

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D0948745	<b>(X3) Date Survey Completed</b>  12/13/2018
<b>Name of Provider or Supplier</b>  West Michigan Dermatology	<b>Street Address, City, State</b>  3290 N Wellness Drive Bldg D Suite #240, Holland, MI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3041</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(6)</p> <p>Test reports. Retain or be able to retrieve a copy of the original report (including final, preliminary, and corrected reports) at least 2 years after the date of reporting. (i) In addition, retain immunohematology reports as specified in 21 CFR 606.160(d) (ii) and pathology test reports for at least 10 years after the date of reporting.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the laboratory failed to retain a copy of the original histopathology Mohs' map for one (#5) of 20 patient charts reviewed for at least 10 years. Findings include: 1. On December 13, 2018 at 12:30 PM, record review of the histopathology Mohs' maps revealed the laboratory did not keep the original map for as least 10 years from the date of reporting. 2. On December 13, 2018 at 12:30 PM when queried, a member of the office staff was unable to provide the surveyor with a copy of the final Mohs' map requested. 3. During the interview on December 13, 2018 at 12:30 PM, a member of the office staff confirmed the final Mohs' map was not retained for at least 10 years from the date of reporting.</p>
<b>D5787</b>	<p><b>TEST RECORDS</b> 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, the laboratory failed to record the time in/out of specimen receipt into the laboratory for the Mohs' tissue and the frozen section specimens for nine (#1, #3-#4, #13 - #14, and #16 - #19) of 20 patient charts audited. Findings include: 1. On December 13, 2018 at 12:30 PM, record review of patients charts revealed the laboratory did not record the in/out time of specimen receipt for the Mohs' tissue and the frozen section onto the Mohs' map as follows: a. specimen #1 - no in time for 2nd stage b. specimen #3 - #4 - no in/out time recorded for two stages c. specimen #13 - no in/out time recorded for 2nd stage d. specimen #14 - no out time recorded for 1st stage e. #16 - #19 - no in/out time recorded on the Mohs' map for all stages 2. During the interview on December 13, 2018 at 12:30 PM, a member of the office staff confirmed the in/out times of the Mohs' specimen were not consistently recorded on the map.