BD SARS-CoV-2 Reagents for BD MAX™ System

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Agenda

- BD mission
- BD MAX System and BioGX SARS-CoV-2 Reagents
- Specimen types
- Results
- Limitations
- Other diagnostics under development
- Q&A
Our mission

BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics and the delivery of care.

- Increasing access
- Improving outcomes
- Mitigating cost pressures
- Protecting patients and healthcare workers
How BD is mobilizing to combat COVID-19

1. Expanding access to COVID-19 diagnostic testing
2. Providing new training on infection control practices
3. Supporting patient management in the ICU
4. Tracking and reporting COVID-19 data and impact
5. Accelerating discovery of potential therapies
6. Preparing for mass vaccination
7. Collaborating with global health agencies
8. Grant making and volunteering on the front lines
BD Approach COVID-19 Diagnostics

- Molecular
- Serology
- Antigen detection
The BD MAX™ System Automates Extraction and Amplification
Simple and Efficient Reagent Design

BD MAX Unitized Reagent Strip

- Reagents and consumables included in unitized reagent strip
- Sample processing control (SPC) is included for assurance of quality results
- Ambient temperature storage
- Broad menu – unique & clinically differentiated IVD assays & Open System Reagents (OSR) for lab developed tests
Simple and Efficient Reagent Design

**BD MAX PCR Cartridge**

- Individual PCR reaction for each well, providing added flexibility
- Each well is sealed to prevent amplicon contamination for assurance of quality results
- Cartridges can be used multiple times until all lanes have been utilized to decrease wastage
BD MAX™ System - uniquely designed to address emerging threats through Open System Architecture

- Fully automated molecular platform ... pathogen extraction, amplification & detection
- Supports IVD assays & **Open System Reagents (OSR)**
- Compliant to FDA’s Guidance Molecular Diagnostic Instruments with Combined Functions (OSR)
- Variable run size (1 to 24 samples) with multiple assays

**Simplified and Efficient Workflow (less than one minute of hands-on time per sample)**

1. Add specimen to Sample Buffer Tube, then to Rack.
2. Load Unitized Reagent Strips with extraction and PCR reagents.
3. Place a PCR cartridge in the reader.
4. Run Test

<1 minute per specimen
Diagnostic testing

• Preanalytical considerations
  – Specimen type
  – Collection device
  – Transport conditions

• Analytical considerations
  – Test platform
  – Test assays
  – Authorized specimen type and collection device
Analytical Considerations

Swab Specimen Collection

- Nasopharyngeal – flocked swab; HCP collected; preferred
- Mid-turbinate – flocked swab; HCP or self-collected; symptomatic only
- Nares x 2 – Foam swab; HCP or self-collected; symptomatic only
- Oropharyngeal – flocked/foam/polyester swab; HCP collected; combine with nares
- Sputum – if productive

Swab Specimen Transport

- Universal Transport Media (UTM) or Viral Transport Media (VTM) preferred
- Lab developed viral transport media
- Liquid Amies transport media
- Phosphate buffered saline

**Recommended Transport Conditions**

- 4°C for up to 72 hours
- Frozen beyond 72 hours
BD SARS-CoV-2 Reagents for BD MAX™ System & Specimen types
**BD MAX™ System assay options**
Utilizing Open System capabilities, consumables and reagents

**VIASURE SARS-CoV-2 S gene Real Time PCR Detection Kit**
- Developed by CerTest and CE-IVD on BD MAX System March 9
- Detects a conserved region of the SARS-CoV2-S gene (single target)
- Distributed by BD in Europe with options for other countries recognizing CE/IVD

**BioGX SARS-CoV-2 Reagents on the BD MAX™ System**
- Launched under the FDA Emergency Use Authorization (EUA) with BD submission
- Assay developed by BioGX on BD MAX System in line with the CDC design (N1/N2 dual target)
- Exclusive distribution by BD in US

**BD SARS-CoV-2 Reagents on the BD MAX™ System**
- Developed by BD based on the CDC design; currently US FDA EUA designation and CE marked to the IVD Directive (98/79/CE) with Health Canada submissions planned
- Provides additional testing capacity for COVID-19 for the US and countries recognizing CE Mark.

*All options require BD TNA-3 Extraction Kit*

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BD SARS-CoV-2 Reagents for the BD MAX™ System

The BD SARS-CoV-2 Reagents for BD MAX™ System is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasal, nasopharyngeal, and oropharyngeal swab samples from individuals suspected of COVID-19 by their healthcare provider.

<table>
<thead>
<tr>
<th>BD SARS-CoV-2 Reagents for BD MAX™ System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Catalog number</td>
</tr>
<tr>
<td>Distributor</td>
</tr>
<tr>
<td>Test type</td>
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<tr>
<td>Platform</td>
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<tr>
<td>Regulatory Status</td>
</tr>
<tr>
<td>Primary use</td>
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<tr>
<td>Appropriate use case</td>
</tr>
<tr>
<td>Gene region</td>
</tr>
<tr>
<td>CLIA requirements</td>
</tr>
<tr>
<td>Kit configuration</td>
</tr>
<tr>
<td>Specimen type(s)</td>
</tr>
<tr>
<td>Transport media</td>
</tr>
<tr>
<td>Time-to-result</td>
</tr>
<tr>
<td>Run capacity</td>
</tr>
<tr>
<td>Reagent storage</td>
</tr>
<tr>
<td>Materials required but not provided</td>
</tr>
</tbody>
</table>
Results & Limitations
Examination and Interpretation of Patient Specimen Results

Assessment of clinical specimen test results should be performed after the external positive and negative controls have been examined and determined to be valid and acceptable.

<table>
<thead>
<tr>
<th>N1 Region</th>
<th>N2 Region</th>
<th>Extraction Control (RNase P)</th>
<th>CoV-2</th>
<th>Result Interpretationab</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pos</td>
<td>Pos</td>
<td>Pos/Neg</td>
<td>Pos</td>
<td>Positive</td>
<td>Report as Positive</td>
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<tr>
<td>Pos</td>
<td>Neg</td>
<td>Pos/Neg</td>
<td>Pos</td>
<td>Positive</td>
<td>Report as Positive</td>
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<tr>
<td>Neg</td>
<td>Pos</td>
<td>Pos/Neg</td>
<td>Pos</td>
<td>Positive</td>
<td>Report as Positive</td>
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<tr>
<td>Neg</td>
<td>Neg</td>
<td>Pos</td>
<td>Neg</td>
<td>Negative</td>
<td>Report as Not Detected</td>
</tr>
<tr>
<td>Neg</td>
<td>Neg</td>
<td>Neg</td>
<td>UNR</td>
<td>UNR</td>
<td>Repeat Testc</td>
</tr>
</tbody>
</table>

abUNR = Unresolved  
Claboratories should report their diagnostic result as appropriate and in compliance with their specific reporting system.  
cRepeat Test by preparing a fresh sample buffer tube from the original primary UVT or UTM sample.

**Source:** BD SARS-CoV-2 Reagents for BD MAX System Package Insert, P0252(01) 2020-4.  
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Results

A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected and the patient is infected with the virus. 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.

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.

Note: Patient management should follow current CDC or Regional guidelines.
Clinical Evaluation
BD SARS-CoV-2 Reagents for BD MAX System

The performance with retrospective collected nasopharyngeal swab clinical samples was evaluated using 30 individual negative clinical samples and 50 contrived positive clinical samples collected from patients with signs and symptoms of an upper respiratory infection.

Low positive and moderate positive contrived clinical samples were prepared by spiking quantified genomic RNA (SARS-CoV-2 USA-WA1/2020 strain) into individual negative clinical matrix to ~1-2x LoD (40 samples) and ~3-5x LoD (10 samples), respectively.

The low positive samples showed 95% agreement with the expected results. All moderate positive sample (~3-5x LoD) were positive and all negative samples were negative in the background of individual clinical sample matrix.

Source: BD SARS-CoV-2 Reagents for BD MAX System Package Insert, P0252(01) 2020-4.

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Limitations

BD SARS-CoV-2 Reagents for BD MAX System

- Reagent Kit has been evaluated only for use in combination with the BD MAX™ ExK™ TNA-3 kit (extraction kit) and the BD MAX System.
- Reliable results depend on the proper sample collection, storage and handling procedures.
- This test is intended to be used for the detection of SARS-CoV-2 RNA in nasopharyngeal and oropharyngeal swab samples collected in BD Universal Viral Transport System (UVT) or Copan Universal Transport Media System (UTM). Testing of other sample types may result in inaccurate results.
- Nasal swabs and mid-turbinate nasal swabs are considered acceptable specimen types for the with the BD SARS-CoV-2 Reagents but performance with these specimen types has not been established. Testing with these swabs is limited to patients with symptoms of COVID-19 (see FDA’s FAQ on Diagnostic Testing for SARS-CoV-2 for additional information).
- Detection of SARS-CoV-2 RNA may be affected by sample collection methods, patient factor (e.g., presence of symptoms), and/or stage of infection.
- As with any molecular test, mutations within the target regions of SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- Due to inherent differences between technologies, it is recommended that, prior to switching from one technology to the next, users perform method correlation studies in their laboratory to qualify technology difference. One hundred percent agreement between the results should not be expected due to aforementioned difference between technologies. Users should follow their own specific policies/procedures.
- False negative or invalid results may occur due to interference. The Rnase P endogenous control is included to help identify the specimens containing substance that may interfere with nucleic acid isolation and PCR amplification.
- Good Laboratory practices and careful adherence to the processing steps specified in the Instructions For Use are necessary to avoid contamination of reagents.
1. Expanding access to COVID-19 diagnostic testing

Novel point of care antigen test to aid in diagnosis

BD is working with research partners to identify candidate designs for use on BD Veritor™ platform and also a visually read lateral flow assay.

May help reduce test burden on strained healthcare systems and public health laboratories.

May be useful for triaging patients; approximately 80% of patients with COVID-19-like symptoms test negative.¹


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1. Expanding access to COVID-19 diagnostic testing

**Novel rapid serology test**

Detects IgM and IgG antibodies against SARS-CoV-2. Identifies antibodies in the blood to help identify those with recent and previous infection. May be helpful for:

- Measuring the impact and spread of COVID-19 in a population.
- Understanding the immune response to COVID-19 infection, including duration of immunity.
- Identifying patients with prior infection for possible participation in research activities such as evaluation of novel treatments, including convalescent plasma.

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