

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2024251	(X3) Date Survey Completed 01/23/2020
Name of Provider or Supplier Dermatology & Laser Surgery Center	Street Address, City, State 6400 Fannin Street, Suite 2720, Houston, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</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> <p>This STANDARD is not met as evidenced by: Based on the review of laboratory proficiency testing log for 1 of 2 tests, patient records, and staff interview, it was revealed the laboratory failed to have documentation of verifying the accuracy of the KOH test at least twice annually for 2018. Findings: 1. Review of PT logs from 2018 - 2019, laboratory failed to verify the accuracy of the KOH twice annually in 2018. 2. A review of all patient records from 2018- 2019, revealed the laboratory tested KOH on four patients in 2018. Patient alias 1 Collected 12/7/2018 KOH - Neg Patient alias 2 Collected 12/10/2018 KOH - Neg Patient alias 3 Collected 12/21/2018 KOH- Neg Patient alias 4 Collected 12/27/2018</p>

KOH - Neg 3. During interview conducted in the conference room on January 23 2019 at 11:00 AM, the Chief Operating Officer confirmed the findings. Key: KOH - Postassium hydroxide Neg - Negative PT - Proficiency Testing

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of histopathology records and interview of facility personnel, the laboratory failed to document the stain quality acceptability of the hematoxylin and eosin (H&E) stain. Findings were: 1. Review of Mohs records from 2018 through 2019 revealed 1 of 27 test dates, the laboratory failed to document the stain quality control for H&E stain on 3/13/18. Mohs testing 03/13/2018 F18-021 F18-022 F18-023 F18-024 F18-025 2. Interview of the Chief Operating Officer on 01/23/2020 at 1130 hours in the conference room confirmed that quality control was not documented on that date.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on the random review of patient test reports and staff interview it was found the laboratory failed to include the name and address where the Mohs and KOH test were performed on 10 out of 10 patient's final test reports Findings included: 1. A review of 10 random patient reports from 2018 and 2019, revealed 10 of 10 pateint reports failed to include the name and address of the testing laboratory. 2. Reveiw of final test reports, revealed that laboratory failed to include the address where testing is performed. 3. Following a review of the reports on 01/23/2020 at 1205 hours in the conference room, the Chief Operating Officer confirmed this is how their reports are printed. Key: KOH - Postassium hydroxide

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the

performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records, and staff interview, it was revealed the technical consultant failed to have documentation of performing competency assessments twice annually for the first year of 1 of 1 testing person in 2019 for KOH testing. The findings were: 1. A review of the laboratory's personnel records from 2018- 2020, revealed one testing person (listed as TP#2 on Form CMS 209). TP#2 was hired November 2018. 2. Review of laboratory records for 2018-2019, revealed no documentation of the twice annual competency for TP#2 for KOH testing. 3. An interview with the Chief Operating Officer on 01/23/2020 at 11:55 hours in the conference room revealed the competency assessments had not been performed. This confirmed the findings. Key KOH - Potassium hydroxide TP - Testing Person CMS - Centers for Medicare and Medicaid Services