the day. Each QC will be logged on the stain QC chart. Any corrections needed for that day will be addressed at that particular time and all changes will be documented." 2. Review of the laboratory's "Mohs Quality Control for Hematoxylin and Eosin" sheet found one QC chart dated August 2022. 3. The inspector requested QC charts for September, October, November, and December 2022 from the laboratory manager. The laboratory manager stated no testing was performed in September or October 2022 and could not locate the QC chart for November. 4. During direct observation on the date of inspection, the December QC chart was only initialed by the Clinical</p>

Consultant. The "slide #, nuclei blue, cytoplasm pink/red, thickness 3-5 microns" and "section complete" columns were not completed by the Clinical Consultant. 5. The LM verified there was no November 2022 QC chart and the December QC chart had not been completed. The interview occurred on 12/21/2022 at 10:52 AM.