Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2139856	(X3) Date Survey Completed 08/10/2018
Name of Provider or Supplier Texas Dermatology And Laser Specialists	**Street Address, City, State** 21727 Ih-10 W, Suite 202, San Antonio, 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	An entrance conference was held 08/10/201818. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 08/10/2018, this facility was found to be NOT in compliance with the CLIA condition level deficiency for the specialties/subspecialties surveyed for 42 CFR. D8100 493.1771 Inspection Requirements An exit conference was held 08/10 /2018. All deficiencies cited were discussed. The exit conference attendees were advised the laboratory was out of compliance and advised of the condition and deficiencies found during the survey. An opportunity for questions and comments was provided.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of laboratory records and confirmed by laboratory staff, the laboratory failed to have documentation of performing twice annual accuracy assessments for Mohs Proficiency testing in 2017. Findings included: 1. Review of the laboratory records titled "Mohs Proficiency Testing" revealed the laboratory failed to have documentation that twice annual accuracy assessments were performed for 2017. 2. The laboratory was asked to provide documentation for 2017 accuracy assessment. No documentation was provided. 3. The findings were confirmed in an interview with laboratory staff on 08/10/18 at 11:30 AM in the breakroom.
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: A. Based on review of the laboratory's records, Quality Control records and confirmed with staff interview, the laboratory failed to define intended reactivity to ensure predictable staining characteristics of Hematoxylin & Eosin (H&E) stain for 15 of 15 days from 11/02/2107 through 07/20/2018. Findings included: 1. The laboratory's written protocol titled "Work Station Set Up" under Section 6.1 stated "A quality control slide will be made from the first patient's tissue of the day for the surgeon to evaluate the staining quality." 2. Review of the laboratory record titled "Slide Quality Control" log revealed a column labeled "Stain (+/-)." The following are the entries for each date: 11/2/17 + 11/3/17 + 12/7/17 + 12/8/17 + 1/4/18 + 2/1/18 + 3/1/18 + 4/12 /18 + 4/13/18 + 5/17/18 + 5/18/18 + 5/25/18 + 6/14/18 + 7/5/18 + 7/20/18 + The laboratory failed to define the intended stain reactivity to ensure predictable characteristics. 3. According to records, the laboratory's annual volume was 100 histopathology tests. 4. The laboratory was asked to provide documentation of H&E stain intended reactivity. No documentation was provided. 5. During an interview on 08/10/2108 at 11:30AM in the breakroom, the laboratory staff confirmed the findings.
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 records and confirmed in staff interview, the laboratory director failed to provide documentation of a Quality Assurance (QA) program to establish and maintain quality laboratory services and to identify failures in quality. Findings included: 1. Review of the laboratory protocol titled "Work Station Set Up Tissue Processing Protocol", revealed the laboratory failed to have documentation of QA program for the establishment and maintenance of quality laboratory services. 2. The laboratory was asked to provide documentation of a QA program. No documentation was provided. 3. During an interview with laboratory staff on 08/10/2018 at 0945 AM in the breakroom, the laboratory staff confirmed that the laboratory did not have a QA program.
D8100	INSPECTION REQUIREMENTS CFR(s): 493.1771 Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable. This CONDITION is not met as evidenced by:

	Based on review of the CMS-116 document and laboratory records, it was revealed the laboratory initiated patient testing before obtaining a CLIA Certificate of Compliance. The effective date for the CLIA certificate was 11/09/2017. (Refer to D8105)
D8105	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(e)(f)(g) (e) Reinspection. CMS or a CMS agent may reinspect a laboratory at any time to evaluate the ability of the laboratory to provide accurate and reliable test results. (f) Complaint inspection. CMS or a CMS agent may conduct an inspection when there are complaints alleging noncompliance with any of the requirements of this part. (g) Failure to permit CMS or a CMS agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate, in accordance with subpart R of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-116 form, review of patient test records and staff interview, the laboratory failed to obtain a CLIA Certificate of Compliance prior to performing histopathology testing on MOHS surgical patient samples. Findings included: 1. A review of the laboratory's CMS-116 form revealed the effective date for the CLIA Certificate of Compliance was 11/09/2017. 2. A review of the laboratory record titled "Patient Information Log" revealed three patients were tested before the CLIA Certificate of Compliance effective date of 11/09/2017. Those patients tested were: Patient 17-001 Tested on 11/02/2017 Patient 17-002 Tested on 11/02/2017 Patient 17-003 Tested on 11/03/2017 3. During an interview on 08/10/2018 at 11:00 in the breakroom, the laboratory staff confirmed the above findings.