

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0962469	(X3) Date Survey Completed 01/26/2022
Name of Provider or Supplier Macomb Physicians Group Pllc	Street Address, City, State 8244 Metro Parkway Suite C, Sterling Heights, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on record review, lack of documentation, and interview with Technical Consultant (TC) #1, the laboratory failed to verify the accuracy of the urine microscopic and the COVID-19 IgM and IgG testing at least twice annually for 1 (January 2020 to January 2022) of 2 years reviewed. Findings include: 1. A record review of the twice a year verification of accuracy documents revealed a lack of documentation as follows: a. urine microscopic - 2 events in 2021 b. COVID-19 IgM and IgG - 1 event 2021 2. An interview on 1/26/2022 at 12:30 and 2:10 pm, TC #1 confirmed there was no verification of accuracy performed for urine microscopic's in 2021 and for the 2 event in 2021 for COVID-19.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p>

This STANDARD is not met as evidenced by:
. Based on record review and interview with Technical Consultant (TC) #1, the laboratory failed to include the patient's scanned final COVID-19 report into the electronic medical records (EMR) for 2 (#3 and #4) of 5 patient charts audited. Findings include: 1. Record review revealed for 2 (#3 and #4) of 5 patient charts audited the final COVID-19 report was not scanned into the patient's EMR file. 2. An interview on 1/26/2022 at 1:11 pm, TC #1 confirmed the final COVID-19 reports were not scanned into the EMR system.

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
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 Technical Consultant #1, the laboratory failed to ensure Testing Personnel #2 performing the duties 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 Technical Consultant (TC) #1, the laboratory failed to ensure personnel performing the TC duty of performing personnel competency assessments was qualified for 6 (Testing Personnel (TP) #4 - #9) of 9 personnel listed on the CMS-209 form. Findings include: 1. A review of the laboratory's personnel competency records revealed TP #2 had performed competency assessments for the following testing personnel: a. TP #4 - performed on 10/28/2020 b. TP #5 - performed on 10/28/2020 c. TP #6 - performed on 10/28/2020 d. TP #7 - performed on 10/28/2020 e. TP #8 - performed on 10/28/2020 f. TP #9 - performed on 10/28/2020 2. A review of the qualifications for TP #2 revealed they did not meet the qualification requirements to perform Technical Consultant responsibilities. 3. An interview on 1/26/2022 at 10:05 am with TC #1 confirmed TP #2 did not meet the qualification requirements to be a Technical Consultant.