Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D0964215	04/21/2021
Name of Provider or Supplier	**Street Address, City, State**	
Mclaren Northern Michigan Medcenter-Petoskey South	1890 Us 131 South Suite 4, Petoskey, 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
D1002	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. This CONDITION is not met as evidenced by: . Based on record review and interview with the laboratory liaison (LL), the laboratory failed to report SARS-Co-V-2 test results as required for 6 (October - December 2020 and January - April 2020) of 6 months of patient testing. Findings include: 1. A record review revealed the laboratory was using 2 different methods of Covid testing as follows: a. BD Veritor Plus Analyzer - started testing on 10/22/2020 b. Cepheid GeneXpert - started testing on 11/23/2021 2. When queried on 4/21/2021 at 10:54 am, the LL informed the surveyor that the laboratory failed to report all patient testing to the health department. 3. An interview on 4/21/2021 at 10:54 am, the LL confirmed the laboratory failed to report all patient testing to the health department, they were reporting only the positive test results.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test

	results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: . Based on record review and interview with the laboratory liaison (LL), the laboratory failed to document corrective action for the out of range humidity readings in the laboratory for 3 months (November and December 2020 and January 2021) of 2 years of documents reviewed. Findings include: 1. A record review of the "Temperature/Humidity Chart/Lab" log showed the range for acceptable humidity is 30 - 95%. The logs revealed for 3 months of 2 years reviewed the following dates the humidity readings were outside the stated range: a. November 2020 - 17-18 and 22-25 b. December 2020 - 5-7 and 30 c. January 2021 - 2 and 30-31 2. An interview on 4/21 /2021 at 11:05 am, the LL confirmed no corrective action had been performed and documented to resolve the out of range humidity readings.