

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2291251	<b>(X3) Date Survey Completed</b>  05/15/2024
<b>Name of Provider or Supplier</b>  Bare Derm Group, Inc	<b>Street Address, City, State</b>  977 Raintree Circle Ste 120, Allen, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, patient final reports and confirmed in interview, the laboratory failed to follow their own policy for KOH testing for two of three patients reviewed in 2024. Findings Included: 1. Review of laboratory policy, "KOH Testing" (Approved by the Laboratory Director on 04/04/2024) revealed the following: "KOH Slide Preparation Non-Vaginal Specimens 1. Label a clean microscope slide with specimen identification. 2. Place the specimen on the slide and add one drop of 10% KOH directly on top of the specimen. 3. Wait up to 30 minutes to allow cellular tissue and debris to dissolve. Alternatively, the slide may be heated by placing the specimen slide on a heating block... 4. Immediately put a coverslip over the specimen for examination. 5. Examine the slide to verify that it is not overfilled and leaking once the cover slip is in place." 2. Review of KOH patient final reports from 2024 revealed the following: a. Patient 1 Documented under the KOH patient result was the following statement: " ...Flame used." b. Patient 2 Documented under the KOH patient result was the following statement: " ...Flame used." The surveyor inquired as to the type of flame used on KOH patient specimens. Testing Person 2 (TP-2) confirmed a lighter was used to dry the slides prior to analysis. 3. In an</p>

interview on 05/15/2024 at 10:38 AM the clinical director confirmed the laboratory failed to follow their own policy for KOH testing for two of three patients reviewed in 2024. Word Key KOH- Potassium Hydroxide

**D6045**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(7)

(b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed;

This STANDARD is not met as evidenced by:  
Based on review of laboratory personnel records, patient final reports, and staff interview, the technical consultant failed to identify the need for training for one of one testing personnel in 2024. Refer to D6066.

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**  
CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:  
Based on review of Centers for Medicare and Medicaid Services (CMS)-209 Personnel Form, laboratory personnel records, patient final reports and confirmed in interview, the laboratory failed to have documentation of training for one of one testing personnel prior to patient testing in 2024. Findings Included: 1. Review of CMS-209 form submitted at survey revealed one of one testing person (TP-1) performing moderate complexity KOH testing on patient specimens. 2. Review of laboratory personnel records revealed no documented training for TP-1 in 2024 for KOH testing. (Note: Laboratory began patient testing in 2024.) The surveyor requested documented training of TP-1 since patient testing began and none was provided. 3. Review of patient final reports revealed three of three KOH patient specimens performed by TP-1 in 2024. Further review revealed two of the three patient specimens were not tested per laboratory policy. Refer to D5401. 4. In an interview on 05/15/2024 at 10:18 AM the clinical director confirmed the laboratory failed to have documentation of training for one of one testing personnel prior to patient testing in 2024. Word Key KOH- Potassium Hydroxide