

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1070017	(X3) Date Survey Completed 05/17/2023
Name of Provider or Supplier Dermatology & Skin Cancer Surgery Center	Street Address, City, State 1790 N Stonebridge Drive, Mckinney, 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 announced recertification survey conducted 05/17/2023 found the facility in substantial compliance with CLIA regulations (42 CFR Part 493). Standard level deficiencies were cited.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy and confirmed in interview, the laboratory failed to ensure their Potassium Hydroxide (KOH) procedure included instructions for interpretation and reporting of KOH results. The findings include: 1. Review of the laboratory policy titled "KOH procedure" revealed: "Collection: Skin, nail, or hair</p>

samples are collected from the infected area on the patient. If the test is being sent to a laboratory, the scrapings are placed in a sterile covered container (folded slips or paper) The scrapings are placed directly onto a microscope slide and are covered with 1-2 drops of 10% or 20% potassium hydroxide. The slide is left to stand until clear, normally between five and fifteen minutes, in order to dissolve skin cells, hair, and debris. To enhance clearing dimethyl sulfoxide (DMSO) can be added to the slide. To make the fungi easier to see. Mainly used to dissolve nails. The slide is gently heated to speed up the action of the KOH. Place slide under a microscope to read." The policy failed to include instructions for interpretation and reporting of KOH preparation results. The surveyor requested documentation of instructions for interpretation and reporting of KOH preparation results. None was provided. 2. During an interview on 05/17/2023 at 03:12 p.m., the Mohs Technician confirmed the above findings.

D5801

TEST REPORT
CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, patient records, and confirmed in interview, the laboratory failed to ensure 10 of 10 patient Potassium Hydroxide (KOH) preparation results were transcribed accurately to the final test report in 2023 (January through April). The findings include: 1. Review of the laboratory's KOH procedure revealed no instructions for interpretation and reporting of KOH results. Refer to D5403. 2. A review of KOH patient final reports from 2023 (January through April) revealed the laboratory failed to accurately transcribe the following 10 patient results: 01/04/2023 MRN: MM0000160053 KOH Log: "KOH (-) Neg" Final Report: "Examination of the slide showed: negative findings within the normal realm" MRN: MM0000159541 KOH Log: "KOH (-) Neg" Final Report: "Examination of the slide showed: no hyphae" 01/11/2023 MRN: MM0000160058 KOH Log: "KOH (-) Neg" Final Report: "Examination of the slide showed: no hyphae" 02/14/2023 MRN: MM0000087546 KOH Log: "KOH (-) Neg" Final Report: "Examination of the slide showed: no hyphae" 02/23/2023 MRN: MM0000048169 KOH Log: "KOH (-) Neg" Final Report: "Examination of the slide showed: no hyphae" 03/28/2023 MRN: MM0000162047 KOH Log: "KOH (+) pos" Final Report: "Examination of the slide showed: budding yeast and branching hyphae" 03/31/2023 MRN: MM0000166541 KOH Log: "KOH (+) pos" Final Report: "Examination of the slide showed: fungal hyphal elements: positive" 04/05/2023 MRN: MM0000141857 KOH Log: "KOH (+) pos" Final Report: "Examination of the slide showed: fungal hyphal elements: positive" 04/10/2023 MRN: MM0000168119 KOH Log: "KOH (-) Neg" Final Report: "Examination of the slide showed: no hyphae" 04/11/2023 MRN: MM0000168245 KOH Log: "KOH (+) pos" Final Report: "A scabies prep was performed on the right medial dorsal foot,

showing mites. The laboratory failed to accurately transcribe results of KOH preparations to the final reports. 3. During an interview on 05/17/2023 at 03:12 p.m., the Mohs Technician confirmed the above findings.