

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2317625	(X3) Date Survey Completed 09/09/2026
Name of Provider or Supplier Ganzer Hahn Dermatology Associates, PLLC	Street Address, City, State 15700 State Route 170, Suite C, Calcutta, 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
D0000	Amended 10/06/2026
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interviews with the Office Manager (OM), Laboratory Manager (LM) and Testing Personnel (TP) #1, the Laboratory Director failed to establish a competency assessment policy and procedure and assess the competency of one out of one Technical Supervisor (TS) based on the responsibilities of the position for the high complexity tissue biopsy grossing procedures performed in the subspecialty of Histopathology. Findings Include: 1. Review of the laboratory's CMS-209, approved by the Laboratory Director via signature and date on 08/28/2026 found one TS qualified and listed to function in the role and responsibilities for the high complexity tissue biopsy grossing procedures performed in the subspecialty of Histopathology. 2. Review of the laboratory's "Quality Assessment Plan... Competency" policy and procedure, approved by the Laboratory Director via signature and date on 01/31/2025 and 01/30/2026 and provided on the date of the inspection lacked instructions to assess the competencies of the TS based on the responsibilities of the position. 3. Review of the laboratory's 2025 and 2026 competency assessment documentation did not find any competency assessment documentation for the TS in 2025 and 2026. 4. The Inspector requested the laboratory's competency assessment policy and procedure and the 2025 and 2026 competency assessment documentation for the TS based on the responsibilities of the position for the tissue biopsy grossing procedures performed from the OM, LM and TP#1. Interviews on 09/09/2026 at 10:15 AM, with OM, LM, and TP#1 confirmed the

	laboratory did not establish a competency assessment policy and procedure for the assessing of competency based on the responsibilities of the TS position. OM, LM and TP#1 confirmed there were no assessments completed for the TS in 2025 or 2026. 5. Record review found this deficient practice had the potential to affect 12,978 out of 12,978 patient tissue biopsy procedures performed in the subspecialty of Histopathology from 02/02/2025 through 09/09/2026.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review and interviews with the Office Manager (OM), Laboratory Manager (LM) and Testing Personnel (TP) #1, the laboratory failed to follow their own policy and procedure for the high complexity tissue biopsy grossing procedures performed in the subspecialty of Histopathology. This deficient practice affected six sampled of a total of 4,326 of the laboratory's 2026 patient tissue biopsy procedures performed in the subspecialty of Histopathology. Findings Include: 1. Review of the laboratory's "Procedure for Grossing Specimens" policy and procedure, approved by the Laboratory Director via signature and date on 01/31/2025 and 01/30/2026 and provided on the date of the inspection, found the following statement: "4. For each specimen, record the dimensions (length X width X depth) and color (tan, shades of brown, brown, tan/brown, pigmented, pink, flesh colored, pink/tan, red, white, yellow, yellow/fatty, or variegated)." 2. Review of six out of six of a total of 4,326 of the laboratory's 2026 patient requisitions with the TP's hand written grossing documentation found they lacked indication of the tissue color. Further review of the same six final test reports revealed only the tissue measurements were reported and lacked tissue color. 3. TP#1 stated in an interview on 09/09/2026 at 1:20 PM that the laboratory did not hand write the color description of each tissue specimen on the requisition and defaults every tissue color description to the color of tan, unless otherwise noted on the requisition. 4. The OM and LM confirmed on 09/09/2026 at 1:21 PM that the laboratory did not follow their policy and procedure for the high complexity tissue biopsy gross testing procedures performed and the tissue color description was not indicated on the final test reports.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on record review, direct observation and interviews with the Office Manager (OM), Laboratory Manager (LM) and Testing Personnel (TP) #1, the laboratory failed

to label secondary containers of reagents, solutions and stains in the Sakura Tissue-Tek VIP E300 tissue processor and the Leica ST 5020 auto stainer with lot numbers and expiration dates which were utilized in the processing of high complexity tissue biopsy testing procedures in the subspecialty of Histopathology. This deficient practice had the potential to affect 12,978 out of 12,978 patient tissue biopsy specimens from 02/02/2025 through 09/09/2026. Findings Include: 1. Review of the laboratory's "Histology Procedure Manual" and "H&E Automated Staining and Coverslipping Procedure" policies and procedures, approved via signature and date by the Laboratory Director on 01/31/2025 and 01/30/2026 and provided on the date of inspection did not find any instructions for labeling reagents, solutions and stains in secondary containers. 2. Direct observation of the laboratory's Sakura Tissue-Tek VIP E300 tissue processor and the Leica ST 5020 auto stainer on 09/09/2026 at 1:25 PM found secondary containers of reagents, solutions and stains labeled only with the contents and lacked indication of lot numbers and expiration dates. 3. On 09/09/2026 at 1:27 PM, the Inspector requested the laboratory's reagent logs and policy and procedure for labeling secondary containers from the OM, LM and TP#1. The OM, LM and TP#1 confirmed the laboratory did not establish reagent logs, did not establish a policy and procedure for labeling secondary containers and did not label secondary containers of reagents, solutions and stains as required by CLIA regulation. The OM, LM and TP#1 were unable to provide the requested documentation on the date of the inspection. 4. Record review found 12,978 patient tissue biopsy specimens were reported between 02/02/2025 and 09/09/2026.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on record review and interviews with the Office Manager (OM), Laboratory Manager (LM) and Testing Personnel (TP) #1, the laboratory failed to ensure final laboratory test reports indicated the name and address of the laboratory location where the tissue biopsy grossing procedures were performed in the subspecialty of Histopathology. This deficient practice affected six of six sampled patient final test reports of 12,978 total patient tissue biopsy grossing procedures performed between 02/20/2025 and 09/09/2026. Findings Include: 1. Review of the laboratory's Form CMS-116, approved by the Laboratory Director via signature and date on 08/28/2026 and provided on the date of the inspection revealed the laboratory performed tissue biopsy grossing procedures. 2. Review of six out of six patient final test reports including the tissue biopsy grossing procedures performed on 05/28/2026 (2), 07/17/2026, 07/20/2026 and 08/14/2026 (2) did not find any indication of the laboratory location where the grossing procedures were performed. 3. The OM, LM and TP#1, on 09/09/2026 at 1:20 PM, confirmed the laboratory's final test reports did not indicate the name and address of the laboratory location where patient tissue biopsy grossing procedures were performed.

D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interviews with the Office Manager (OM), Laboratory Manager (LM) and Testing Personnel (TP) #1, the Technical Supervisor (TS) failed to provide technical supervision in accordance with CFR 493.1451 of this subpart. Findings Include: 1. The TS failed to verify and demonstrate that it could obtain performance specifications comparable to those established by the manufacturer. (Refer to D6115) 2. The TS failed to evaluate and document the semi-annual competency assessment within the first year of testing of two out of two TP (#1 and #2) for the high complexity tissue biopsy grossing procedures performed in the subspecialty of Histopathology. (Refer to D6127) 3. The TS failed to evaluate and document the annual competency assessment after the first year of testing for two out of two TP (#1 and #2) for the high complexity tissue biopsy grossing procedures performed in the subspecialty of Histopathology. (Refer to D6128)
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on record review and interviews with the Office Manager (OM), Laboratory Manager (LM) and Testing Personnel (TP) #1, the Technical Supervisor (TS) failed to verify and demonstrate that the laboratory could obtain performance specifications comparable to those established by the manufacturer for the Hyperclean 2 Fume Control Hood, Microtome HM 325 Microtome, Boekel Illuminated Waterbath, Tissue Tek 4 Cryo Console, Tissue Tek 4 Embedding Console, Premier Paraffin Dispenser, Leica CV 5030 Coverslipper, Quincy 10 GC Oven, American Standard Optical and Olympus BX45 microscopes to include accuracy and precision which were utilized in the processing of high complexity patient tissue biopsy specimens in the subspecialty of Histopathology. This deficient practice had the potential to affect 12,978 out of 12,978 patient tissue biopsy specimens from 02/02/2025 through 09/09/2026. Findings Include: 1. Review of the laboratory's CMS-209, approved via signature and date by the Laboratory Director on 06/28/2026 and provided on the date of inspection revealed one individual qualified and listed to function in the role and responsibilities as a TS. 2. Review of the laboratory's "Histology Procedure Manual", approved via signature and date by the Laboratory Director on 01/31/2025 and 01/30/2026 and provided on the date of inspection did not find any instructions for performance specification validations of equipment prior to use for patient tissue biopsy specimens. 3. Review of the laboratory's performance specification documentation provided on the date of inspection found the Laboratory Director's approval of the Sakura Tissue-Tek VIP E300 and the Leica ST 5020 Stainer on 01/31/2025 with no other performance specification validation documentation for any other equipment utilized

in the processing of high complexity patient tissue biopsy specimens. 4. On 09/09 /2026 at 1:15 PM, the Inspector requested the laboratory's performance specification validation policy and procedure and their approved performance specification validation studies to include accuracy and precision for the Hyperclean 2 Fume Control Hood, Microtome HM 325 Microtome, Boekel Illuminated Waterbath, Tissue Tek 4 Cryo Console, Tissue Tek 4 Embedding Console, Premier Paraffin Dispenser, Leica CV 5030 Coverslipper, Quincy 10 GC Oven, American Standard Optical and Olympus BX45 microscopes from the OM, LM and TP#1. The OM, LM an TP#1 confirmed the laboratory did not establish a performance specification validation policy and procedure and did not conduct performance specification validation studies on the above listed equipment prior to implementing the processing of high complexity patient tissue biopsy specimens on 02/02/2025. The OM, LM and TP#1 were unable to provide the requested documentation on the date of the inspection.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:
Based on record review and interviews with the Office Manager (OM), Laboratory Manager (LM) and Testing Personnel (TP) #1, the Technical Supervisor (TS) failed to evaluate and document the semi-annual competency assessment within the first year of testing of two out of two TP (#1 and #2) for the high complexity tissue biopsy grossing procedures performed in the subspecialty of Histopathology. Findings Include: 1. Review of the laboratory's CMS-209, approved by the Laboratory Director via signature and date on 08/28/2026 found one individual qualified and listed to function in the role and responsibilities of a TS and listed two TP (#1 and #2) qualified to perform high complexity tissue biopsy grossing procedures in the subspecialty of Histopathology. 2. Review of the laboratory's "Quality Assessment Plan...Competency" policy and procedure, approved by the Laboratory Director via signature and date on 01/31/2025 and 01/30/2026 and provided on the date of the inspection, found the following statement: "The Laboratory Director or designee will perform competency assessments on all testing personnel every six months for the first year and annually thereafter." 3. Review of the laboratory's 2025 and 2026 competency assessment documentation for TP#1 and TP#2 revealed by evidence of signature and date that TP#1 assessed the competency of TP#2 and TP#2 assessed the competency of TP#1 in 2025 and 2026. 4. The Inspector requested the laboratory's 2025 and 2026 semi-annual competency assessment documentation assessed by the qualified and listed TS or General Supervisor (GS), also listed as the Laboratory Director, for the tissue biopsy grossing procedures performed by TP#1 and TP#2 from the OM, LM and TP#1. The OM confirmed the 2025 and 2026 competency assessments for TP#1 and TP#2 were not conducted by the qualified and listed TS or GS. TP#1 stated they assessed the competency of TP#2 and TP#2 assessed the competency of TP#1. The OM, LM and TP#1 were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 09/09/2026 at 10:10 AM. 5. Record review found this deficient practice had the potential to affect 12,978 out of 12,978 patient tissue biopsy procedures performed in the subspecialty of Histopathology from 02/02/2025 through 09/09/2026.

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Office Manager (OM), Laboratory Manager (LM) and Testing Personnel (TP) #1, the Technical Supervisor (TS) failed to evaluate and document the annual competency assessment after the first year of testing for two out of two TP (#1 and #2) for the high complexity tissue biopsy grossing procedures performed in the subspecialty of Histopathology. Findings Include: 1. Review of the laboratory's CMS-209, approved by the Laboratory Director via signature and date on 08/28/2026 found one individual qualified and listed to function in the role and responsibilities of a TS and listed two TP (#1 and #2) qualified to perform high complexity tissue biopsy grossing procedures in the subspecialty of Histopathology. 2. Review of the laboratory's "Quality Assessment Plan...Competency" policy and procedure, approved by the Laboratory Director via signature and date on 01/31/2025 and 01/30/2026 and provided on the date of the inspection, found the following statement: "The Laboratory Director or designee will perform competency assessments on all testing personnel every six months for the first year and annually thereafter." 3. Review of the laboratory's 2026 competency assessment documentation for TP#1 and TP#2 revealed by evidence of signature and date that TP#1 assessed the competency of TP#2 and TP#2 assessed the competency of TP#1 in 2026. 4. The Inspector requested the laboratory's 2026 competency assessment documentation assessed by the qualified and listed TS or General Supervisor (GS), also listed as the Laboratory Director, for the tissue biopsy grossing procedures performed by TP#1 and TP#2 from the OM, LM and TP#1. The OM confirmed the 2026 competency assessments for TP#1 and TP#2 were not conducted by the qualified and listed TS or GS. TP#1 stated they assessed the competency of TP#2 and TP#2 assessed the competency of TP#1. The OM, LM and TP#1 were unable to provide the requested documentation on the date of the inspection. The interviews occurred on 09/09/2026 at 10:10 AM. 5. Record review found this deficient practice had the potential to affect 12,978 out of 12,978 patient tissue biopsy procedures performed in the subspecialty of Histopathology from 02/02/2025 through 09/09/2026.