

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0918081	(X3) Date Survey Completed 11/10/2022
Name of Provider or Supplier Medical And Surgical Dermatology Cntr	Street Address, City, State 108 West Pleasant Street, Mount Pleasant, 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	An onsite survey conducted 11/10/2022 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory policy, specimen log, patient slides, and confirmed in interview the laboratory failed to follow its policy for the accessioning and labeling of five of ten patient slides for MOH'S testing reviewed in April of 2022. The findings include: 1. Review of the laboratory policy titled "Quality Control", section VI "Labeling and Storage of Specimens" included the following instructions: "PROCEDURE: When the specimens arrive to the laboratory, the technician assigns each case its own accession number. The number is recorded in a log book. The slide will be labeled with the patients last name, the Dr.'s initials along with the current year and the accession number. The level of Mohs Surgery is also indicated. The quadrant number will be indicated." 2. Review of the specimen logbook, for April 2022, had the following five patient accession numbers that did not correspond to the accession number on the patient slides: Date: Accession on Log: Accession on Slide 4/04/2022: 04-001: 04-008 4/11/2022: 04-002: 04-009 4/12/2022: 04-003: 04-010 4/13/2022: 04-004: 04-012 The patient with slide accession 04-011 was not in the patient logbook for accession comparison. 3. In an interview on 11/10/2022 at 10:30 hours, in the laboratory, the practice nurse confirmed that the accession numbers on the above patient slides did not match the patient accessions designated in the laboratory logbook.</p>

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 laboratory records, patient final reports, laboratory policy, and confirmed in an interview the laboratory failed to include the name and address of the laboratory location where KOH testing was performed for five of five patients who had potassium hydroxide (KOH) testing reviewed in September and October of 2022. The findings include: 1. Review of the laboratory specimen log had the following five days where individual KOH testing was reported in September and October of 2022: 9/6/2022 9/27/2022 9/29/2022 10/19/2022 10/25/2022 2. Review of patient final reports for the patients tested and reported on the above days did not include the name and address of the laboratory location where the KOH testing was performed. 3. In a review of the laboratory policy titled "Quality Control", section VII "Test Reports" included the following instructions: "Test reports are to indicate the name and address of our laboratory, the specific test being performed and the test results." 4. In an interview on 11/10/2022 at 10:00 hours, in the laboratory, the practice nurse confirmed that the patient's final report did not include the name and address of the laboratory location.