

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  23D2264181	<b>(X3) Date Survey Completed</b>  06/10/2024
<b>Name of Provider or Supplier</b>  Mymichigan Health Medical Center Dermatologic	<b>Street Address, City, State</b>  4201 Campus Ridge Drive, Midland, 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>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by:                      . Based on observation, record review, and interview with the Senior Manager, Practice Manager, Director of Quality and Patient Safety, and the Supervisor of Ambulatory Quality, the laboratory failed to perform and document annual maintenance of the Microscope for 18 (December 2022 to June 2024) of 18 months reviewed. Findings include: 1. The surveyor observed two microscopes during a tour of the laboratory on 6/10/24 at 9:27 am. 2. A review of the laboratory's "Microscope Care" procedure revealed a section stating, "At least annual servicing will be performed and documented per regular service contracts." 3. A review of the laboratory's microscope service records revealed the most recent maintenance performed was in December 2022. 4. An interview on 6/10/24 at 12:07 pm the Senior Manager, Practice Manager, Director of Quality and Patient Safety, and the Supervisor of Ambulatory Quality confirmed the microscopes had not been serviced since December 2022.</p>
<b>D6079</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(a)(b)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Practice Manager, the Laboratory Director failed to ensure compliance with 493.51 Notification requirements for laboratories issued a certificate of compliance for five (January 2024 to June 2024) of five months since the laboratory changed locations. Findings include: 1. The surveyor arrived at the laboratory's address, 2660 W Sugnet Road, at 9:00 am and the laboratory was locked. The surveyor asked a representative about the laboratory and was directed to the new location, at 4201 Campus Ridge Drive. 2. The surveyor requested documentation of the submission the laboratory made to the State Agency on 6/10/24 at 9:20 am to meet the following notification requirements listed at 493.51: a. "Laboratories issued a certificate of compliance must meet the following conditions: (a) Notify HHS or its designee within 30 days of any change in-- (1) Ownership; (2) Name; (3) Location; (4) Director; or (5) Technical supervisor (laboratories performing high complexity only). (b) Notify HHS no later than 6 months after performing any test or examination within a specialty or subspecialty area that is not included on the laboratory ' s certificate of compliance, so that compliance with requirements can be determined. (c) Notify HHS no later than 6 months after any deletions or changes in test methodologies for any test or examination included in a specialty or subspecialty, or both, for which the laboratory has been issued a certificate of compliance." 3. An interview on 6/10/24 at 12:07 pm with the Practice Manager confirmed the laboratory moved locations in January 2024 and had not notified the State Agency with the change in location within 30 days.