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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 37D2090362 | (X3) Date Survey Completed 01/17/2018 |
| Name of Provider or Supplier Skin Clinic, The | Street Address, City, State 1606b W Jones, Duncan, 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 findings were reviewed with the histotechnician at the conclusion of the survey. |
| D5417 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, and interview with the histotechnician, the laboratory failed to ensure expired staining materials had not been used. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor, the laboratory performed H&E (Hematoxylin and Eosin) stains on frozen sections of tissues obtained during Mohs surgical procedures and from skin biopsies. The stained tissues were examined microscopically for diagnosis; (2) The surveyor reviewed stain QC (Quality Control) records from 07/01/16 through 12/31/17. Each monthly record included the lot number and expiration date of the Eosin Y stain in use during the month; (3) The surveyor identified from the records, Eosin Y stain (Lot #334166) with the manufacturer's expiration date "05/2017," had been used to stain patient slides for interpretation on 6 of the 6 days of patient testing from 06/01/17 to 06/30/17: (a) 06/05/17 (b) 6/08/17 (c) 06/13/17 (d) 06/16/17 (e) 06/20/17 (f) 06/29/17 (4) The surveyor reviewed the records with the histotechnician who agreed, expired Eosin Y stain had been used to stain patient slides for interpretation on the dates listed above.</p> |
| D5805 | <p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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</p> |

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 ensure a test report included positive patient identification. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor, the laboratory performed H&E (Hematoxylin and Eosin) stains on frozen sections of tissues obtained during Mohs surgical procedures and from skin biopsies. The stained tissues were examined microscopically for diagnosis; (2) During the survey, the surveyor reviewed H&E slides and patient test reports for 13 biopsy and Mohs surgical cases. The surveyor identified the Mohs surgical case number for 1 of the 13 result reports reviewed, was incorrect on the patient test report, as follows: (a) Patient #3: Testing performed on 03/16/17: (i) The Mohs case number documented on the H&E slides and in the patient test log was, "S17Mohs-025;" (ii) The Mohs case number documented on the patient test report was "S0F17Mohs-025." (3) The surveyor asked the histotechnician to explain how the laboratory labeled H&E slides from cases. The histotechnician explained the case number for the H&E slides included a letter indicating the laboratory site, the two digits for the year, Mohs or OF (biopsy) for the surgery type, and a preassigned sequential number; (4) The surveyor reviewed the findings with the histotechnician who agreed the laboratory failed to ensure the test report listed above, include the correct case number for positive identification.

D5821

TEST REPORT

CFR(s): 493.1291(k)

When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report.

This STANDARD is not met as evidenced by:

Based on a review of records and interview with the histotechnician, the laboratory failed to ensure patient test reports indicated the were corrected. Findings include: (1) At the beginning of the survey, the histotechnician stated to the surveyor, the laboratory performed H&E (Hematoxylin and Eosin) stains on frozen sections of tissues obtained during Mohs surgical procedures and from skin biopsies. The stained tissues were examined microscopically for diagnosis; (2) The surveyor reviewed the laboratory's "Quality Assurance/Testing Results" forms, which stated that, "Each quarter at random 10-20 frozen section test results will be monitored to identify appropriate lab performance. The reports generated will be checked for accuracy and appropriate treatment plan. A corrective action form will be used to document errors as needed."; (3) The surveyor then reviewed the quarterly quality assurance results from 07/01/16 through 12/31/17 and identified the following information: (a) 3rd

Quarter 2017-Performed 08/31/17: The laboratory reviewed records from 28 biopsy case numbers and identified the test report for 1 patient was found to have an error: (i) Patient #1: (aa) Documentation on the patient test log indicated the margins of the surgery site were clear in the sections examined, but the comment was omitted from the result in the EMR (Electronic Medical Record) and on the patient test report; (bb) The laboratory corrected the result in the EMR and added the comment. However, there was no documentation on the printed test report that the result had been corrected. (b) 1st Quarter 2017-Performed 03/14/17: The laboratory reviewed records from 12 Mohs case numbers and identified the test report for 1 patient was found to have an error: (i) Patient #2: (aa) The patient test report stated the surgery was performed on the "Rt. forehead." The Mohs map and photos of the patient before and after surgery, showed the surgical site was the left forehead' (bb) The laboratory corrected the result in the EMR and added a comment the patient test result had been corrected. However, there was no documentation on the printed test report that the result had been corrected. (4) The surveyor reviewed the findings with the histotechnician who agreed the laboratory failed to have a system which clearly indicated test results had been corrected. NOTE: The interpretive guidelines at 493.1291(k)(2) stated, "Corrected reports, either hard copy or electronic, must clearly indicate both the corrected result(s) and the fact that the report is a corrected report."