Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2123635	05/18/2018
Name of Provider or Supplier	**Street Address, City, State**	
South Texas Skin Cancer Center - Nb	66 Gruene Park Drive, Suite 210, New Braunfels, 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 failed to meet the following conditions of the CLIA regulations found at CFR 42 493.1 through 493.1780: 493.1771 Condition: Inspection Requirements
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 the laboratory's policies, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessments in 2017 for histology specimens. The findings were: 1. A review of the laboratory's policy titled "MOHS Histopathology Quality Assurance" revealed: "Cases will be selected that occur at six (6) month intervals. These will include 3 biopsy slides and 3 Mohs sections." 2. A review of the laboratory's records revealed the laboratory selected the following cases: a) January 2017 - June 2017 2 biopsy 3 Mohs b) July 2017 - December 2017 1 biopsy 3 Mohs 3. Further review of the accuracy assessments revealed the assessments for 2017 were performed in May 2018. The laboratory was asked to provide documentation of accuracy assessments being performed in 2017. No documentation was provided. 4. An interview with the administrator on 05/18/2018 at 1100 hours in the office revealed the accuracy assessments for 2017 were performed in May 2018. She stated assessments were not performed in 2017. This confirmed the findings.
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 laboratory's CLIA certificate, patient test records and staff interview, it was revealed the laboratory failed to obtain a CLIA certificate prior to performing patient testing (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 Certificate of Compliance, review of patient test records, and staff interview, it was revealed the laboratory failed to obtain a CLIA certificate prior to testing patient samples. The findings were: 1. A review of the laboratory's Certificate of Compliance revealed the laboratory's certificate was issued by CMS on 12/27/2016. 2. A review of the laboratory's patient test records from September 2016 to December 2016 revealed the laboratory started performing testing on 09/02/2016. From 09/02/2016 to 12/26/2016 the laboratory performed 28 tests (see patient alias list). 3. An interview with the administrator on 05/18/2018 at 1000 hours in the break room revealed the laboratory performed patient testing starting in September 2016.2011. After her review of the records, she agreed the laboratory had performed patient testing prior to obtaining its CLIA certificate. This confirmed the findings.