

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0925945	(X3) Date Survey Completed 08/24/2021
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the Laboratory Director (LD) failed to attest to the routine integration of the hematology proficiency testing samples into the patient workload for 1 (3rd event 2019) of 2 events reviewed for 2 years. Findings include: 1. Record review of the Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing documents, the Laboratory Director (LD) failed to sign the attestation statement sheet for the 3rd event in 2019 of 2 events reviewed for 2 years. 2. An interview on 8/24/2021 at 10:26 am, the OM confirmed the LD did not sign the attestation statement sheet.</p>
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 Office Manager (OM), the laboratory failed to have a written request for patient testing from an authorized person for 1 (#13) of 14 patient charts audited. Findings include: 1. Record review revealed for 1 (#13) of 14 patient charts audited the laboratory did not have a written request for laboratory testing by an authorized person for the potassium hydroxide (KOH) and the</p>

	<p>wet mount testing completed on 7/14/2020. 2. An interview on 8/24/2021 at 11:50 am, the OM confirmed the patients paper chart did not contain a written order for the KOH and wet mount testing.</p>
<p>D5777</p>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(b)(c)</p> <p>(b) The laboratory must have a system to identify and assess patient test results that appear inconsistent with the following relevant criteria, when available: (b)(1) Patient age. (b)(2) Sex. (b)(3) Diagnosis or pertinent clinical data. (b)(4) Distribution of patient test results. (b)(5) Relationship with other test parameters. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to document the comparison studies for the sampling of the patient specimens in the open mode versus the closed mode on the Beckman Coulter Act diff hematology analyzer for 2 (August 2019 to August 2021) of 2 years of testing. Findings included: 1. Record review revealed the laboratory lacked the documentation to show comparison studies were performed and documented twice a year for 2 (August 2019 to August 2021) of 2 years of testing. 2. An interview on 8/24/2021 at 9:55 am, the OM confirmed the laboratory failed to perform and document the comparison studies twice a year.</p>
<p>D5803</p>	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Office Manager (OM), the laboratory failed to have the final potassium hydroxide (KOH) and wet mount testing results maintained as part of the patient's paper chart for 1 (#13) of 14 patient charts reviewed. Findings include: 1. A record review for 1 (#13) of 14 patient charts reviewed revealed a lack of documentation in the patient's paper chart for the KOH and wet mount specimen tested on 7/14/2020. 2. An interview on 8/24/2021 at 11:50 am, the OM confirmed the patient's final KOH and wet mount testing results was not maintained in the patient's paper chart.</p>
<p>D6018</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p>

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Office Manager (OM), the Laboratory Director (LD) and Testing Personnel (TP) failed to ensure proficiency testing reports were reviewed for 2 (3rd event in 2019 and 1st event in 2020) of 2 events reviewed. Findings include: 1. A review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing documents revealed a lack of review of results by the LD or designee and the TP listed on the attestation statement sheet for the following testing events: a. 3rd event in 2019 b. 1st event in 2020 2. An interview on 8/24/2021 at 10:26 am, the OM confirmed the 2 events listed above were not reviewed by the LD and the TP listed on the attestation statement sheet.
Repeat Deficiency from 1/11/2017 survey

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 the Office Manager and Testing Personnel #6, performing the responsibilities of a Technical Consultant met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure the personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035.

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 (OM), the laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified for 4 (Testing Personnel [TP] #5 - #8) of 10 personnel listed on the CMS-209 form. Findings include: 1. A review of the personnel competency records revealed the OM and TP #6 had performed competency assessments on the TP for the following dates: a. TP #6 - OM performed on 9/18/2019 and 9/22/2020 b. TP #7 - TP #6 performed on 9/18/2020 and 9/22/2020 c. TP #8 - TP #6 performed on 9/18/2020 and 9/22/2020 d. TP #9 - TP #6 performed on 1/20/2020 2. A review of the qualifications for the OM and TP #6 revealed they did not meet the qualification requirements to perform Technical Consultant responsibilities. 3. An interview on 8/24/2021 at 9:36 am, the OM confirmed the personnel performing the Technical Consultant responsibilities did not meet the qualification requirements to be Technical Consultants.