Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2194863	02/08/2021
Name of Provider or Supplier	**Street Address, City, State**	
Central Utah Dermatology	861 N Main, Richfield, UT	

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
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 patient slide labeling procedure review, patient slides reviewed, and interview with staff, the laboratory failed to establish and follow a policy for documenting corrective actions taken for labeling Mohs micrographic histopathology slides for 2 of 5 cases reviewed. The laboratory performed approximately 80 Mohs micrographic frozen section blocks per year. Findings include: 1. Slide labeling procedure review included instructions to label slides by letters for more than one site for the same patient. Arabic (regular) numbers for each stage, the pathology number, the patient's last name, and the date. 2. Patient's slides reviewed for Mohs surgery performed on 09/02/2020 at 10:20 A.M. for removal of a Basal Cell Carcinoma located on the left lateral neck. The slides were numbered FS 1 progressing through the next stage to FS 2 then skipped to FS 3. FS 3 was for a specimen from a nasal side wall from the same patient. The slide numbering continued to FS 4 and FS 5 for deeper stages from the left lateral neck on the same patient. The slides failed to include the slide or pathology number on the slide or on the Mohs map. 3. In an interview with the director on 02/08/2021 at approximately 3:45 P.M., the director confirmed the process was not followed during the early days of testing. The director confirmed the laboratory lacked a written policy for corrective action documentation.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification,

	either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on histopathology test records review, patient test reports review, and interview with staff, histopathology test reports failed to include an identification number corresponding to the side the laboratory examined to make the diagnosis or an identification number assigned to the specimen or patient's identification for 7 of 7 pathology test reports reviewed for testing performed from 09/01/2020 to 02/08/2021. The laboratory performed approximately 100 biopsies for the 4th quarter of 2020. Findings include: 1. The laboratory test record review included a review of the slides for patients listed in the laboratory histopathology log record. 2. The slides included the pathology number printed on the slides by the slide preparatory laboratory (example BDT20-XXXXA for a one specimen biopsy. 3. Laboratory test reports failed to include the slide number printed on the specimen slide on the diagnostic test report but included a pathology number (example CUD 20-XXXX). The laboratory lacked a record for how or when to assign the CUD number to the specimen or patient. 4. In an interview conducted on 02/08/2021 at approximately 3:50 P.M. the director confirmed the laboratory lacked a process to provide a specimen identification number and a patient name on the test report.
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 procedure manual review, lack of documentation and interview with staff, the laboratory director failed to establish a quality assessment program that included general laboratory (example: proficiency testing review, confidentiality and competency policies); pre-analytic (example: test requisition and specimen collection, processing, storage, and transportation); analytic (specimen identification, diagnosis, and specimen slide quality); and post-analytic (example test report accuracy, corrected reports, and reference laboratory reports). The laboratory performed approximately 350 primary biopsy diagnoses and 80 Mohs micrographic frozen section histopathology tests per year. Findings include: 1. The procedure manual lacked a written quality assessment plan to describe the activities to perform, the frequency of the activities, and how the quality assessment activities are documented. 2. In an interview with the director on 02/08/2021 at approximately 3:45 P.M. the director confirmed the laboratory had not yet established a quality assessment program for dermatopathology testing.