

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D1084790	(X3) Date Survey Completed 04/20/2021
Name of Provider or Supplier Mclaren Northern Michigan Med Center-Boyne City	Street Address, City, State 1249 M 75 South, Boyne City, 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	<p>REPORTING OF SARS-CoV-2 TEST RESULTS</p> <p>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 record review and interview with Testing Personal (TP) #2, the laboratory failed to report SARS-Co-V-2 test results as required for 73 of 73 patient tests performed since the Cepheid GeneXpert instrument was installed on 12/03/2020. Findings include: 1. A record review of the "Genexpert Log" revealed for 73 of 73 patient tests performed, the laboratory failed to report all positive and negative patient results to the health department. 2. When queried on 4/20/2021 at 1:10 pm, TP2 would only confirm that positive test results had been forwarded onto the health department. 3. An interview on 4/20/2021 at 1:10 am, TP2 confirmed the laboratory was not reporting all patient SARS-CoV-2 testing to the health department, they were reporting only the positive tests.</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 Testing Personnel (TP) #2, the laboratory failed to have a written or electronic request for patient testing from an authorized</p>

	<p>person for 1 (#15) of 19 patient charts reviewed. Findings include: 1. A record review revealed for 1 (#15) of 19 patient charts reviewed the laboratory did not have a written or electronic request for the hematology complete blood cell count (CBC) by an authorized person. 2. An interview on 4/20/2021 at 12:57 pm, TP2 confirmed there was no written or electronic orders for the patient CBC testing.</p>
<p>D5787</p>	<p>TEST RECORDS CFR(s): 493.1283(a)</p> <p>The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #2, the laboratory failed to maintain a record system that included the identity of the testing personnel on the final laboratory report for 1 (#8) of 19 patient charts reviewed. Findings include: 1. A record review for 1 (#8) of 19 patient charts reviewed revealed the identity of the testing personnel was not recorded on the "Urine Sediment Results" form. 2. A interview on 4/20/2021 at 1:07 pm with TP2, confirmed the testing personnel failed to provide their initials on the urine sediment result form.</p>
<p>D5805</p>	<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> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel (TP) #2, the laboratory failed to include the test results on the final report in the laboratory information system (LIS) for 1 (#8) of 19 patient charts reviewed. Findings include: 1. A record review revealed for 1 (#8) of 19 patient charts reviewed, the final urine microscopic result was not recorded on the "Urine Sediment Results" form prior to being scanned into the LIS. 2. A interview on 4/20/2021 at 1:07 pm, TP2 confirmed the final results in the LIS system did not contain any laboratory results for the test requested.</p>