Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0505556	08/09/2021
Name of Provider or Supplier	**Street Address, City, State**	
Central Texas Dermatology	102 Westlake Drive # 100, 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	A recertification survey was performed on August 9, 2021. 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
D3041	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(6) Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting. This STANDARD is not met as evidenced by: Based on review of patient test reports, patient logs, and interview the laboratory failed to retain Mohs and frozen biopsy interpretations for at least 10 years from the report date for 827 Mohs and 21 frozen section biopsy interpretations from 08/09 /2011 - 12/31/2013. Findings follow. A. Review of 2 of 2 patient test reports older than 2 years, but less than 10 years, showed the MS-9726 2013 Mohs report and the FS-817 2014 frozen section biopsy dermatopathology interpretation were not retained for 10 years. B. Review of the Mohs patient logs showed from 08/09/2011 - 12/21 /2011 there were 147 cases/patients from MS-9091 - MS-9238; in 2012 there were 324 cases/patients from MS-9239 - MS-9563; in 2013 there were 356 cases/patients from MS-9564 - MS-9920. C. Review of the Frozen section biopsy dermatopathology interpretation patient logs showed from 08/23/2011 - 12/31/2011 there were 3 cases /patients from FS-790 - FS 793; in 2012 there were 8 cases/patients from FS-794 - FS-802; in 2013 there were 10 cases/patients from FS-803 - FS-813. D. Interview with the histotechnologist on August 9, 2021 at 1535 hours in the breakroom confirmed they only kept the histopathology test reports for 7 years per the Texas Administrative Code.

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 the laboratory policies and procedures, accuracy assessments, patient logs, and interview, the laboratory failed to verify the accuracy of dermatopathology interpretations of its frozen section biopsies at least twice annually for 2 of 2 years reviewed in 2019, 2020, and 2021. Findings follow. A. Policy and Procedure Review: 1.Review of the laboratory statement from 09/2009 signed by the previous laboratory director, stated "the Laboratory Director will insure that at least twice annually there is verification of the accuracy of potassium hydroxide tests, histopathology diagnosis and frozen section histopathology diagnosis." 2. Review of the policy and procedure titled Quality Assurance Manual under Comparison of Test Results stated, "any test performed in the laboratory for which proficiency testing is not available will be verified at least twice a year and the results will be reviewed by the Laboratory Director." B. Accuracy assessments for dermatopathology interpretations of frozen section biopsies were requested on August 9, 2021 at 1435 hours but not provided. C. Review of the frozen biopsy log showed from 08/09/2019-12-31/2019 there were 5 cases/patients reported, in 2020 there were 23 cases/patients reported, and from 01/01/2021 - 08/09/2021 there were 13 cases/patients reported. D. Interview with the histotechnologist on August 9, 2021 at 1430 hours in the breakroom confirmed accuracy assessments for frozens were not performed. II. Based on review of laboratory policies and procedures, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to perform twice per year accuracy assessments for Mohs in 2019, 2020, and 2021. Findings follow. A. Policy and Procedure Review: 1.Review of the laboratory statement from 09/2009 signed by the previous laboratory director, stated "the Laboratory Director will insure that at least twice annually there is verification of the accuracy of potassium hydroxide tests, histopathology diagnosis and frozen section histopathology diagnosis." 2. Review of the policy and procedure titled Quality Assurance Policy under Comparison of Test Results stated, "any test performed in the laboratory for which proficiency testing is not available will be verified at least twice a year and the results will be reviewed by the Laboratory Director." B. Review of the American Society for Mohs Surgery (ASMS) Peer Review for 2020 and 2019 showed one case reviewed per year. Review of the 2020 case stated, "the 1st and 2nd reviewer found your case not to be unsatisfactory. You are required to submit another case, but you will not receive participation towards Fellow maintenance without satisfactory results. In another attempt to receive satisfactory results, you may submit another case for evaluation no later than April 30, 2021." The ASMS Peer Review Case Evaluation Form showed case number 21011 was not reviewable with the comments "Stage 1 not marked to indicate inking on map" and "marked tumor location needs to be more specific since tumor seen on slide does not match area of hashtag (#) symbols used." C. Review of the pre-survey paperwork showed approximately 630 Mohs cases were performed per year. D. Interview with the histotechnologist on August 9, 2021 at 1435 hours in the breakroom confirmed after a review of the findings, the 2020 case submitted was not satisfactory, and confirmed twice per year accuracy assessments were not performed, that the ASMS Peer Review reviewed only one case per year, and no other accuracy assessments were performed in 2019, 2020, and 2021. In addition, since the 2020 case was not satisfactory, no accuracy assessments were performed for 2020.

D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory policies and procedures, pre-survey paperwork, and interview, the laboratory director failed to approve, sign, and date the laboratory's policies and procedures prior to use. Findings follow. A. Review of the laboratory's policies and procedures showed the following procedures titled Quality Assurance Manual, Potassium Hydroxide Examination, and twice per year accuracy assessments (see D5217) named the previous laboratory director. B. Review of the Potassium Hydroxide Examination procedure under Review Policy stated, "This procedure manual is reviewed by the director annually and at other times as required by major changes in procedure or other circumstances affecting laboratory performance of test." It was last signed by the previous laboratory director 05/10/2000. C. Review of the pre-survey paperwork showed the previous laboratory director left in March 2020. D. Interview with the histotechnologist on August 9, 2021 at 1445 hours in the breakroom confirmed the previous laboratory director left in March of 2020, and the current laboratory policies and procedures were not approved, signed, and dated by the current laboratory director.
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 review of laboratory policies and procedures, competency evaluations and interview, the technical consultant (also the laboratory director) failed to evaluate the competency of all testing personnel performing KOH (potassium hydroxide) for fungal elements and scabies for 3 of 3 testing personnel (not including the laboratory director). Findings follow. A. Review of the laboratory policies and procedures showed the following procedures titled Quality Assurance Manual stated under Personnel Assessment, "If the laboratory has employees, the Laboratory Director will use personal observation to perform an ongoing evaluation of all employees of the laboratory to ensure competence in job performance." B. Competency evaluations for testing personnel #2-4 listed on the CMS-209 were requested on August 9, 2021 at 1415 hours in the breakroom but not provided. C. Interview with the histotechnologist on August 9, 2021 at 1615 hours in the breakroom confirmed there were no competency evaluations for testing personnel.
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 the laboratory policies and procedures, accuracy assessments, patient test reports, patient logs, pre-survey paperwork, and interview the laboratory director failed to provide overall managment and direction of the laboratory (see D6087 and D6082).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of patient test reports, patient logs, laboratory policies and procedures, pre-survey paperwork and interview the laboratory director failed to provide quality laboratory services for all aspects of test performance. Findings follow. 1. Based on review of patient test reports, patient logs, and interview the laboratory failed to retain Mohs and frozen biopsy interpretations for at least 10 years from the report date for 827 Mohs and 21 frozen section biopsy interpretations from 08 /09/2011 - 12/31/2013 (see D3041). 2. Based on review of the laboratory policies and procedures, pre-survey paperwork, and interview, the laboratory director failed to approve, sign, and date the laboratory's policies and procedures prior to use (see D5407).
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 laboratory policies and procedures, accuracy assessments, patient logs, pre-survey paperwork, and interview the laboratory director failed to ensure Mohs and frozen section biopsy interpretations had accurate and reliable results when they failed to participate in twice per year accuracy assessments (see D5217).