Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D2184520	11/05/2020
Name of Provider or Supplier	**Street Address, City, State**	
Minnesota Monitoring Inc	2901 Louisiana Ave N, Minneapolis, MN	

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
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: . Based on observation, review of test result reports, and interview with laboratory personnel, the laboratory performed testing outside the scope of their CLIA Certificate of Waiver. Findings are as follows: 1. An open Orient Gene COVID-19 IgG/IgM Rapid Test Cassette test kit with lot number 2004158 and expiration date 2022/04 was observed in the processing area upon investigation entry at 2:25 p.m. on 11/03/20. 2. Testing personnel RN1 and RN2 indicated they were both trained and able to perform the Orient Gene antibody test at 2:40 p.m. on 11/03/20. 3. In an interview on 11/03/20 at 3:20 p.m., the Laboratory Supervisor (LS) indicated all antibody testing was being sent to a reference laboratory and none was performed on-site. 4. The Orient Gene COVID-19 IgG/IgM Rapid Test Cassette test kit was not in the processing area upon investigation exit at 4:15 p.m. on 11/03/20, nor reentry at 3:35 p.m. on 11/05/20. 5. Two COVID-19 IgG/IgM Rapid test result reports obtained from the facility on 10/20

	/20 were received by the State Agency from the complainant via email at 9:57 p.m. on 11/03/20. RN1 performed both tests. RN1 was not in the facility for interview on 11 /05/20. 6. In an interview at 3:40 p.m. on 11/05/20, RN2 indicated she performed the Orient Gene antibody test in April and May 2020. She was away from the facility until 10/29/20. She indicated she had not performed any Orient Gene antibody tests since returning. The test kit was available for use on 10/29/20 and 11/03/20. When reporting for work on 11/05/20, she was informed the laboratory was no longer performing the Orient Gene antibody test. 7. In an interview at 3:45 p.m. on 11/05/20, RN3 indicated she performed the Orient Gene antibody test in April and May 2020. She was away from the facility in June. When she returned in early July, the Orient Gene antibody test was available for use each day she worked; nearly every Thursday. The test was not available for use on 11/05/20. RN3 estimated she performed 2-3 Orient Gene antibody tests per month in July through October 2020. 8. Two open Orient Gene COVID-19 IgG/IgM Rapid Test Cassette test kit with lot number 2004158 and expiration date 2022/04 were observed in the LS's office at 3:55 p.m. on 11/05/20. A total of 48 test cassettes remained in the test kits. The LS indicated 252 test cassettes had been used as the facility had obtained 300 tests in a single shipment. 9. In an interview at 4:05 on 11/05/20, the LS indicated she was not aware the testing personnel were performing the Orient Gene antibody test. She stated the testing personnel must have retrieved the test kits from the storage location in her office without her knowledge. .
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: . Based on observation, review of the manufacture's instructions for use, and interview with the Laboratory Supervisor (LS), the laboratory failed to ensure testing personnel followed the manufacturer's instructions for sample processing and test result reporting. Findings are as follows: 1. The laboratory performed the Quidel Sofia 2 SARS Antigen FIA test. Open test kits with lot number 143489 and expiration date 09 /02/21 were observed and in use in the processing area upon investigation entry at 2: 25 p.m. on 11/03/20. 2. Testing began on 07/08/20 as indicated by the LS at 3:30 p.m. on 11/03/20, during observation of the testing area . A Quidel Sofia analyzer was observed in use. 3. The manufacturer's instructions for use, Sofia SARS Antigen FIA, indicated the following: -A single collection and dispense of the patient sample using the 120 uL fixed volume disposable pipette provided with the test kit was required. The pipette was designed to collect and dispense the correct amount of patient sample. -Test Fact Sheets must accompany all test result reports. 4. During observation of sample processing at 2:25 p.m. through 2:45 p.m. on 11/03/20, testing personnel RN1 and RN2 were observed processing 2 samples each. RN1 and RN2 used the disposable pipettes to collect and dispense each patient sample from the processing tube to the test cartridge multiple times until all sample was transferred from the tube. 5. Test result reports were observed as delivered to patients without the required test Fact Sheet at 3:10 p.m. on 11/03/20. Test Fact Sheets were not available in the processing area or the testing area for delivery to patients with the test result reports. 6. The laboratory did not use a testing log or other means to record daily patient or testing information. The LS indicated at 3:15 on 11/03/20, that photographs of

	positive patient test results were retained for reporting purposes and indicated the total number of tests could be retrieved from the Sofia analyzer when not in test mode. 7. In an interview at 3:10 p.m. on 11/03/20, the LS confirmed test fact sheets were not provided with the test result reports. At 3:40 p.m. on 11/03/20, the LS confirmed sample pipetting did not follow the manufacturer's instructions for use. The LS explained the manufacturer's service representative instructed the laboratory to pipette all of the patient sample into the test cartridge. This guidance was not in writing. 8. In an email received at 4:46 p.m. on 11/04/20, the LS indicated the laboratory had performed 1,024 Sofia 2 SARS antigen tests.