

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 51D0692280	(X3) Date Survey Completed 05/04/2021
Name of Provider or Supplier Ganzer-Hahn Dermatology Associates PLLC	Street Address, City, State 300 Wharton Circle Suite 180, Triadelphia, WV	
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	An announced, on site, recertification survey was conducted at Ganzer-Hahn Dermatology Associates PLLC on May 4, 2021, by the West Virginia Office of Laboratory Services. The laboratory was surveyed to assess compliance with the Federal Clinical Laboratory Improvement Amendment (CLIA) regulations under 42 CFR 493. Specific deficiencies are explained below.
D5609	<p>HISTOPATHOLOGY CFR(s): 493.1273(e)(f)</p> <p>(e) The laboratory must use acceptable terminology of a recognized system of disease nomenclature in reporting results. (f) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to (f) document quality control (QC) for the H&E staining process on each day of patient testing. 1. Review of MOHs patient testing logs and H&E QC logs from January 2020 thru April 2021 identified no QC documented for 2 of 8 patient testing days in February 2020 (2/6 and 2/20), 1 of 7 patient testing days in April 2020 (4/29), 1 of 12 patient testing days in June 2020 (6/11), 2 of 8 patient testing days in July 2020 (7/8 and 7/9), 3 of 9 patient testing days August 2020 (8/5, 8/6, and 8/19), and 2 of 9 patient testing days November 2020 (11/18 and 11/19). 2. An interview with the laboratory supervisor 5/4 /2021 at 10:00 AM confirmed the findings.</p>
D6093	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p>

This STANDARD is not met as evidenced by:

Based on record review and interview the laboratory director failed to ensure that quality control (QC) was performed and documented for the H&E staining process on each day of MOHs patient testing. Findings: 1. Review of MOHs patient testing logs and H&E QC records from January 2020 thru April 2021 identified 11 days that MOHs patient testing was performed and no QC was documented (see D5609)