

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0857705	(X3) Date Survey Completed 02/09/2023
Name of Provider or Supplier Family Care Physicians	Street Address, City, State 39500 W 10 Mile Road Ste 100, Novi, 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
D3000	<p>FACILITY ADMINISTRATION CFR(s): 493.1100</p> <p>Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe.</p> <p>This CONDITION is not met as evidenced by: . Based on a lack of records and interview with the Technical Consultant (TC), the laboratory failed to report positive SARS-CoV-2 test results as required for 2 (testing on 12/16/2022 and 1/03/2023) of 25 patients tested since the laboratory started testing in December 2022. Findings include: 1. An interview on 2/09/2023 at 11:32 am with the TC revealed the laboratory started testing in December of 2022 and had a total of 25 patients tested with 2 positive tests for SARS-CoV-2. 2. The surveyor requested documentation of the laboratory's attempts to report positive SARS-CoV-2 results using its SARS-CoV-2 antigen test system to the health department on 2/09/2023 at 11:32 am and it was not made available. 3. An interview on 2/09/2023 at 11:32 am, the TC confirmed the laboratory had no documentation showing the 2 patients that had tested positive were reported to the health department.</p>
D6033	<p>TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409</p> <p>The laboratory must have a technical consultant who meets the qualification</p>

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 Technical Consultant, the laboratory failed to ensure the office manager, performing the duties of a Technical Consultant, has 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.

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 Technical Consultant, the laboratory failed to ensure personnel performing the technical consultant duty of performing testing personnel competency assessments was qualified for 1 (office manager) of 2 personnel performing testing personnel competency assessments. Findings include: 1. A review of the laboratory's personnel competency records revealed the Technical

Consultant had a competency assessment performed on November 17, 2021, and November 4, 2022, by the office manager. 2. The surveyor requested the qualifications of the office manager on 2/09/2023 at 9:31 am and the documentation was not made available. 3. A interview on 2/09/2023 at 9:31 am, the TC confirmed the office manager did not have the qualifications to perform the duties of a technical consultant.