Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2275994	10/18/2023
Name of Provider or Supplier	**Street Address, City, State**	
Bare Derm Group, Inc	1005 W Ralph Hall Pkwy Suite 207, Rockwall, 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	An announced onsite initial survey was performed on October 18, 2023, and the laboratory was found to NOT be in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1250 Analytic Systems 493.1403 Laboratory Director, (moderate complexity). 493.1441 Laboratory Director, (high complexity)
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on surveyor observation, review of laboratory documentation and confirmed in interview, the laboratory failed to meet the requirements of the analytic systems for 7 of 7 months in 2023 (March-September) as evidenced by: I. The laboratory failed to have policies in place that included all required components of laboratory testing for 7 of 7 months in 2023 (March-September). (Refer to D5403) II. The laboratory failed to document Toluidine Blue 1% control slides for intended reactivity each day of patient testing for 20 of 20 histopathology patients tested in September 2023. (Refer to D5473) III. The laboratory failed to have a corrective action policy in place for all analytic phases of testing for 7 of 7 months in 2023 (March -September). (Refer to D5779) IV. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems 7 of 7 months in 2023. (Refer to D5791)

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory documentation and confirmed in interview, the laboratory failed to have policies in place that included all required components of laboratory testing for 7 of 7 months in 2023 (March-September). (Note: Laboratory performed analysis of histopathology specimens and Potassium Hydroxide (KOH) slide testing.) Findings Included: 1. Review of the laboratory's policy manual revealed the laboratory failed to implement policies for the following components of the services provided by the laboratory for patient testing: a. Requirements for histopathology and KOH: patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection b. Microscopic examination, including the detection of inadequately prepared histopathology or KOH slides. c. Step-by-step performance of the histopathology and KOH testing procedures, including interpretation of results. d. Preparation of slides, reagents, stains, and other materials used in testing. e. Control procedures for histopathology staining. f. Corrective action to take when control results fail to meet the laboratory's criteria for acceptability. g. The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threating results, or panic, or alert values. 2. During an interview on 10/18/2023 at 10:25 a.m., in the laboratory, the clinical director confirmed the laboratory failed to have policies in place that included all required components of laboratory testing for 7 of 7 months in 2023 (March-September).
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

	This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documents, patient test logs, and confirmed in interview, the laboratory failed to document Toluidine Blue 1% control slides for intended reactivity each day of patient testing for 20 of 20 histopathology patients tested in September 2023. Findings Included: 1. During a tour of the facility on 10/18/2023 at 10:00 a.m., the surveyor observed a Toluidine Blue 1% staining station used for patient specimens. 2. Review of laboratory documents revealed no documentation of Toluidine Blue 1% control slides for intended reactivity each day of patient testing. 3. Review of patient test logs revealed the following patients tested when Toluidine Blue 1% control slide reactivity was NOT documented: September 2023 Procedure date: 09/05/2023 a. Patient 1 (See Patient Identification Sheet) Case Number: AFR-128 Procedure Date: 09/06/2023 b. Patient 2 Case Number: AFR-129 c. Patient 3 Case Number: AFR-130 Procedure Date: 09/07/2023 d. Patient 4 Case Number: AFR-131 e. Patient 5 Case Number: AFR-132 f. Patient 6 Case Number: AFR-133 Procedure Date: 09/12/2023 g. Patient 7 Case Number: AFR-134 Procedure Date: 09/14/2023 h. Patient 8 Case Number: AFR-135 i. Patient 9 Case Number: AFR-136 j. Patient 10 Case Number: AFR-137 Procedure Date: 09/19/2023 k. Patient 11 Case Number: AFR-138 l. Patient 12 Case Number: AFR-139 m. Patient 13 Case Number: AFR-140 n. Patient 14 Case Number: AFR-141 Procedure Date: 09/20/2023 o. Patient 15 Case Number: AFR-142 p. Patient 16 Case Number: AFR-143 q. Patient 17 Case Number: AFR-144 r. Patient 18 Case Number: AFR-145 s. Patient 19 Case Number: AFR-146 t. Patient 20 Case Number: AFR-147 4. During an interview on 10 /18/2023 at 11:15 a.m., in the laboratory, the clinical director confirmed the laboratory failed to document Toluidine Blue 1% control slides for intended reactivity each day of patient testing for 20 of 20 histopathology patients tested in September 2023.
D5779	CORRECTIVE ACTIONS CFR(s): 493.1282(a) Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documentation, and confirmed in interview, the laboratory failed to have a corrective action policy in place for all analytic phases of testing for 7 of 7 months in 2023 (March-September), as evidenced by: I. The laboratory failed to have policies in place that included all required components of laboratory testing for 7 of 7 months in 2023 (March-September). (Refer to D5403) II. The laboratory failed to document Toluidine Blue 1% control slides for intended reactivity each day of patient testing for 20 of 20 histopathology patients tested in September 2023. (Refer to D5473)
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

	This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documentation, patient test logs and staff interview, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems for 7 of 7 months in 2023 (March-September), as evidenced by: I. The laboratory failed to have policies in place that included all required components of laboratory testing for 7 of 7 months in 2023 (March-September). (Refer to D5403) II. The laboratory failed to document Toluidine Blue 1% control slides for intended reactivity each day of patient testing for 20 of 20 histopathology patients tested in September 2023. (Refer to D5473) III. The laboratory failed to have a corrective action policy in place for all analytic phases of testing for 7 of 7 months in 2023 (March-September). (Refer to D5779)
D5803	TEST REPORT CFR(s): 493.1291(b) Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request. This STANDARD is not met as evidenced by: Based on review of KOH patient specimen logs, final patient reports and confirmed in interview, the laboratory failed to ensure 1 of 2 final KOH patient results was available in the patient's medical record in May 2023. Findings Included: 1. Review of laboratory KOH patient specimen logs revealed 2 KOH patients tested in 2023. 2. Review of final KOH patient reports revealed the following patient result listed on the KOH log and NOT available in the patient's medical record: Date of Service: 05/25 /2023 Sample Identification Number: 115346PAT000000223 Results: Negative 3. During an interview on 10/18/2023 at 12:15 p.m., in the laboratory, the clinical director confirmed the laboratory failed to ensure 1 of 2 final KOH patient results was available in the patient's medical record in May 2023. Word Key: KOH- Potassium Hydroxide
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor observation, review of laboratory documentation, patient specimen logs, patient final reports, personnel records and confirmed in interview, the laboratory director failed to provide overall management and direction of moderate complexity testing for 7 of 7 months in 2023 (March-September), as evidenced by: I. The laboratory director failed to ensure testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in moderate complexity testing for 7 of 7 months in 2023 (March-September). (Refer to D6004) II.

	The laboratory director failed to ensure an approved procedure manual was available for moderate complexity testing performed for 7 of 7 months in 2023 (March-September). (Refer to D6031)
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor observation, review laboratory documentation, patient specimen logs, patient final reports, and confirmed in interview, the laboratory director failed to ensure testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in moderate complexity testing 7 of 7 months in 2023 (March-September), as evidenced by: I. The laboratory failed to have policies in place that included all required components of laboratory testing for 7 of 7 months in 2023 (March-September). (Refer to D5403) II. The laboratory failed to have a corrective action policy in place for all analytic phases of testing for 7 of 7 months in 2023 (March-September). (Refer to D5779) III. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems for 7 of 7 months in 2023 (March-September). (Refer to D5791) IV. The laboratory failed to ensure 1 of 2 final KOH patient results was available in the patient's medical record in May 2023. (Refer to D5803)
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory documentation, and confirmed in interview, the laboratory director failed to ensure an approved procedure manual was available for moderate complexity testing performed for 7 of 7 months in 2023 (March-September). (Refer to D5403)
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: The technical consultant failed to ensure the laboratory had documentation of training for performing moderate complexity testing (KOH slide testing) for 1 of 1 testing personnel in 2023. 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 (CMS -209) form, laboratory's personnel records, KOH patient specimen logs, final patient reports and confirmed in interview, the laboratory failed to have documentation of training for 1 of 1 testing persons to qualify them to perform moderate complexity testing in 2023. Findings Included: 1. Review of CMS 209 form revealed Testing Person-2 (TP-2), who only performed moderate complexity laboratory testing. 2. Review of laboratory personnel records revealed no KOH (moderate complexity) training documentation for TP-2. The inspector inquired if TP-2 possessed documentation of training in another location, the clinical director stated the facility did not document training for TP-2. 3. Review of laboratory KOH patient specimen logs revealed 2 KOH patients tested in May 2023 by TP-2: a. Date of Service: 05/04/2023 Sample Identification Number: 115346PAT000001323 Results: Negative Performed by: TP-2 b. Date of Service: 05/25/2023 Sample Identification Number: 115346PAT000000223 Results: Negative Performed by: TP-2 (Note: This patient result was NOT documented in the patient's medical record. Refer to D5803.) 4. During an interview on 10/18/2023 at 10: 43 p.m., in the laboratory, the clinical director confirmed the laboratory failed to have documentation of training for 1 of 1 testing persons to qualify them to perform moderate complexity testing.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor observation, review of laboratory documentation, patient specimen logs, patient final reports, personnel records and confirmed in interview, the laboratory director failed to provide overall management and direction of high complexity testing for 7 of 7 months in 2023 (March-September), as evidenced by: 1. The laboratory director failed to ensure testing systems performed in the laboratory

	provided quality laboratory services for all aspects of test performance in Histopathology for 7 of 7 months in 2023 (March-September). (Refer to D6079) 2. The laboratory director failed to ensure a quality control program was established and maintained to ensure the quality of laboratory services provided for 7 of 7 months in 2023 (March-September). (Refer to D6093) 3. The laboratory director failed to ensure quality assurance programs were established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur for 7 of 7 months in 2023 (March-September). (Refer to D6094) 4. The laboratory director failed to ensure an approved procedure manual was available for high complexity histopathology testing performed between March and September 2023. (Refer to D6106)
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documentation, patient specimen logs, patient final reports, and confirmed in interview, the laboratory director failed to ensure testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in Histopathology for 7 of 7 months in 2023 (March-September), as evidenced by: I. The laboratory failed to have policies in place that included all required components of laboratory testing for 7 of 7 months in 2023 (March-September). (Refer to D5403) II. The laboratory failed to document Toluidine Blue 1% control slides for intended reactivity each day of patient testing for 20 of 20 histopathology patients tested in September 2023. (Refer to D5473) III. The laboratory failed to have a corrective action policy in place for all analytic phases of testing for 7 of 7 months in 2023 (March-September). (Refer to D5779) IV. The laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and when indicated, correct problems identified in the analytic systems 7 of 7 months in 2023 (March-September). (Refer to D5791)
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) 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. This STANDARD is not met as evidenced by:

	Based on surveyor observation, review of laboratory documentation, and confirmed in interview, the laboratory director failed to ensure a quality control program was established and maintained to ensure the quality of laboratory services provided, as evidenced by: 1. The laboratory failed to document Toluidine Blue 1% control slides for intended reactivity each day of patient testing for 20 of 20 histopathology patients tested in September 2023. (Refer to D5473)
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on surveyor observation, review of the laboratory documentation and staff interview, it was revealed the laboratory director failed to ensure quality assurance programs were established and maintained to ensure the quality of laboratory services provided and to identify failures in quality as they occur for 7 of 7 months in 2023 (March-September). Refer to D5791
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on surveyor observations, review of laboratory documentation, and confirmed in interview, the laboratory director failed to ensure an approved procedure manual was available for high complexity histopathology testing performed for 7 of 7 months in 2023. (March-September). (Refer to D5403)