

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0944519	(X3) Date Survey Completed 05/17/2021
Name of Provider or Supplier Premier Medicine Pc	Street Address, City, State 20290 Middlebelt Road, Livonia, 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 the Laboratory Director (LD), Testing Personnel (TP) #1, and an in-house physician, the laboratory failed to report SARS-CoV-2 test results as required for 3 (3/01/2021 to 5/17/2021) of 3 months of testing with the BD Veritor System Rapid Detection SARS-CoV-2. Findings include: 1. A tour of the laboratory on 5/17/2021 at 8:59 am revealed a BD Veritor System for SARS-CoV-2 testing on the counter. 2. When queried on 5/17/2021 at 9:25 am, TP1 stated that testing began on 3/01/2021 and that positive and negative test results had not been forwarded onto the local and/or state health department. 3. An interview on 5/17/2021 at 9:25 am, the LD, TP1, and the in-house physician confirmed the laboratory was not reporting negative and positive patient SARS-CoV-2 testing to the local and/or state health department.</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 the Laboratory Director (LD), the</p>

laboratory failed to have a written or electronic request for patient testing from an authorized person for 2 (#13 and #14) of 14 patient charts reviewed. Findings include: 1. A record review revealed for 2 (#13 and #14) of 14 patient charts reviewed the laboratory did not have a written or electronic request for the toxicology testing by an authorized person. 2. An interview on 5/17/2021 at 11:45 am, the LD confirmed there was no written or electronic orders for the patient toxicology testing.

D5805

TEST REPORT
CFR(s): 493.1291(c)

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.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the Laboratory Director (LD), the laboratory failed to ensure the correct name and address of the laboratory location where toxicology testing is performed was on the final test report for 14 (Patients #1-#14) of 14 patient charts reviewed. Findings include: 1. A record review for 14 (#1 - #14) of 14 patient charts reviewed revealed the correct name and address of the laboratory performing the toxicology testing was not on the final report. 2. An interview on 5/17/2021 at 12:10 pm, the LD confirmed the laboratory reports did not have the testing laboratories name and address on the final reports.