

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2284819	(X3) Date Survey Completed 09/23/2025
Name of Provider or Supplier Bare Derm Group, Inc	Street Address, City, State 834 Us Hwy 82 Ste 102, Gainesville, 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 laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
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 review of laboratory policies, laboratory twice annual accuracy records, frozen section patient logs, and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated histopathology (frozen sections) procedures at least twice annually for two of two testing events in 2024. Findings included: 1. Review of the laboratory's "Quality Assurance Program" policy stated: "Quality Assurance Indicators ... Comparison of Test Results Twice annually, slides from randomly chosen Mohs and in-house biopsy specimens will be sent to a dermatopathologist for evaluation of slide adequacy and second opinion of results from the Mohs surgery procedure. A request will be made for consulting slides to be returned to [XX], M.D., and accompanying reports will be filed in the Mohs laboratory as part of the quality assurance record." 2. Review of the laboratory's twice annual accuracy records revealed there were no twice annual accuracy assessment records for frozen sections for two of two events in 2024. 3. Review of the laboratory's frozen section patient logs for 2024 revealed 66 frozen sections were performed. 4. During an interview on 09/23/2025 at 12:00 p.m., the Clinical Director confirmed laboratory failed to verify the accuracy of non-regulated histopathology (frozen sections) procedures at least twice annually for two of two testing events in 2024.</p>
D6102	LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(12)

(e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results;

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, personnel files and confirmed in interview, the laboratory director failed to ensure documentation of site-specific training for one of two testing personnel (TP-2) performing high complexity testing- Mohs. Findings included: 1. Review of the laboratory's policy titled "Quality Assurance Program" stated: "It is the policy of the laboratory that all personnel must implicitly adhere to the policies and procedures published in this laboratory Procedure Manual ... All laboratory personnel are trained properly commensurate with their positions, duties, and responsibilities." 2. A review of the laboratory's personnel records revealed TP-2 had no documentation of site-specific training (demonstrating that they can perform all testing operations for this laboratory) to perform high complexity testing- Mohs. 3. During an interview on 09/23/2025 at 12:00 p.m., the Clinical Director confirmed the laboratory director failed to ensure documentation of site-specific training for one of two testing personnel (TP-2) performing high complexity testing- Mohs.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of Center for Medicare and Medicaid Services (CMS) 209 form, personnel records, and confirmed in staff interview, the laboratory director failed to specify, in writing, the responsibilities and duties for one of two clinical consultants (CC-2) and one of two testing persons (TP-2) engaged in clinical consultation and performance of high complexity testing. Findings included: 1. Review of CMS 209 form listed CC-2/TP-2 as a clinical consultant and a testing person of high complexity testing; histopathology-Mohs. 2. Review of the CC-2/TP-2's personnel record revealed the laboratory director did not specify in writing the responsibilities and duties for clinical consultant or testing person. 3. During an interview on 09/23/2025 at 12:00 p.m., the Clinical Director confirmed the laboratory director failed to specify, in writing, the responsibilities and duties for one of two clinical consultants (CC-2) and one of two testing persons (TP-2) engaged in clinical consultation and performance of high complexity testing.