Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0481662	08/31/2018
Name of Provider or Supplier	**Street Address, City, State**	
Dallas Associated Dermatologists - Baylor	411 N Washington Ave Ste 4000, Dallas, 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 Certified Dermatology Tech and Histology Manager were at the entrance conference conducted 08/31/2018. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Certified Dermatology Tech and Histology Manager on 08/31/2018. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiency cited was discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas Department of State Health Services, Health Facility Compliance Arlington Group.
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 American Proficiency Institute (API) Proficiency Testing (PT) records and confirmed in interview, the laboratory failed to retain result forms for Potassium Hydroxide (KOH) test for 2 of 3 testing events in 2017 (2017-2, 2017-3) and 1 of 1 testing event in 2018 (2018-1). Findings included: 1. Review of the API PT records for 2017 and 2018 revealed the laboratory did not retain the result forms submitted to the PT company for the following events and samples tested: 2017-2: PT samples KOH-3 and KOH-4 (attestation signed 09/06/17) 2017-3: PT samples KOH-5 and KOH-6 (attestation signed 10/06/17) 2018-1: PT samples KOH-1 and KOH-2 (results reviewed and signed 02/27/18) 2. During an interview on 08/31/2018 at 9:30 am, the Certified Dermatology Tech confirmed the above findings. The laboratory was unable to provide the result forms for the above events.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a)

	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. This STANDARD is not met as evidenced by: Based on review of laboratory's policies, potassium hydroxide (KOH) records and confirmed in interview, the laboratory failed to follow their own written policy for ensuring the laboratory director signed KOH records for 2017 (01/2017 through 05 /2017). Findings included: 1. Review of "KOH QUALITY CONTROL" records for 2017 stated, "Split specimen; one from each doctor. Document doctor's results. Lab Director to read one of the split specimens and will document results in Control Specimen Results." Review of "KOH QUALITY CONTROL; Accuracy and Reliability of Test Method" 2017 records stated, "One KOH procedure will be split into two specimens. The provider performing the KOH procedure will collect the specimen on two slides then read one slide and document the results below. The Lab Director's designee will read the second side and document the results below under Control. This procedure will be performed two times a year." 2. Review of "KOH QUALITY CONTROL" records for 2017 included the following 6 patient specimens for KOH test: Patient #3174238; read by a provider on 01/11/17 and Testing Person -7 read the slide 01/13/17. Patient #3000165; read by a provider on 01/30/17 and Testing Person -7 read the slide 01/31/17. Patient #3062682; read by a provider on 02/08/17 and Testing Person -7 read the slide 02/10/17. Patient #3177740; read by a provider on 04/06/17 and Testing Person -7 read the slide 04/07/17. Patient #3160935; read by a provider on 04/27/17 and Testing Person -7 read the slide 04/28/17. Patient #3178047; read by a provider on 05/04/17 and Testing Person -7 read the slide 05/05 /17. The split specimens were not read by the laboratory director. The form included a section for the "Lab Director Signature" but was signed and dated by TP-7 on 02/12 /18. The laboratory director had not delegated these duties to TP-7 in writing. 3. Review of "KOH QUALITY CONTROL; Accuracy and Reliability of Test Method" 2017 records included two specimens for accuracy and reliability in 01/2017, as follows: Patient #3174238; read by a provider on 01/11/17 and Testing Person -7 read the slide 01/13/17. Patient #3000165; read by a provider on 01/30/17 and Testing Person -7 read the slide 01/31/17. The procedure performed twice a year did not include the laboratory director's signature for reading the slides. The form included a section for the "Lab Director or Designee Signature" and was signed and dated by TP-7 on 01/31/17. The laboratory director had not delegated these duties to TP-7 in writing. The laboratory failed to ensure they followed their own written policies for the above KOH procedures. 4. During an interview on 08/31/2018 at 9:46 am, the Certified Dermatology Tech and Histology Manager confirmed the above findings. The laboratory was unable to provide delegated duties for TP-7 by the laboratory director.
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: Based on review of the laboratory's procedure manual, Hematoxylin & Eosin (H&E) stain records, and in interview with staff, the laboratory failed to ensure their written policy included the H&E intended reactivity to ensure predictable staining characteristics. Findings included: 1. The laboratory's procedure manual included "COVERSLIPPING SLIDES" and stated, "Quality Control Slide Mohs: 1. First Mohs case of the day; 2. Slides are given to doctor to determine predictable staining characteristics and if any corrective action is needed; 3. If corrective action is needed doctor will give feedback to lab; 4. Lab will make corrections and re-process a new QA slide; 5. Mohs Slide QA log is kept in the lab and updated daily." The policy did not include the stain used for patient slides. The written policy did not include defined intended reactivity of H&E stain to to ensure predictable staining characteristics. 2. Review of H&E stain records "Mohs Slide QA" from 01/03/2017 through 07/31/2018 revealed everyday of patient testing, a slide was used to determine quality of stain. The form included "Slide Mohs#," "Date," "Quality," and "Comments/Corrective Action." For the "Quality" of each slide/each day it was documented "OK." Intended reactivity of H&E stain was not documented to ensure predictable staining characteristics. 3. According to records, the laboratory's annual volume was 1,465 histopathology tests. 4. During an interview on 08/31/2018 at 12:08 pm, the Certified Dermatology Tech reviewed and confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, humidity records and confirmed in interview, the laboratory failed to define the humidity range according to cryostat manufacturer operating conditions from 03/2018 through 08/2018. Findings included: 1. Review of Microm HM 505E cryostat manufacturer's instructions for "Operating Conditions" stated, "+5C - +40C (at a max. rel humidity of 60%." Review of Advantik

	cryostat manufacturer's instructions for "Relative Humidity" stated, "Max. 60% RH up to 35C." (The laboratory had two cryostats) 2. Review of humidity records from 03 /2018 through 08/2018 revealed the defined range was 20% to 80%. The laboratory did not define the humidity range in accordance with cryostat's manufacturer's instructions (maximum of 60%). Documented humidity values were not within the manufacturer's range of maximum of 60% (Refer to D5785). 3. During an interview on 08/31/2018 at 2:00 pm, the Certified Dermatology Tech and Histology Manager reviewed and confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of potassium hydroxide (KOH) records, patient charts and confirmed in interview, the laboratory used expired KOH reagent when reading two patient slides on 11/17/16 and 11/18/16. Findings included: 1. Review of "KOH - LABORATORY TEST REQUISITION AND REPORT LOG" included documented "Potassium Hydroxide 10%; Reagent Lot # K13A11; Expiration Date: 10/2016." The following patient specimens had a KOH test performed: Patient #3102069; Date: 11/17 /16, Time: 2:30 pm; Result was negative Patient #3124358; Date 11/18/16, Time: 2:45 pm; Result was negative The laboratory used expired KOH reagent (expiration 10 /2016) on the above mentioned patient specimens. 2. Review of Patient #3124358 chart included KOH results documented and for Patient #3102069 chart, KOH results were not documented. 3. During an interview on 08/31/2018 at 10:30 am, the Certified Dermatology Tech and Histology Manager reviewed and confirmed the above findings.
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 the laboratory's procedure manual, Hematoxylin & Eosin (H&E) stain records, and in interview with staff, the laboratory failed to ensure documentation of H&E intended reactivity to ensure predictable staining characteristics in 2017 and 2018 (01/03/2017 through 07/31/2018). Findings included: 1. The laboratory's procedure manual included "COVERSLIPPING SLIDES" and stated, "Quality Control Slide Mohs: 1. First Mohs case of the day; 2. Slides are given to doctor to determine predictable staining characteristics and if any corrective action is needed; 3. If corrective action is needed doctor will give feedback to lab; 4. Lab will make corrections and re-process a new QA slide; 5. Mohs Slide QA log is kept in the lab and updated daily." The written policy did not include defined intended

	reactivity of H&E stain to to ensure predictable staining characteristics (Refer to D5403). 2. Review of H&E stain records "Mohs Slide QA" from 01/03/2017 through 07/31/2018 revealed everyday of patient testing, a slide was used to determine quality of stain. The form included "Slide Mohs#," "Date," "Quality," and "Comments /Corrective Action." Review of "Mohs Slide QA" records from 01/03/2017 through 07 /31/2018 revealed the following (random sampling): 01/03/2017: Slide Mohs# M17-001; Quality: "OK" 02/15/2017: Slide Mohs# M17-148; Quality: "OK" 03/29/2017: Slide Mohs# M17-333; Quality: "OK" 04/17/2017: Slide Mohs# M17-400; Quality: "OK" 05/10/2017: Slide Mohs# M17-482; Quality: "OK" 02/13/2018: Slide Mohs# M18-183; Quality: "OK" 04/16/2018: Slide Mohs# M18-396; Quality: "OK" 05/31 /2018: Slide Mohs# M18-570; Quality: "OK" 06/12/2018: Slide Mohs# M18-608; Quality: "OK" 07/26/2018: Slide Mohs# M18-748; Quality: "OK" Intended reactivity of H&E stain was not documented to ensure predictable staining characteristics. 3. According to records, the laboratory's annual volume was 1,465 histopathology tests. 4. During an interview on 08/31/2018 at 12:08 pm, the Certified Dermatology Tech reviewed and confirmed the above findings.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, humidity records and confirmed in interview, the laboratory failed to document corrective actions taken when humidity was not within the manufacturer's defined humidity for 97 of 98 documented days from 03/2018 through 08/2018. Findings included: 1. Review of Microm HM 505E cryostat manufacturer's instructions for "Operating Conditions" stated, "+5C - +40C (at a max. rel humidity of 60%." Review of Advantik cryostat manufacturer's instructions for "Relative Humidity" stated, "Max. 60% RH up to 35C." (The laboratory had two cryostats) 2. Review of humidity records from 03/2018 through 08 /2018 revealed the defined range was 20% to 80%. The laboratory did not define the humidity range in accordance with cryostat's manufacturer's instructions (maximum of 60%). The following documented days were not within the manufacturer's range of maximum of 60% (random sampling from 97 days): 03/05/2018: 70% 03/06/2018: 70% 03/07/2018: 70% 03/12/2018: 70% 03/13/2018: 70% 04/02/2018: 70% 04/03 /2018: 70% 04/05/2018: 70% 04/06/2018: 70% 04/09/2018: 70% 05/10/2018: 70% 05 /11/2018: 70% 05/14/2018: 70% 05/15/2018: 70% 05/17/2018: 70% 06/07/2018: 70% 06/08/2018: 70% 06/11/2018: 70% 06/12/2018: 70% 06/14/2018: 70% 07/17/2018: 70% 07/19/2018: 71% 07/20/2018: 70% 07/23/2018: 70% 07/24/2018: 70% 08/06 /2018: 70% 08/07/2018: 70% 08/09/2018: 70% 08/10/2018: 70% 08/13/2018: 70% Corrective actions were not documented when the humidity was not within range. 3. During an interview on 08/31/2018 at 2:00 pm, the Certified Dermatology Tech and Histology Manager reviewed and confirmed the above findings.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from

	the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, potassium hydroxide (KOH) patient logs, patient charts and in interview with staff, the laboratory failed to ensure 2 of 7 patients KOH results were reported in the patient's chart in a timely manner (11/2016 and 11 /2017). Findings included: 1. Review of the laboratory's policy for KOH tests stated, "Reporting Results: Results are reported along with patient identification information, name of requesting physician, and comments that indicate the diagnosis and/or any abnormalities found." 2. Review of "KOH-LABORATORY REQUISITION AND REPORT LOG(s)" from 11/2016 and 11/2017 revealed the following patient KOH results documented: Patient #3102069; (ordering Provider's name); Date: 11/17/2016; Time: 2:30 pm; Type Test: Fungal; Result (+ or - only): a zero with a slash through it was reported (negative). Patient #3046370; (ordering Provider's initials); 11/02/2017; Time: 3:34 pm; Type Test: (none checked for); Result (+ or - only): + (positive). The laboratory's practice was documenting the patient's result in the log and then transcribing it manually in the patient's chart ("Visit Note"). The laboratory was asked to provide the above mentioned patients charts to review the KOH results for those dates. The charts were provided and KOH results were not transcribed in the patients charts. 3. During an interview on 08/31/2018 at 10:30 am, the Certified Dermatology Tech and Histology Manager reviewed and confirmed the above findings.