

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0381425	(X3) Date Survey Completed 10/02/2019
Name of Provider or Supplier Northwestern Michigan Dermatology	Street Address, City, State 550 Munson Ave, Suite 200, Traverse City, 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Mohs' Technician (MT), the laboratory failed to have an electronic request for patient testing from an authorized person for the mycology potassium hydroxide (KOH) testing for 1 (#1) of 10 patient charts audited. Findings include: 1. Record review revealed for 1 of 10 patient charts audited, the patient did not have an electronic request for the KOH testing in the patient's electronic medical record (EMR) and that the office did not have a patient on file by that name. 2. On October 2, 2019 at approximately 1:00 pm when queried, the MT was not able to find the patient in question in the data base of their EMR system and the patient was not on the daily schedule for October 31, 2017. 3. During the interview on October 2, 2019 at approximately 1:00 pm, the MT acknowledged no electronic order or patient file was available in the EMR system.</p>
D5787	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p>

This STANDARD is not met as evidenced by:
 . Based on record review and interview with the Mohs' Technician (MT), the laboratory failed to maintain a record system that included the specimen receipt time into the laboratory for each stage/level of tissue specimen for 13 (M09-634, M17-469, M17-659, M18-101, M18-159, M18-311, M18-445, M18-582, M19-35, M19-193, M19-368, M19-541, and M19-648) of 13 Mohs' patient charts audited. Findings include: 1. Record review for 13 of 13 Mohs' cases reviewed, the laboratory failed to include the specimen receipt time into the laboratory for processing on each stage /level on the final Mohs' map as follows: a. M09-634 - no time for levels 1 and 2 b. M17-469 - no time for levels 1 and 2 c. M17-659 - no time for level 1 d. M18-101 - no time for level 1 e. M18-159 - no time for level 1-3 f. M18-311 - no time for level 1 and 2 g. M18-445 - no time for level 1 and 2 h. M18-582 - no time for level 1 i. M19-35 - no time for level 1-3 j. M19-193 - no time for level 1 k. M19-368 - no time for level 1 and 2 l. M19-541 - no time for level 1 m. M19-648 - no time for level 1-3 2. During the interview on October 2, 2019 at approximately 1:45 pm, the MT acknowledged the final Mohs' map scanned into the patient's chart did not contain the specimen receipt times for each stage/level.

D5803

TEST REPORT
 CFR(s): 493.1291(b)

Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.

This STANDARD is not met as evidenced by:
 . Based on lack of documentation and interview with the Mohs' Technician (MT), the laboratory failed to have the final mycology potassium hydroxide (KOH) result maintained as part of the patient's chart in the electronic medical record (EMR) system for 1 (#1) of 10 patient charts audited. Findings include: 1. Lack of documentation for 1 (#1) of 10 patient charts audited revealed the final test report for the KOH testing was not maintained in the patient's EMR system. 2. The EMR database did not contain a patient with the name written on the "KOH Log". 3. During the interview on October 2, 2019 at approximately 1:00 pm, the MT acknowledged the lack of documentation for the KOH testing in the patient's chart as that patient did not exist in the EMR system.

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 lack of documentation, record review, and interview with the Mohs' Technician (MT), the laboratory failed to provide the patient's potassium hydroxide

results on the "KOH Log" for 2 (#8 and #10) of 10 patient charts audited. Findings include: 1. Lack of documentation on the "KOH Log" of the final KOH test result prompted further investigation into 2 of 10 patient charts audited. 2. Record review of the patient's electronic medical record (EMR) revealed the laboratory reported out a final result for the KOH testing for 2 (#8 and #10) of 10 patient charts. 3. During the interview on October 2, 2019 at approximately 1:00 pm, the MT acknowledged there was no documentation on the "KOH Log" of the test result and that a result was entered into the patient's EMR.