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This standing prescription order is issued by Dr. Ryan Westergaard, Chief Medical Officer and State Epidemiologist for the Department of Health Services (DHS) of the State of Wisconsin, at the direction of Secretary-designee Andrea Palm. This order authorizes trained personnel to collect and analyze COVID-19 point of care testing samples, in accordance with the conditions of this order. This order may not be used unless the COVID-19 test is conducted in accordance with the following requirements related to patient eligibility, confirmatory testing, staff training, safety, and appropriate plan of care.

This order authorizes the use of tests with Food and Drug Administration (FDA) authorization that are distributed by the United States Department of Health and Human Services or by the State of Wisconsin. A list of tests with an Emergency Use Authorization is available from the FDA[1] and includes the following:

Test Name	Instrument Required	Specimen Types
Quidel Sofia 2 SARS Antigen FIA	Sofia 2 FIA Analyzer	Nasal Pharyngeal (NP) or Nasal swab Collect within 5 days of symptom onset
BD Veritor System for Rapid Detection of SARS-CoV-2	BD Veritor Plus Analyzer	Nasal swab Collect within 5 days of symptom onset
LumiraDx SARS-Cov-2 Ag Test	LumiraDX Instrument	Nasal swab Collect within 12 days of symptom onset
Abbott BinaxNOW COVID-19 Ag Card*	None	Nasal swab Collect within 7 days of symptom onset

** The Abbott BinaxNOW COVID-19 Ag card test was not assessed for persons under age 22 in the FDA EUA. Therefore, testing of children with this product is considered off-label use. However, the FDA provided guidance that such off-label use may be appropriate in some settings where access to highly sensitive tests is inadequate.*

To be valid under this order, the COVID-19 POC test must be conducted in accordance with the following requirements:

- Tests must be used on patients who meet DHS-established eligibility criteria.[a]
- Organizations administering tests must ensure patients have access to confirmatory testing, when indicated.[b]
- Tests must be administered in accordance with instructions specified by the manufacturer, in an environment with a CLIA certificate or waiver.[c]
- Patients must provide at least verbal consent for testing, and be provided with appropriate educational materials approved by DHS.[d]
- Organizations administering tests must submit all results and required patient-level data to public health agencies within 24 hours of test administration.[e]

See further instructions and resources on next page

[a] Eligibility Criteria: Adults and children with symptom(s) or exposure to COVID-19, as identified in DHS COVID-19 Health Alert #13, *Recommendations for COVID-19 Testing*, who have any one or more symptom suggestive of COVID-19, OR have been in close contact with a person with confirmed or suspected COVID-19, regardless of symptoms OR have been instructed to receive testing by a public health agency. Organizations intending to use POC tests for asymptomatic screening should consult with DHS for authorization before testing individuals without any history of symptoms or exposure.

[b] Confirmatory Testing: Patients with symptoms who receive a negative POC result or asymptomatic individuals with a positive POC result must receive a second, confirmatory test within 48 hours, as identified in the DHS COVID-19 Health Alert #17, *Important Considerations for Use of COVID-19 Antigen Tests*.

[c] CLIA Certificate: All COVID-19 POC tests must be conducted in an environment with a certificate or waiver under the CLIA, 42 U.S.C. §263a. CLIA waivers and certificates may be obtained through the Centers for Medicare and Medicaid Services[3].

[d] Patient education: DHS-supported point of care testing must address the following requirements to support all individuals receiving a COVID-19 test:

1. Patients must provide verbal consent, attesting to their eligibility for testing and understanding of the testing process, documented by Staff. Parental consent must be obtained for patients ages 0-17 years.
2. Patients must be provided a copy of the privacy notice.
3. Patients must be provided educational materials about the meaning of COVID-19 test results and the importance of isolation and quarantine.
4. Test results must be reported to the patient immediately upon receipt of the test result, with assurance of appropriate follow-up by local public health regarding isolation and contact tracing, if positive.

[e] Data Collection and Reporting: Test results must be reported to the State of Wisconsin and to federal authorities (HHS). Reporting account set-up[4] and guidance[4] is available from DHS.

This Order is effective as of the date below and shall remain effective until withdrawn by Dr. Westergaard. Dr. Westergaard retains the right to modify or supplement this Order as needed.

_____ 10-28-2020

Dr. Ryan Westergaard, MD, PhD, MPH — Date

Chief Medical Officer and State Epidemiologist for Communicable Diseases
Wisconsin Department of Health Services

[1] COVID-19 tests with FDA EUA https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidinvitrodev
[2] Department of Health Services Health Alert Network https://www.dhs.wisconsin.gov/covid-19/han.htm
[3] Quick Start Guide to Applying for a CLIA Certificate https://www.cms.gov/files/document/cms-clia-laboratory-quick-start-guide-remediated.pdf
[4] DHS COVID-19 Health Care Providers, Reporting and Surveillance guidance https://www.dhs.wisconsin.gov/covid-19/providers.htm and account set up http://www.slh.wisc.edu/wlr-request/