Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0864975	04/13/2021
Name of Provider or Supplier	**Street Address, City, State**	
Northern Michigan Regional Laboratory	95 Livingston Blvd, Gaylord, 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
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: . Based on observation and interview with the Technical Consultant (TC), the laboratory failed to test control material in the same manner as patient specimens tested for SARS-CoV-2 for 2 (February 2021 to April 2021) of 2 months the laboratory has been using the BD Max test system. Findings include: 1. An interview on 4/13/21 at 10:44 am with the TC revealed the laboratory started testing for SARS-CoV-2 using the BD Max test system in February 2021. 2. During a tour of the laboratory on 4/13/21 at 8:59 am, the surveyor observed two ventilation hoods in the laboratory. Testing Personnel #2 indicated the laboratory used the PLAS Labs benchtop hood to prepare quality control to be performed using the BD Max SARS-CoV-2 assay and the LabConco ventilation hood was used to prepare patient specimens to be tested. 3. An interview on 4/13/21 at 2:00 pm with the TC confirmed the laboratory was not performing control procedures in the same manner as patient specimens for SARS-CoV-2 testing using the BD Max test system.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

	This CONDITION is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory director failed to meet the qualification requirements for moderate complexity testing and provide overall management and direction in accordance with 493.1407 of this subpart. Findings include: 1. The laboratory failed to employ a laboratory director that met the qualification requirements for moderate complexity testing. Refer to D6003. 2. The laboratory director failed to ensure the BD Max SARS-CoV-2 test system could provide quality results. Refer to D6012. 3. The laboratory director failed to ensure the laboratory's Individualized Quality Control Plan (IQCP) was approved by the laboratory director before putting it into use. Refer to D6020.
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in 493.1407; or (b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under 493.1406; or (b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located. Laboratory director qualifications on or before February 28,

1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance. (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (b)(1) Be a physician certified in anatomical 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; (b)(2) Be a physician who: (b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or (b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board in one of the laboratory specialties; or (b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or (b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification; (b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and (b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or (b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties; (b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either: (b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience; (b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or (b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Technical Consultant (TC), the laboratory failed to employ a laboratory director that met the qualification requirements for moderate complexity testing for 11 (May 2020 to April 2021) of 11 months the laboratory has been operating. Findings include: 1. A record review of

	Laboratory Director's personnel record revealed a lack of documentation of the following: a. Board certification in anatomic or clinical pathology; or b. Documentation of laboratory training during medical residency; or c. Documentation of at least 1 year of experience directing or supervising nonwaived testing; or d. Documentation of completion of 20 continuing medical education credit hours in laboratory practice. 2. An interview with the TC on 4/13/21 at 2:00 pm revealed the laboratory did not have documentation for the Laboratory Director to qualify for directing moderate complexity testing. 3. The laboratory was provided 7 days after the survey to supply documentation and it was not made available.
D6012	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(i) 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)(3) Ensure that-- (e)(3)(ii) The test methodologies selected have the capability of providing the quality of results required for patient care; This STANDARD is not met as evidenced by: . Based on record review and interview with the Technical Consultant, the laboratory director failed to ensure the BD Max SARS-CoV-2 test system could provide quality results for 2 (February 2021 to April 2021) of 2 months the test system has been in use. Findings include: 1. A review of the laboratory's records revealed a lack of verification of performance specifications documentation for the BD Max SARS-CoV-2 test system. 2. A review of the laboratory's "Test Procedure Process Management: Test Procedures, Verification, Calibration & Report Generation" policy revealed a section stating, "When NMRL introduces an unmodified, FDA-cleared or approved test system the following steps will be completed before reporting patient test results: a. Demonstration that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: i . Accuracy ii . Precision iii . Reportable range of test results for the test system b. Verification that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. 3. An interview on 4/13/21 at 2:00 pm with the TC confirmed the laboratory did not have documentation verifying the performance specifications of the BD Max test system and the laboratory director did not review performance specifications prior to the test system being used for patient testing.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by:

	. Based on record review and interview with the Technical Consultant (TC), the laboratory director failed to review and approve the laboratory's Individualized Quality Control Plan (IQCP) before it was put it into use for 9 (June 2020 to April 2021) of 11 months reviewed. Findings include: 1. A review of the laboratory's IQCP for SARS-CoV-2 testing on the Luminex Aries analyzer revealed the laboratory director approved the plan on 4/12/21. 2. An interview on 4/13/21 at 2:00 pm with the TC revealed the laboratory had been using the IQCP since June 2020 without the laboratory director's approval.