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ASIA EDITION

Abbott's COVID-19 antigen test receives FDA emergency use authorization

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Abbott's BinaxNOW™ COVID-19 Ag Card is a rapid, reliable & affordable tool for detecting active coronavirus infections at massive scale

Abbott, a global healthcare leader recently announced that the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for its BinaxNOW™ COVID-19 Ag card rapid test for detection of COVID-19 infection. Abbott will sell this test for $5. It is highly portable (about the size of a credit card), affordable and provides results in 15 minutes. BinaxNOW uses proven Abbott lateral flow technology, making it a reliable and familiar format for frequent mass testing through their healthcare provider. With no equipment required, the device will be an important tool to manage risk by quickly identifying infectious people so they don't spread the disease to others.

In data submitted to the FDA from a clinical study conducted by Abbott with several leading U.S. research universities, the BinaxNOW COVID-19 Ag Card demonstrated a sensitivity of 97.1% (positive percent agreement) and specificity of 98.5% (negative percent agreement) in patients suspected of COVID-19 by their healthcare provider within the first seven days of symptom onset.

Under FDA EUA, the BinaxNOW COVID-19 Ag Card is for use by healthcare professionals and can be used in point-of-care settings that are qualified to have the test performed and are operating under a CLIA (Clinical Laboratory Improvement Amendments) Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. The BinaxNOW COVID-19 Ag Card can be used as a first line of defense to identify people who are currently infected and who should isolate themselves to help prevent the spread of the disease.