

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1021286	(X3) Date Survey Completed 06/27/2023
Name of Provider or Supplier Us Dermatology Partners Georgetown	Street Address, City, State 700 San Gabriel Village Blvd, Ste 105, Georgetown, 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, pre-survey paperwork, and interview, 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 June 22, 2023 at 1400 hours but not provided. C. Interview with the Office Manager on June 22, 2023 at 1400 hours confirmed they did not have a pregnancy testing log. Interview with the Mohs histotechnologist on June 22, 2023 at 1405 hours confirmed they did not document the internal procedural controls. D. Review of the CMS Form 116 showed approximately 250 pregnancy tests were performed annually.</p>

D3037

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(4)

Proficiency testing records. Retain all proficiency testing records for at least 2 years.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records, and interview, the laboratory failed to retain the attestation statements for three of five events reviewed for KOH (potassium hydroxide) for fungal elements, and Scabies. Findings follow. A. Review of the AAB (American Association of Bioanalysts) PT records from the 1st and 2nd events of 2023, and the 1st, 2nd, and 3rd events of 2022 showed the 1st and 2nd events of 2023 and the 3rd event of 2022 were missing the signed attestation statements. The attestation statement attests that samples were tested in the same manner as patient samples. B. Interview with the Office Manager on June 22, 2023 at 1145 hours acknowledged she submitted the attestation statements with the results, but did not print a copy for her records.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's instructions, quality control (QC) records, testing logs, and interview, the laboratory failed to document the reactivity of the Hematoxylin and Eosin (H&E) stain to ensure predictable staining characteristics for their quality control used in Mohs testing for 7 out of 7 months reviewed. Findings follow. A. Review of the Instructions for Use for the EpreDia Hematoxylin 7212 under Intended Use stated "Hematoxylin is intended be used as a nuclear stain for the diagnosis of general pathology specimens." And under Introduction stated the Hematoxylin will form "a distinct blue-purple color characteristic of hematoxylin stains." And under Hematoxylin 7211 & 7212 stated it "provides consistent well-delineated nuclear staining results". Review of the Instructions for Use for the EpreDia Eosin-Y w/Phloxine under Intended Use stated "Eosin is intended to be used as a cytoplasmic stain for the diagnosis of general pathology specimens." And under Eosin-Y w/Phloxine stated "Eosin-Y w/Phloxine is a ready to use alcoholic, acidified counterstain to which phloxine B has been added." And under Eosin w/Alcoholic stated, "stains the cytoplasm of muscle, red blood cells, and connection tissue three distinct color hues of pink to red...[and] provides clear cytoplasmic and nuclear contrast". B. Review of the Mohs Control Slide Quality Assurance Log from 11/1/22 to 6/21/23 for 79 QC events showed Satisfactory or Unsatisfactory for the stain, but did not define what was considered satisfactory. C. Random review of the Mohs testing log showed the following cases were tested as listed by date of service and case number: Date of service Mohs Case # 1. 05/16/23 GTD23349 2. 04/04/23 GTD23236 3. 02/22/23 GTD23126 4. 01/09/23 GTD23011 5. 11/14/22 GTD22673 D. Interview with the Office Manager on June 22, 2023 at 1350 hours confirmed the QC form does not define what satisfactory is for the H&E stain.

D5787

TEST RECORDS

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on review of patient testing logs, pre-survey paperwork, and interview, the laboratory failed to document all their testing records on a log for KOH for fungal elements and Scabies performed in the laboratory for 17 of 17 months reviewed. Findings follow. A. Review of the KOH and Scabies logs showed from 01/01/2022 - 06/22/2023, there were 18 KOH and 1 scabies tests recorded. B. Interview with the Office Manager on June 22, 2023 at 1210 hours acknowledged they don't have a complete log for KOH and Scabies performed, the log was only for the ones they do peer reviews on. They were also unable to provide a complete list of who performed the KOH and Scabies and when the tests were performed. C. Review of the CMS Form 116 showed approximately 30 KOH and Scabies tests were performed annually.

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 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 six of ten Mohs maps reviewed. Findings follow. A. Random review of ten Mohs maps from 05/16/2023 - 11/01/2021 showed six were missing the 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 Mohs case #: Date of Service Mohs Case # 1. 01/09/23 GTD23-011 2. 11/14/22 GTD22-673 3. 10/07/22 GTD22-560 4. 08/15/22 GTD22-448 5. 01/31/22 GTD22-064 6. 11/01/21 GTD21-637 B. Interview with the Office Manager on June 21, 2023 at 1330 hours acknowledged Technical Supervisor #3 travels and likes using his own map, and that's why it is different from the one in the office.