

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2095661	<b>(X3) Date Survey Completed</b> 06/20/2023
<b>Name of Provider or Supplier</b> Us Dermatology Partners	<b>Street Address, City, State</b> 1300 E 6th Ave, Belton, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	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.
<b>D1001</b>	<p><b>CERTIFICATE OF WAIVER TESTS</b> 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, and interview, the laboratory failed to document the internal controls for the hCG (Human Chorionic Gonadotropin) Pregnancy Test Cassette for five of five months 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. Review of the Urine Pregnancy Test Log from 01/05/23 - 06/14/23 showed + results in the "Controls (+)" column. Review of the log showed 47 patient tests were performed from 01/05/23 - 06/14/23. C. Interview with the Lead Medical Assistant on June 20, 2023 at 1425 in the conference room could not describe what they were looking for when marking + for the Control (+) column. Further interview with the Lead Medical Assistant on June 20, 2023 at 1430 in the lab stated the column was used to verify the patient's</p>

result is negative. Interview with a second Medical Assistant on June 20, 2023 at 1430 in the lab could not answer what they were looking for when marking a + in the Control (+) column.

**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:

I. Based on review of the laboratory's policy and procedure, Mohs maps, and interview, the laboratory failed to include the key on the Mohs map for the symbols indicating the marking dyes on the sections used on eight of eight Mohs maps reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Mohs Procedure, approved 12/21/22, stated "The solid line \_\_\_\_ designates RED dye, the dash line - - - designates BLUE dye, the ^ ^ ^ ^ symbol designates GREEN dye, and the oooo symbol designates yellow." B. Random review of eight Mohs maps from 05/17/23 - 08/09/21 showed symbols for the marking dyes used, but there was no key on the map to show what colors the symbols were, as listed by date of service and accession number: Date of Service Accession # 1. 05/17/23 B1968 2. 03/22/23 B1900 3. 12/07/22 B1808 4. 09/07/22 B1715 5. 06/08/22 B1623 6. 03/04/22 B1534 7. 12/15/21 B1459 8. 08/09/21 B1369 C. Interview with the histotechnologist on June 20, 2023 at 1450 in the conference room confirmed the Mohs surgeon used symbols on the Mohs map, that the map was not in color, and there was no key on the map for the symbols used. II. Based on review of the patient log, slides, patient chart, Mohs map, and interview, the laboratory failed to ensure the correct case number was on the patient chart and Mohs map for one of eight cases reviewed. Findings follow. A. Review of the Mohs test log showed one case, on 08/09/2021 had an accession number of B1369. B. Review of the slides for the patient showed the slides were labeled with case number B1369. C. Review of the patient chart showed on the service date 08/09/2021, a different case number: B1379. D. Review of the Mohs map from 08/09/2021, showed case number B1379. E. Interview with the histotechnologist on June 20, 2023 at 1455 in the conference room confirmed the patient's chart and Mohs map had the wrong case number, that it should be B1369.