

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0925945	(X3) Date Survey Completed 03/01/2023
Name of Provider or Supplier Michigan Adult & Child Medicine	Street Address, City, State 11885 E 12 Mile Rd Suite 100a, Warren, 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
D6019	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.</p> <p>This STANDARD is not met as evidenced by:</p> <p>. Based on record review and interview with the Office Manager, the Laboratory Director failed to ensure the approved corrective action plan was followed when proficiency testing was found to be unacceptable for 2 (first and second hematology events of 2022) of 3 testing events reviewed. Findings include: 1. A review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records revealed the laboratory received an unacceptable score for the following analytes: a. 2022 Hematology Event 3 i. Leukocytes sample AT-11 received the score of "Fail" ii. Erythrocytes sample AT-11 received the score of "Fail" iii. Hemoglobin sample AT-11 received the score of "Fail" iv. Hematocrit sample AT-11 received the score of "Fail" b. 2022 Hematology Event 1 i. Erythrocytes sample AT-1 received the score of "Fail" ii. Hematocrit sample AT-1 received the score of "Fail" 2. A review of the laboratory's "Proficiency Testing (PT)" procedure revealed a section titled "Troubleshooting Failed and 'Not Graded' PT Results" stating, "If any PT test sample result is graded as "Unacceptable" or "Fail," take action to identify and correct the problem, even if the overall event received a passing grade. Document all troubleshooting actions on the PT Event Report." 3. The surveyor requested documentation of corrective action performed because of the unacceptable results</p>

listed above on 3/1/23 at 2:20 pm and it was not made available. 4. An interview on 3/1/23 at 2:20 pm with the Office Manager confirmed corrective action was not performed and documented for the proficiency testing events listed above.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:
. Based on record review and interview with the Office Manager, the laboratory failed to ensure Testing Personnel #5, performing the duties of a Technical Consultant, had met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035. ***This is a repeated deficiency previously cited at the 8/24/21 recertification survey***

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity

testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Office Manager, the laboratory failed to ensure personnel performing the technical consultant duty of performing testing personnel competency assessments was qualified for 1 (Testing Personnel #5) of 2 personnel performing testing personnel competency assessments. Findings include: 1. A review of the laboratory's personnel competency records revealed the following testing personnel had a competency assessment performed by Testing Personnel #5: a. Testing Personnel #6 on 9/9/22 b. Testing Personnel #7 on 9/9/22 c. Testing Personnel #8 on 9/9/22 d. Testing Personnel #9 on 1/31/22, 7/5/22, and 2/6/23 e. Testing Personnel #10 on 6/13/22 and 12/18/22 2. The surveyor requested the qualifications of Testing Personnel #5 to qualify as a Technical Consultant on 3/1/23 at 2:20 pm and the documentation was not made available. 3. An interview on 3/1/22 at 2:20 pm with the Office Manager revealed Testing Personnel #5 was not qualified as a Technical Consultant and had been performing the Technical Consultant duty of testing personnel competency assessments. ***This is a repeated deficiency previously cited at the 8/24/21 recertification survey***