

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2239995	(X3) Date Survey Completed 06/02/2022
Name of Provider or Supplier Farady Dermatology Associates Db a Central	Street Address, City, State 1500 W 34th Street, 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	<p>A recertification survey was performed on The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory's policies and procedures, pre-survey paperwork, internet search, review of pre-survey paperwork, quality control (QC) records, test reports, slides, and interview the laboratory failed to monitor and evaluate the overall quality of the analytic systems and correct identified problems in Histopathology test systems. 1. The laboratory failed to have a procedure that covered the quality control of the stains for five of five months reviewed (see D5403). 2. The laboratory failed to have a procedure for the accuracy assessments of dermatopathological interpretations for five of five months reviewed (see D5403). 3. The laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Hematoxylin and Eosin (H&E) stain used in dermatopathological interpretations</p>

stained predictably for five of five months reviewed. (see D5473). 4. The laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Immunohistochemical (IHC) stains and Special stains for the interpretation of dermatopathological specimens for five of five months reviewed (see D5601). 5. The laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems for five of five months reviewed (see D5791).

D5403

PROCEDURE MANUAL
CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory's policies and procedures, interview, and pre-survey paperwork, the laboratory failed to have a procedure that covered the quality control of the stains for five of five months reviewed (see D5473 and D5601). Findings follow. A. Review of the laboratory policy and procedure did not include quality control. B. Interview with the Director of Operations on June 2, 2022 at 1215 confirmed they were lacking procedures. C. Review of pre-survey paperwork showed the laboratory began testing Jan 3, 2022. II. Based on review of the laboratory's policies and procedures, interview, and pre-survey paperwork, the laboratory failed to have a procedure for the accuracy assessments of dermatopathological interpretations for five of five months reviewed. Findings follow. A. Review of the laboratory policy and procedure did not include accuracy assessments. B. Interview with the Director of Operations on June 2, 2022 at 1215 confirmed they were lacking procedures. C. Review of pre-survey paperwork showed the laboratory began testing Jan 3, 2022. NOTE: There was no documentation of peer reviews to survey date.

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 internet search, review of pre-survey paperwork, quality control (QC) records, test reports, slides, interview, and EMA query, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Hematoxylin and Eosin (H&E) stain used in dermatopathological interpretations stained predictably for five of five months reviewed. Findings follow. A. Review of the pre-survey paperwork showed dermatopathological interpretations began 01/03/2022. B. Internet search of the stain used for the dermatopathological slides interpreted in the laboratory showed the following characteristics of the stain: "the nuclei are stained blue, whereas the cytoplasm is pink". C. Quality control records were requested at 0955 hours on June 2, 2022 but not provided. D. The following test reports/cases with the H&E stain were reviewed: Accession # Date Reported 1. 1452 02/07/2022 2. 2216 02/16/2022 3. 3201 03/07/2022 4. 3805 03/18/2022 5. 4210 03/23/2022 6. 5113 04/05/2022 7. 6026 04/19/2022 8. 7078 05/11/2022 9. 7517 05/12/2022 10. 7771 05/20/2022 11. 7773 05/20/2022 12. 7955 05/23/2022 13. 8130 05/25/2022 14. 8354 05/31/2022 E. Review of the slides showed the laboratory did receive slides labeled "H&E first" for the H&E QC slide. Accession #4210 reported on 03/23/2022 contained an H&E first slide. F. Interview with the Director of Operations on June 2, 2022 at 1030 hours acknowledged the lab that prepared his slides and performed the technical component did that and confirmed there was no documentation of the quality control for the H&E stain. G. Per EMA query, test volume to date for the dermatopathological interpretations was 1,196.

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 test reports, quality control (QC) records, interview, and pre-survey paperwork, the laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Immunohistochemical (IHC) stains and Special stains for the interpretation of dermatopathological specimens for five of five months reviewed. Finding follow. A. Review of 7 of 7 test reports/cases from 03/18/2022 - 05/31/2022 did not include QC for the intended reactivity to ensure predictable staining characteristics for the following IHC and Special stains: Accession # Date Reported IHC/Special Stain 1. 3805 03/18/2022 Mart 1 2. 4210 03/23/2022 Mart 1 3. 7771 05/20/2022 Font-Masson 4. 7773 05/20/2022 SOX-10 5. 7955 05/23/2022 SOX-10 6. 8130 05/25/2022 PAS/F 7. 8354 05/31/2022 Mart 1 B. Quality control records were requested but not provided on June 2, 2022 at hours 1130. C. Interview with the Director of Operations on June 2, 2022 at 1130 hours confirmed the performance of the quality control for IHC and Special stains were not recorded on the test report. D. Review of the pre-survey paperwork showed dermatopathological interpretations began 01/03/2022.

<p>D5791</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, interview, and pre-survey paperwork the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems identified in the analytic systems for five of five months reviewed (see D5473 and D5601). Findings follow. A. Review of the laboratory policy and procedure did not include quality assurance. B. Interview with the Director of Operations on June 2, 2022 at 1215 confirmed they were lacking procedures. C. Review of pre-survey paperwork showed the laboratory began testing Jan 3, 2022.</p>
<p>D6076</p>	<p>LABORATORY DIRECTOR CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of internet search, review of pre-survey paperwork, quality control (QC) records, test reports, slides, interview the laboratory director failed to provide overall management and direction (see D6093 and D6094).</p>
<p>D6093</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on internet search, review of pre-survey paperwork, quality control (QC) records, test reports, slides, interview, and EMA query, 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 intended reactivity to ensure predictable staining characteristics for the Hematoxylin and Eosin (H&E) stain used in dermatopathological interpretations stained predictably for five of five months reviewed (see D5473). 2. The laboratory failed to document the intended reactivity to ensure predictable staining characteristics for the Immunohistochemical (IHC) stains and Special stains for the interpretation of dermatopathological specimens for five of five months reviewed (see D5601).</p>

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment 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 policy and procedure, interview, and pre-survey paperwork, the laboratory director failed to ensure a quality assessment program was established and maintained to assure the quality of laboratory services provided and to identify failures as they occur (see D5791).

D6106

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(14)

The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.

This STANDARD is not met as evidenced by: