

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2196860	(X3) Date Survey Completed 08/31/2023
Name of Provider or Supplier Realskin Dermatology	Street Address, City, State 6612 Woodway Dr., Building A, Suite 2, Waco, 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	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, patient testing logs, interview, and pre-survey paperwork, the laboratory failed to document the internal controls for the hCG (Human Chorionic Gonadotropin) Pregnancy Test Cassette for two of two years reviewed. Findings follow. A. Review of the Medline hCG Pregnancy Test Cassette (urine) package insert (effective 03/20/2015) under Quality Control stated, "Internal procedural controls are included in the test. A red line appearing in the control region (C) is the internal [positive] procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result." B. The Urine Pregnancy Test Log was requested on August 31, 2023 at 1605 hours but not provided. C. Interview with the Lead Nurse on August 31, 2023 at 1605 hours confirmed they did not have a pregnancy testing log and they did not document the internal procedural controls. They documented the test result, lot number, and expiration date of the pregnancy test in the patient's chart. D. Review of the CMS Form 116 showed approximately 162 pregnancy tests were performed annually.</p>
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's policies and procedures, accuracy assessments, pre-survey paperwork, and interview, the laboratory failed to perform twice a year accuracy assessment of Mohs for 1 of 3 events reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled General Laboratory Quality Systems, reviewed 01/11/2023, at 6. Proficiency Testing Policy under Procedure stated, "As there is no formal proficiency testing for Mohs, cases will be submitted for a peer-to-peer review with another Mohs surgeon, Dermatopathologist, or Pathologist on a biannual basis." B. Review of the accuracy assessments from 2021 and 2022 showed 1 event performed in 2022 on 04/22/2022. Additional accuracy assessments were requested on August 31, 2023 at 1415 hours but not provided. C. Review of the CMS Form 116 showed approximately 700 Mohs stages were performed annually. D. Interview with the histotechnologist on August 31, 2023 at 1415 hours in the patient room confirmed the findings. II. Based on review of the laboratory's policy and procedures, accuracy assessments, and interview, the laboratory failed to perform twice a year accuracy assessments for grossing Mohs specimens for 2 of 2 years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled General Laboratory Quality Systems, reviewed 01/11/2023, at 6. Proficiency Testing Policy under Procedure stated, "As there is no formal proficiency testing for Mohs, cases will be submitted for a peer-to-peer review with another Mohs surgeon, Dermatopathologist, or Pathologist on a biannual basis." The procedure did not include accuracy assessments for grossing performed by the histotechnologist. B. Accuracy assessments for grossing were requested on August 31, 2023 at 1430 hours but not provided. C. Interview with the histotechnologist on August 31, 2023 at 1430 hours in the patient room confirmed accuracy assessments for grossing in Mohs testing was not performed.

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 review of the patient test reports, Mohs map, and slides, the laboratory failed to include a stage in the test report for one of ten Mohs test reports reviewed. Findings follow. A. Review of ten randomly selected Mohs cases showed Mohs case W23-96 was missing a Stage in the visit notes which also served as the patient test report. Review of the visit notes for the Mohs Surgery only documented 2 stages. B. Review of the Mohs map showed there were 3 stages. C. Review of the case slides

showed a total of nine slides labeled for stages 1, 2, and 3. D. Interview with the histotechnologist on August 31, 2023 at 1555 hours in the patient room confirmed the patient note was incorrect based on the Mohs map and slides, and added they would correct the surgery notes.