

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0950291	(X3) Date Survey Completed 12/17/2018
Name of Provider or Supplier Coastal Dermatology	Street Address, City, State 1310 34th Street N Suite C, Texas City, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records and confirmed in an interview, the laboratory failed to document at least twice annually the accuracy of 1 of 1 tests in 2017. (Mohs) Findings were: 1. A review of laboratory testing records from 2017 and 2018 revealed no documentation of the laboratory verifying the accuracy for the Mohs test for 2017. 2. An interview with laboratory director on 12/17/18 at 1350 hours in the laboratory confirmed the above findings. He stated that he thinks it was performed but he didn't know where the documentation was kept.</p>
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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 general laboratory systems requirements specified at 493.1231 through 493.1236.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory policies, laboratory records, and confirmed in interview, the laboratory quality assessment failed to identify that the laboratory did not perform and/or assess the twice annual accuracy assessment for all tests performed in the laboratory. Findings were: 1. Review of the laboratory policy Quality Assurance (QAQC.01, approved 8/21/17) revealed "the laboratory participates in a peer review twice a year. This peer review is the reciprocal reading of randomly selected cases/slides by another qualified physician." 2. Review of the laboratory records revealed no documentation of the twice annual accuracy for 2017. Cross refer to D5217. 3. An interview with the laboratory director on 12/17/18 at 1405 hours in the laboratory 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 the manufacturer's instructions, laboratory records, patient final reports and confirmed in interview, the laboratory failed to have documentation to monitor the operating temperature and humidity for the Avantik QS12 cryostat for the Mohs histopathology testing. Findings were: 1. Review of the instructions for use for the Avantik QS12 cryostat (388159) revealed the operating environment as 15-30 C and humidity up to 60%. 2. Review of the laboratory records from 2017 through 2018 revealed no documentation of the laboratory monitoring the room temperature or humidity. 3. Random review of patient test records from 2017 and 2018 revealed the laboratory performed patient testing. Patient ID date 17-001 020/8/17 17-006 03/13 /17 17-010 04/03/17 17-026 06/05/17 17-031 07/10/17 17-044 09/11/17 17-052 10/02 /17 17-064 11/06/17 17-070 12/04/17 18-006 1/29/18 18-016 02/26/18 18-055 08/06 /18 18-062 10/15/18 18-067 11/05/18 4. An interview with the laboratory director on 12/17/18 at 1410 hours in the laboratory confirmed the above findings.