Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D1090193	09/25/2019
Name of Provider or Supplier	**Street Address, City, State**	
Skin Clinic, The	307 Radio Road, Durant, OK	

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	The recertification survey was performed 09/25/19. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the histotechnician at the conclusion of the survey.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a review of records, policy and procedure, and interview with the histotechnician, the laboratory failed to follow its policy and procedure for corrective action documentation. Findings include: (1) At the beginning of the survey, the histology technician stated to the surveyor the laboratory performed microscopic interpretations on skin specimens obtained during Mohs surgical procedures and biopsies. Frozen sections were made from the samples and mounted on microscope slides. The slides were stained with H&E (Hematoxylin and Eosin) and examined microscopically by the laboratory director for diagnosis; (2) The surveyor reviewed the laboratory's policy and procedure manual and identified the quarterly Quality Assurance policy. It stated the following: (a) "The Laboratory Director reviews all quality charts and logs on at least a quarterly basis;" (b) "All out of control situations not resolved by a single repeat analysis will be reviewed by the Laboratory Director as soon as practical after the event;" (c) "The Laboratory Director will review the corrective action to ensure that appropriate action is taken and proper procedures were followed;" (d) "A Corrective Action Request Form will be filled out whenever a problem arises that cannot be resolved by a simple repeat analysis;" (e) "The form will be reviewed by the Laboratory Director and brought to the staff meeting if

	appropriate." (3) The surveyor then reviewed the quarterly Quality assurance documents, which stated each quarter 10-20 frozen section tests were reviewed to identify appropriate laboratory performance, checked for accuracy, completion, Mohs maps were scanned, and if an appropriate treatment plan had been made for each patient; (4) The surveyor then reviewed the quarterly Quality Assurance documents from the 4th quarter 2017 through the 3rd quarter in 2019. Documentation on the 4th quarter quality assurance review performed 11/14/17, showed that one frozen section report had not been completed (Patient #1-biopsy of chest skin performed 11/14/17). The surveyor could not locate a Corrective Action Request Form in the records; (5) The surveyor asked the histotechnician if corrective action had been taken for the incomplete patient test report and if a Corrective Action Form had been completed and was available for review. The histotechnician stated to the surveyor corrective action had been taken for the incomplete report, but the Corrective Action Form had not been completed.
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 a review of records and interview with the histotechnician, the laboratory failed to provide the date of the final test report for testing performed in the laboratory. Findings include: (1) At the beginning of the survey, the histology technician stated to the surveyor the laboratory performed microscopic interpretations on skin specimens obtained during Mohs surgical procedures and biopsies. Frozen sections were made from the samples and mounted on microscope slides. The slides were stained with H&E (Hematoxylin and Eosin) and examined microscopically by the laboratory director for diagnosis; (2) The surveyor reviewed frozen section test reports from 14 patients with testing performed between 11/27/17 and 08/26/19 and identified for 1 of the 14 patient reports, the laboratory failed to include the date of the final report (Patient #2-Mohs surgery performed 09/11/18). The final test report was dated as "09/13/18" and not the correct date of "09/11/18." The surveyor reviewed the findings with the histotechnician who stated to the surveyor, the test report listed above did not include the correct final date on which the patient testing had been performed.