

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2141565	(X3) Date Survey Completed 10/24/2019
Name of Provider or Supplier Complete Dermatology	Street Address, City, State 508 Medical Center Blvd #380, Conroe, 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.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory policies and records, and confirmed in interview, the laboratory failed to document the competency for the technical supervisor and general supervisor. Findings were: 1. Review of the CMS 209 revealed 1 technical supervisor and 1 general supervisor. 2. Review of the laboratory records revealed no documentation of a policy nor a competency for the technical supervisor or general supervisor. 3. An interview with the director of clinical operations on 10/24/19 at 0930 hours in the exam room confirmed the above findings. She was unaware the laboratory was required to have a competency for the technical supervisor or general supervisor.</p>
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>

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. (Mohs) Findings were: 1. Review of the laboratory records from 2018-2019 revealed no documentation of the laboratory verifying at least twice annually the accuracy of Mohs for 2018. 2. An interview with the histotech on 10/24/19 at 0950 hours in an exam room confirmed the above findings. She stated that she started late in October 2018 and the laboratory had not started the twice annual accuracy assessment until 2019.

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 of the laboratory records, patient test records, and confirmed in interview, the laboratory failed to document the acceptability of the H/E (Hematoxylin and eosin) stain for the Mohs test. Findings were: 1. Review of the laboratory records from 2018-2019 revealed no documentation of the acceptability of the H/E stain for Mohs from 04/22/19-10/22/19. 2. Random review of the laboratory records from 04/22/19-10/22/19 revealed documentation the laboratory performed patient testing on the following dates. Date Patient ID 10/22/19 MS19-330; MS19-334 10/14/19 MS19-313; MS19-317 09/30/19 MS19-295; MS19-298 09/17/19 MS19-266; MS19-268 08/19/19 MS19-238; MS19-240 08/05/19 MS19-212; MS19-214 07/22/19 MS19-195; MS19-197 07/09/19 MS19-182 06/24/19 MS19-163; MS19-164 06/03/19 MS19-141; MS19-145 05/20/19 MS19-135; MS19-138 05/06/19 MS19-122; MS19-126 3. An interview with the histotech on 10/24/19 at 0955 hours in the exam room confirmed the above findings. She stated that their logs changed and the column for the QC slide was overlooked. She also stated that the QC slides were made for each of the above dates.

D6117

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(4)

The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

This STANDARD is not met as evidenced by:
Based on review of the laboratory records and confirmed in interview, the laboratory director failed to ensure the laboratory documented the acceptability of the H/E (Hematoxylin and eosin) stain for the Mohs test. Refer to D5473