

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0378556	(X3) Date Survey Completed 06/09/2021
Name of Provider or Supplier Dermatology & Skin Surgery Center	Street Address, City, State 2121 Spring Arbor Rd, Jackson, MI	
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
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 record review, lack of documentation, and interview with the Regional Manager (RM), the laboratory failed to verify the accuracy of its mycology and parasitology testing at least twice annually for 1 (2020) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of the mycology and parasitology verification of accuracy testing for 1 (2020) of 2 years reviewed. 2. An interview on 6/09/2021 at 9:53 am, the RM confirmed the laboratory did not have documentation of mycology and parasitology verification of accuracy testing for 2020.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with the Regional Manager (RM), the laboratory failed to document the intended quality of the Hematoxylin and Eosin (H & E) stain each day of Mohs' testing for 2 (June 2019 to</p>

June 2021) of 2 years reviewed. Findings include: 1. A record review of the "Daily Procedure Mohs Lab" policy states in step 15 "Cut one section from first block to use for Hematoxylin and eosin control." 2. A record review for 14 (#1 - #14) Mohs' maps reviewed for 2 (June 2019 to June 2021) of 2 years reviewed revealed a lack of documentation for the H & E stain quality each day of Mohs' testing. 3. An interview on 6/09/2021 at 12:15 pm, the RM confirmed the quality of the H & E stain was not documented on days of Mohs' testing.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
. Based on record review, lack of documentation, and interview with the Regional Manager (RM), the Technical Consultant (TC) failed to evaluate the competency of testing personnel performing the moderately complex mycology and parasitology testing for 2 (Testing Personnel (TP) #10 and #11) of 11 testing personnel in 2020. Findings include: 1. A record review of the laboratory's established "Personnel Competency Policy/Procedure" revealed the TC is to perform competency on an annual basis for personnel after the initial 6 month at hire. 2. A record review revealed a lack of documentation for 2 (TP #10 and #11) of 11 TP performing the mycology and parasitology testing in 2020. 3. An interview on 6/08/2021 at 12:26 pm, the RM confirmed there was no documentation of competency in 2020 for TP #10 and #11.