

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0948745	(X3) Date Survey Completed 04/07/2021
Name of Provider or Supplier West Michigan Dermatology	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to retain analytic system records of cryostat maintenance for 1 (2019) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation for the performance of maintenance for the laboratory's two cryostats in 2019. 2. An interview on 4/7/21 at 10:44 am with the Office Manager confirmed the laboratory did not retain documentation of cryostat maintenance in 2019.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager, the laboratory failed to follow policies to assess competency for 2 (Testing Personnel #2 and #3) of 10 testing personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency records revealed a lack of documentation of competency for two testing personnel performing mohs micrographic surgery</p>

histopathology testing in 2019: a. Testing Personnel #2 b. Testing Personnel #3 2. A review of the laboratory's "Personnel Competency Policy and Procedure" revealed a section stating, "Testing personnel will be reviewed prior to testing patients' specimens to ensure that all personnel have the appropriate education and experience, have received that appropriate training for the type and complexity of services offered, and have demonstrated that they can perform all testing operations reliably, and can provide and report accurate results. Testing personnel must be reviewed every six months during the first year of testing and annually thereafter." 3. An interview on 4/7/21 at 11:15 am with the Office Manager confirmed the testing personnel listed above did not have documented competency assessments in 2019 for histopathology testing.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager, the laboratory failed to verify the accuracy of its histopathology testing at least twice annually for 1 (2019) of 2 years reviewed. Findings include: 1. A review of the laboratory's records revealed a lack of documentation of histopathology verification of accuracy testing in 2019. 2. A review of the laboratory's "Proficiency Testing Procedures" revealed a section stating, "It is up to each testing personnel to have another testing personnel confirm TWO readings per year for each test you do. You will need to complete one PT for each test before June. When they have all been completed and turned in, you will get your second set -round two- which needs to be done before December." 3. An interview on 4/7/21 at 11:15 am with the Office Manager confirmed the laboratory did not have documentation of histopathology verification of accuracy testing for 2019. ***This is a repeated deficiency previously cited during the 7/18/16 recertification survey***