

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2097493	(X3) Date Survey Completed 10/09/2026
Name of Provider or Supplier Brenham Dermatology	Street Address, City, State 1910 Neibuhr Street, Brenham, TX	
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	The Brenham Dermatology laboratory was found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, CLIA requirements for laboratories as a result of a recertification survey on 10/09/2026 and recertification is recommended. Standard level deficiencies were cited.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, reagent log, interview, and presurvey paperwork, the laboratory failed to retain the chemical name and concentration (if applicable), manufacturer, lot number, expiration date, received date, and open date of the chemicals and stains for the Hematoxylin and Eosin (H&E), Toluidine Blue (T. Blue), and MART 1 stains used in the laboratory for Mohs testing for 24 of 24 months reviewed from 10/09/2024 - 10/09/2026. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Policy and Procedure Manual, no approval date, did not include a section for the documentation of chemicals and stains. B. The reagent log was requested on October 9, 2026 at 12:40 hours but not provided. C. Interview with the histotech on October 9, 2026 at 12:40 hours in the breakroom confirmed chemical and stain records such as lot number, expiration date, open date and received date were not retained by the laboratory. D. Review of the CMS Form 116 showed an estimated annual volume of 6112 Mohs blocks and special stains.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

Based on review of laboratory's policy and procedure, accuracy assessments, and interview, the laboratory failed to perform twice a year accuracy assessments of its Frozen Section Biopsies for the dermatopathology interpretations for three of four events in 2024 and 2025. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Policy and Procedure Manual, no approval date, at B. Proficiency Testing stated "2. For permanent section histology, slides representing two biopsies will be submitted for review by another CLIA- certified laboratory every six months. Slides should represent both malignant and benign diagnoses." B. One peer review was reviewed from 2025, additional accuracy assessments for the dermatopathology interpretations of Frozen Section Biopsies were requested on October 9, 2026 at 1200 hours but not provided. C. Interview with the Laboratory Director on October 9, 2026 at 1230 hours in the breakroom confirmed twice a year accuracy assessments for frozen section biopsies were not performed.

D6128

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 review of the laboratory's policy and procedure, competency evaluations, pre-survey paperwork, and interview, the technical supervisor failed to evaluate and document the performance of Mohs surgeons responsible for high complexity testing in Mohs testing at least annually for two of two years reviewed in 2024 and 2025. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Policy and Procedure Manual, no approval date, at C. Competency Assessment, stated, "Purpose: Laboratory personnel will be evaluated and assessed at 6 and 12 months and on an annual basis thereafter to assess their competency in cutting tissue, and the various staining procedures." The policy and procedure did not include Mohs surgeons performing patient testing. B. Review of annual competency evaluations for Mohs surgeons showed no competency evaluations for Mohs surgeons performing testing in 2024 and 2025 for testing personnel #2 (as listed on the CMS Form 209, testing personnel #1 also listed as Laboratory Director). Competency evaluations were requested on October 9, 2026 at 1115 hours but not provided. C. Review of the CMS Form 116 showed an estimated annual volume of 6112 Mohs blocks and special stains. D. Interview with the Office Manager on October 9, 2026 at 1115 hours in the breakroom confirmed the technical supervisor did not perform competency evaluations for Mohs surgeons performing patient testing.