Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2163160	04/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Epidermatology Greenbriar	4101 Greenbriar Dr #305, Houston, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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: I. Based on a review of the laboratory's accuracy assessment records from 2020 and staff interview, it was revealed the laboratory failed to have documentation of verifying the accuracy of Mohs slides at least twice annually in 2020. Findings include: 1. A review of the laboratory's accuracy assessment records revealed the laboratory failed to have documentation of verifying the accuracy of the Mohs slides at least twice annually in 2020. 2. An interview with testing person #2 (as indicated on the CMS 209 form) on 4/28/21 at 10:20 a.m. in the laboratory, after review of the records, confirmed the above findings. II. Based on a review of laboratory's CMS 116 application, a review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy

	assessments for KOH (potassium hydroxide) preparations in 2019 and 2020. Findings include: 1. A review of the laboratory's CMS 116 application revealed the laboratory performs an estimated 24 KOH preparations annually. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for the KOH preparations in 2019 and 2020. 3. An interview with testing person #2 (as indicated on the CMS 209 form) on 4/28/21 at 10: 20 a.m. in the laboratory confirmed that the twice annual accuracy assessments were not done in 2019 and 2020 for KOH testing.
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: I. Based on a review of laboratory's procedure manual, a review of the laboratory's testing records, and staff interview, it was revealed that the laboratory failed to have a written procedure for how it will ensure the accuracy, at least twice annually, for KOH (potassium hydroxide) preparations and MOHS slides. Findings include: 1. A review of the laboratory's procedure manual revealed the laboratory failed to have a written procedure for how it will perform the twice annual accuracy assessments for KOH preparations and MOHS slides. 2. An interview with testing person #2 (as indicated on the CMS 209 form) on 4/28/21 at 10:05 a.m. in the laboratory, confirmed the above findings. II. Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to make available a written procedure for the laboratory personnel to follow for performing KOH (potassium hydroxide) preparations. Findings include: 1. A review of the laboratory's policies revealed no documentation of a written procedure for KOH preparations including the following: a) Requirements for patient preparation b) Microscopic examination c) Step-by-step performance of the procedure d) Preparation of slides e) Corrective action 2. An interview with testing person #2 (as indicated on the CMS 209 form) on 4 /28/21 at 9:40 a.m. in the laboratory revealed that the laboratory did not have a policy for KOH preps. This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)

	The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor observation, a review of the User's Manual for the AmScope Microscope, and staff interview it was revealed the laboratory failed to have documentation of monitoring the temperature and humidity in the nurse's station where the AmScope Microscope was stored. Findings include: 1. During a tour of the facility on 4/28/21 at 9:30 a.m. the following laboratory equipment, used for patient testing, was found in the nurse's station: AmScope 120 Series Serial number: 1843925 2. A review of the User's Manual for AmScope Microscope revealed the following requirements: "Do not place the microscope in direct sunlight or in high heat. Keep it indoors in a dry and clean place with temperatures between 32 -100 degrees F (0 - 40 degrees C), and in maximum relative humidity of 85%." 3. The laboratory was asked to provide documentation of monitoring the temperature and humidity in the nurse's station for compliance with the manufacturer's instructions. No documentation was provided. 4. An interview with testing person #2 (as indicated on the CMS 209 form) on 4/28/21 at 9:30 a.m. in the laboratory revealed the facility did not monitor the temperature or humidity in the nurse's station. This confirmed the above findings. Key: F = Fahrenheit C = Celsius
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observation and staff interview, it was revealed that the laboratory failed to label stain reagents with the type of stain, the lot number, and preparation /expiration dates for 17 of 17 containers. Findings include: 1. Surveyor observation on 4/28/21 at 10:20 a.m. in the laboratory found 17 unlabeled containers of stain reagents used for tissue staining. There was no documentation of what stain was in the containers, the lot numbers of the stains, or the preparation/expiration dates. 2. An interview with testing person #2 (as indicated on the CMS 209 form) on 4/28/21 at 10: 20 a.m. in the laboratory confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and

	specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, a review of the the laboratory's Temperature Logs from February 2019 to September 2020, a random review of patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of performing corrective action for 45 of 82 days from February 2019 to September 2020 when the Cryostat temperature readings were documented outside of the laboratory's acceptable range. Findings include: 1. A review of the laboratory's policy titled 'Tissue Processing Protocol for Mohs Micrographic Surgery' revealed the following: "The operational temperature for cold-section processing in this laboratory regarded as (-23 to -28 degrees Celsius)." 1. A review of the laboratory's Temperature Logs from February 2019 to September 2020 revealed the following 45 days where the Cryostat temperature readings exceeded the laboratory's acceptable range and no corrective action was documented: 2/6/19 -22C 2/15/19 -22C 3/6/19 -22C 3/13/19 -22C 3/18/19 -22C 4/1/19 -21C 4/10/19 -21C 4/11/19 -21C 4/17 /19 -21C 4/24/19 -22C 5/1/19 -22C 5/15/19 -21C 6/26/19 -22C 7/15/19 -20C 7/29/19 -21C 7/31/19 -22C 8/7/19 -22C 8/21/19 -22C 9/25/19 -22C 10/2/19 -21C 10/7/19 -22 C 10/23/19 -22C 10/30/19 -22C 11/11/19 -22C 11/18/19 -21C 12/16/19 -22C 12/18 /19 -22C 1/15/20 -22C 1/27/20 -22C 2/5/20 -22C 2/10/20 -22C 2/24/20 -22C 3/4/20 -22C 3/18/20 -22C 3/23/20 -22C 4/22/20 -22C 4/29/20 -22C 6/10/20 -22C 7/8/20 -22 C 7/15/20 -22C 7/29/20 -22C 8/12/20 -22C 8/19/20 -22C 8/26/20 -22C 9/16/20 -22C 2. A random review of patient test records revealed the following 8 patient specimens were processed when the Cryostat temperature was documented outside of the acceptable ranges: Patient Specimen ID: TSCGB2019-041 Processed 4/17/19 Patient Specimen ID: TSCGB2019-042 Processed 4/17/19 Patient Specimen ID: TSCGB2019-047 Processed 4/24/19 Patient Specimen ID: TSCGB2019-051 Processed 5/1/19 Patient Specimen ID: TSCGB2019-053 Processed 5/15/19 Patient Specimen ID: TSCGB2020-096 Processed 8/12/20 Patient Specimen ID: TSCGB2020-105 Processed 8/26/20 Patient Specimen ID: TSCGB2020-110 Processed 9/16/20 3. An interview with testing person #2 (as indicated on the CMS 209 form) on 4/28/21 at 11:20 a.m. in the laboratory, after review of the records, confirmed the above findings. Key: C = Degrees Celsius
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel files, and staff interview, it was revealed the technical consultant failed to perform competency assessments on 2 of 2 testing personnel for moderate complexity testing- KOH (potassium hydroxide) preparations. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 2 testing personnel that performed KOH preparations. 2. A review of the laboratory's personnel files revealed that there was no documentation of the technical consultant performing competency assessments for the 2 testing personnel (testing person #5 and testing person #6) performing KOH preparations. 3.

	An interview with testing person #2 (as indicated on the CMS 209 form) on 4/28/21 at 10:05 a.m. in the laboratory revealed there was no documentation of competency assessments for the 2 testing personnel. This confirmed the above findings.
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 a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of site-specific training for 2 of 2 testing personnel performing moderate complexity testing- KOH preparations. Findings include: 1. A review of the laboratory's CMS 209 form revealed the laboratory identified 2 testing personnel performing moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of site-specific training for testing person #5 and testing person #6 (demonstrating that they can perform all testing operations for this laboratory) to perform moderate complexity testing- KOH preparations. 3. An interview with testing person #2 on 4/28/21 at 10:00 a.m. in the laboratory, after review of the records, confirmed the above findings. Key: KOH - potassium hydroxide
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must 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 a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, a review of patient test records, and staff interview, it was revealed the laboratory director failed to ensure documentation of site-specific training for 3 of 4 testing personnel performing high complexity testing- grossing of histology specimens for MOHS testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the the laboratory identified 4 testing personnel performing high complexity testing- grossing of histology specimens for MOHS testing. 2. A review of the laboratory's personnel records revealed testing person #2, testing person #3, and testing person #4 had no documentation of site-specific training (demonstrating that they can perform all testing operations for this laboratory) to perform high complexity testing- grossing of histology specimens for MOHS testing. 3. An interview with testing person #2 on 4/28/21 at 10:10 a.m. in the laboratory, after review of the records, confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's 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 a review of the laboratory's submitted CMS 209 form, a review of the laboratory's personnel files, and staff interview, it was revealed that the laboratory failed to have documentation of the technical supervisor performing competency assessments in 2019, 2020 and 2021, on 2 of 3 testing personnel for high complexity testing- grossing of histology specimens for MOHS testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified 3 testing personnel performing high complexity testing- grossing of histology specimens for MOHS testing. 2. A review of the laboratory's personnel records revealed no documentation of the technical supervisor performing competency assessments for the following 2 testing personnel for high complexity testing: Testing person # 2 - start date 1/1/2019 - missing 2 competency assessments within the first year of testing Testing Person # 3 - start date 3/1/20 - missing 2 competency assessments within the first year of testing 3. An interview with testing person #2 (as indicated on the CMS 209 form) on 4/28/21 at 10:05 a.m. in the laboratory, after review of the records, confirmed the above findings.