

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0504849	(X3) Date Survey Completed 07/30/2024
Name of Provider or Supplier Austin Dermcare	Street Address, City, State 3807 Spicewood Springs Rd, Ste 200, Austin, 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. Standard level deficiencies were cited.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, pre-survey paperwork, and interview, the laboratory failed to have a procedure that covered the quality control (QC) of the stains for two of two years reviewed (see D5473 and D5601). Findings follow. A. Review of the laboratory's policies and procedures did not include</p>

quality control. C. Review of the CMS Form 116 showed an estimated annual test volume of 11,000 in histopathology. D. Interview with the Clinic Manager on July 29, 2024 at 1130 hours in the breakroom confirmed they did not have a section on QC in their policy and procedure.

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 laboratory's policies and procedures, test reports, quality control (QC) records, pre-survey paperwork, 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 diagnostic interpretations of histopathology specimens for six out of 10 days of testing reviewed. Findings follow. A. Review of the laboratory's policies and procedures did not include the documentation of quality control (see D5403). B. Random review of patient test reports against available quality control records revealed six out of 10 days of testing without QC for the H&E stain as listed by date reported and accession numbers: Date Reported Accession Number 1. 09/14/2023 GTW23-7874 2. 12/07/2023 GTW23-10855 3. 02/20/2024 GTW24-1360 4. 04/25/2024 GTW24-2988 5. 05/10/2024 GTW24-3295 6. 05/14/2024 GTW24-3514 C. Review of QC records submitted to the processing lab did not include H&E QC [on recuts] for the above dates of testing. D. Review of the CMS Form 116 showed an estimated annual test volume of 11,000 in histopathology. E. Interview with the Laboratory Director on July 29, 2024 at 1100 in the breakroom acknowledged she would perform QC on the H&E for recuts. Interview with the Clinic Manager on July 29, 2024 at 1205 hours in the breakroom confirmed there was no documentation of QC for the H&E for the above dates of testing.

D5601

HISTOPATHOLOGY

CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, test reports, quality control (QC) records, email, pre-survey paperwork, and interview, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Special Stains for the diagnostic interpretation of dermatopathology specimens for five out of six reports reviewed. Finding follow. A. Review of the laboratory's

policies and procedures did not include the documentation of quality control (see D5403). B. Random review of test reports from 09/08/2022 - 05/14/2024 with Immunohistochemical (IHC)/Special stains revealed five out of six reports reviewed in which the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the following IHC/Special stains, as listed by date reported, accession number, and IHC/special stain: Date Reported Accession number IHC/Special Stain 1. 09/14/2023 GTW23-7874 PAS, VVG 2. 12/07/2023 GTW23-10855 PAS 3. 02/20/2024 GTW24-1360 PAS 4. 04/25/2024 GTW24-2988 PAS 5. 05/10/2024 GTW24-3295 PAS C. Review of QC records submitted to the processing lab did not include QC on the Special Stains for the above dates of testing. D. Review of an email from the Tyler office stated "no order/QC form submitted since DX has standing order" for the above dates of testing. E. Review of the CMS Form 116 showed an estimated annual test volume of 11,000 in histopathology. F. Interview with the Clinic Manager on July 29, 2024 at 1050 hours in the breakroom acknowledged they did not keep the results of the controls, but would send to the processing laboratory in Tyler. Interview with the Clinic Manager on July 29, 2024 at 1205 hours in the breakroom confirmed there was no QC record for the above dates of testing. KEY: PAS = Periodic Acid-Schiff VVG = Verhoeff-Van Gieson

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, slides, presurvey paperwork, and interview, the laboratory failed to report the results on one of seven test reports with Immunohistochemical (IHC)/Special stains reviewed. Findings follow. A. Random review of test reports and slides from 09/08/2022 - 05/14/2024 showed seven cases with IHC/Special Stains. Review of the test reports revealed Accession number GTW23-5353 reported 06/20/2023 was missing the result of the PAS stain. B. Review of slides for Accession number GTW23-5353 showed one slide for the PAS stain. C. Review of the CMS Form 116 showed an estimated annual test volume of 11,000 in histopathology. D. Interview with the Clinic Manager on July 29, 2024 at 1115 hours in the breakroom confirmed the findings. KEY: PAS = Periodic Acid-Schiff

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, test reports, quality control (QC) records, email, pre-survey paperwork, and interview, the laboratory director failed to ensure the quality control programs were established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings follow. 1. 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 diagnostic interpretations of histopathology specimens for six out of 10 days of testing reviewed (see D5473). 2. The laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Special Stains for the diagnostic interpretation of dermatopathology specimens for five out of six reports reviewed (see D5601).