Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0504849	09/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Austin Dermcare	3807 Spicewood Springs Rd, Ste 200, Austin, 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 initial survey was performed on The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
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 review of pre-survey paperwork, accuracy assessments, and interview, the laboratory failed to perform twice a year accuracy assessments of its dermatopathology interpretations for one of one year reviewed. Findings follow. Review of the Listing of Tests Performed in the Facility listed dermatopathology interpretations. Review of the Annual Test Volume & Proficiency Testing Programs Worksheet showed Histopathology testing began in Sept 2021. Review of the CMS form 116 showed an annual test volume of 500. Accuracy assessments for the dermatopathology interpretations were requested on September 13, 2022 at 1105 hours but not provided. There were no patient testing logs available for review at the time of the survey (see D5787). Interview with the Laboratory Director on September 13, 2022 at 1105 hours in the office confirmed accuracy assessments were not performed. She said she did weekly peer reviews via email, but had no documentation for review. Further interview with the Laboratory Director at 1120 confirmed she did not have any procedures for accuracy assessments. II. Based on review of the pre-survey paperwork, accuracy assessments, interview, the CMS database, the laboratory

	failed to verify the accuracy of its KOH (potassium hydroxide) for fungal elements tests at least twice annually for one of two years reviewed. Findings follow. Review of the Annual Test Volume & Proficiency Testing Programs Worksheet showed KOH testing began in Jan 2017 and had an estimated annual test volume of 190 for KOH. Review of the CMS form 209 showed testing personnel #1 - 5 were performing moderately complexity testing. Review of the Laboratory Personnel form showed testing personnel #1 - 4 were hired 01/20/2017, and testing personnel #5 was hired 07 /01/2022. Review of accuracy assessments from 2020 and 2021 showed no peer reviews or quizzes performed in 2021 for two of two events for KOH. Interview with the office manager on September 13, 2022 at 0955 in the office confirmed they did not have documentation of twice per year accuracy assessments for KOH and Scabies in 2021. She confirmed she did not have any procedures for accuracy assessments. Review of the CMS 116 database showed that prior to the current certificate of registration, the laboratory submitted a CMS 116 on 05/26/2020 to change the certificate type to PPMP effective 05/07/2020 from a previous certificate of compliance and was last inspected on 03/02/2018. III. Based on review of the pre-survey paperwork, accuracy assessments, interview, the CMS database, the laboratory failed to verify the accuracy of its Mineral Oil for Scabies tests at least twice annually for one of two years reviewed. Findings follow. Review of the Annual Test Volume & Proficiency Testing Programs Worksheet showed Scabies testing began in Jan 2017 and had an estimated annual test volume of 10 for Scabies. Review of the CMS form 209 showed testing personnel #1 - 5 were performing moderately complexity testing. Review of the Laboratory Personnel form showed testing personnel #1 - 4 were hired 01/20/2017, and testing personnel #5 was hired 07/01/2022. Review of accuracy assessments from 2020 and 2021 showed no peer reviews or quizzes performed in 2021 for two of two events for Scabies. Interview with the office manager on September 13, 2022 at 0955 in the office confirmed they did not have documentation of twice per year accuracy assessments for Scabies in 2021. She confirmed she did not have any procedures for accuracy assessments. Review of the CMS 116 database showed that prior to the current certificate of registration, the laboratory submitted a CMS 116 on 05/26/2020 to change the certificate type to PPMP effective 05/07/2020 from a previous certificate of compliance and was last inspected on 03/02/2018.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of pre-survey paperwork, observation, and interview, the laboratory failed to have a means of creating a patient/case log for dermatopathology interpretations performed in the laboratory for one of one years reviewed. Findings follow. Review of the Listing of Tests Performed in the Facility listed dermatopathology interpretations. Review of the Annual Test Volume & Proficiency Testing Programs Worksheet showed Histopathology testing began in Sept 2021. Review of the CMS form 116 showed an annual test volume of 500. Testing logs for dermatopathology interpretations were requested on September 13, 2022 at 1200

	hours but not provided. Interview with the Laboratory Director on September 13, 2022 at 1200 hours acknowledged she was unable to produce a list of cases reported using paper logs or electronically.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the pre-survey paperwork, accuracy assessments, interview, the CMS database, the laboratory director failed to ensure accuracy assessments of its KOH (potassium hydroxide) for fungal elements and Mineral Oil for Scabies were performed at least twice annually for one of two years reviewed in 2020 and 2021 (see D5217).
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on review of competency evaluations, pre-survey paperwork, and interview, the Laboratory Director failed to ensure competency evaluations were performed for individuals performing KOH (potassium hydroxide) for fungal elements and Scabies at least annually for four of four testing personnel for 2 of 2 years reviewed (refer to D6054).
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by:

	Based on review of competency evaluations, pre-survey paperwork, and interview, the technical consultant failed to document the performance of individuals performing KOH (potassium hydroxide) for fungal elements and Scabies at least annually for four of four testing personnel for 2 of 2 years reviewed. Findings follow. Review of competency evaluations from 2020 and 2021 for KOH for fungal elements and Scabies showed none for 2020 and 2021 (and partially completed for 2022). Competency evaluations were requested but not provided on September 13, 2022 at 0950 hours. Review of the Annual Test Volume & Proficiency Testing Programs Worksheet showed KOH and Scabies testing began in Jan 2017 and had an estimated annual test volume of 190 for KOH, and 10 for Scabies. Interview with the office manager on September 13, 2022 at 0955 in the office confirmed competency evaluations were not done in 2020 and 2021. Follow up interview with the Laboratory Director on September 13, 2022 at 0955 hours in the conference room confirmed there were no procedures for competency evaluations for KOH and Scabies, and answered that she did not directly observe patient testing (one component of competency evaluations).
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 review of pre-survey paperwork, accuracy assessments, interview, CMS database, the laboratory director failed to provide overall management and direction of the laboratory (see D6087).
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of the pre-survey paperwork, accuracy assessments, interview, CMS database, the laboratory director failed to ensure accuracy assessments of its dermatopathology interpretations were performed at least twice annually for one of one year reviewed (see D5217).