POOLED TESTING FACT SHEET FOR HEALTHCARE PROVIDERS

Xpert® Xpress SARS-CoV-2– Cepheid Updated: April 10, 2020
Baxter Regional Medical Center Pooled Sample Testing June 22, 2020

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Xpert Xpress SARS-CoV-2 test for grouped testing on pooled samples ina p[opulation with ≤10% COVID-19 prevalence.

The Xpert Xpress SARS-CoV-2 test is authorized for use on respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider. Baxter Regional Medical Center (BRMC) has applied for an Emergency Use Authorization (EUA) for testing on pooled samples from asymptomatic patients for screening purposes in order to conserve scarce testing resources. This measure is necessary to ensure that sufficient inventory of testing supplies are available throughout this emergency in the face of inconsistent and insufficient resources supplied by vendors. Without pooling, BRMC is not able to consistently provide timely SARS-CoV-2 testing to meet the needs of our patients and providers while complying with State and Federal testing requirements including but not limited to screening pre-surgical patients, residents entering or returning to long term care facilities or prior to physician clinic visits.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Xpert Xpress SARS-CoV-2 test.

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

* SARS-CoV-2 screening by pooled testing for the detection of COVID-19 will be performed on asymptomatic individuals with no known exposure to COVID-19 in the last 14 days. If a patient is symptomatic, individual testing will be performed.

* The Xpert Xpress SARS-CoV-2 test is used to test nasopharyngeal or mid-turbinate swab using the GeneXpert Dx laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests in accordance with EUA specified instructions

* Pooled screening will only be performed in BRMC's main Laboratory located at 624 Hospital Drive

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)* . For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (*see links provided in "Where can I go for updates and more information" section).

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

What is group testing on pooled samples and how does it differ from the regular method?

* Group testing on pooled samples has been used by American and global blood suppliers for decades to conserve scarce and hard to obtain testing resources. The difficulty to obtain and in consistency in supply of reagents during this COVID-19 emergency necessitates the need for similar strategic applications to ensure the safety of our communities we serve.

* This technique is a simple modification of the Cepheid Xpert Express SARS-CoV-2 method for analysis of asymptomatic patients in pools of up to five samples. If any pool tests positive for either target RNA segments (E or N2), all five patient samples in the pool will be tested individually following the Cepheid Xpert Express SARS-CoV-2 Standard of Operation (SOP).

* The analytical phase of the test is not modified, and the performance of the pooled testing has been verified to have the same Limit of Detection (LoD) of 250 viral copies per mL.

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The Xpert Xpress SARS-CoV-2 test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories and healthcare providers in patient care settings using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of COVID-19.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

Risks to a patient of a false negative include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

What is an EUA?

BRMC has submitted for an Emergency Use Authorization (EUA) for the grouped testing of pooled samples. The United States (U.S.) FDA has made Cepheid Xpert Express SARS-CoV-2 available under this emergency access mechanism. The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An In-Vitro Diagnostic (IVD) made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used). The same is true for the EUA request made by BRMC for group testing of pooled samples.

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**