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

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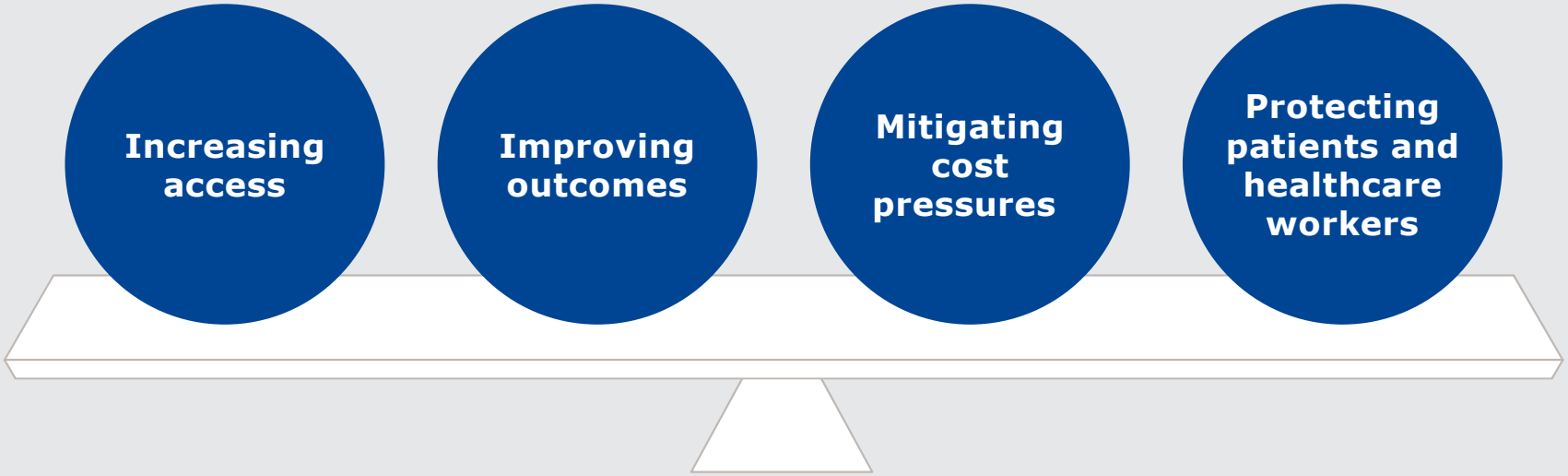
Agenda

- 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.



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

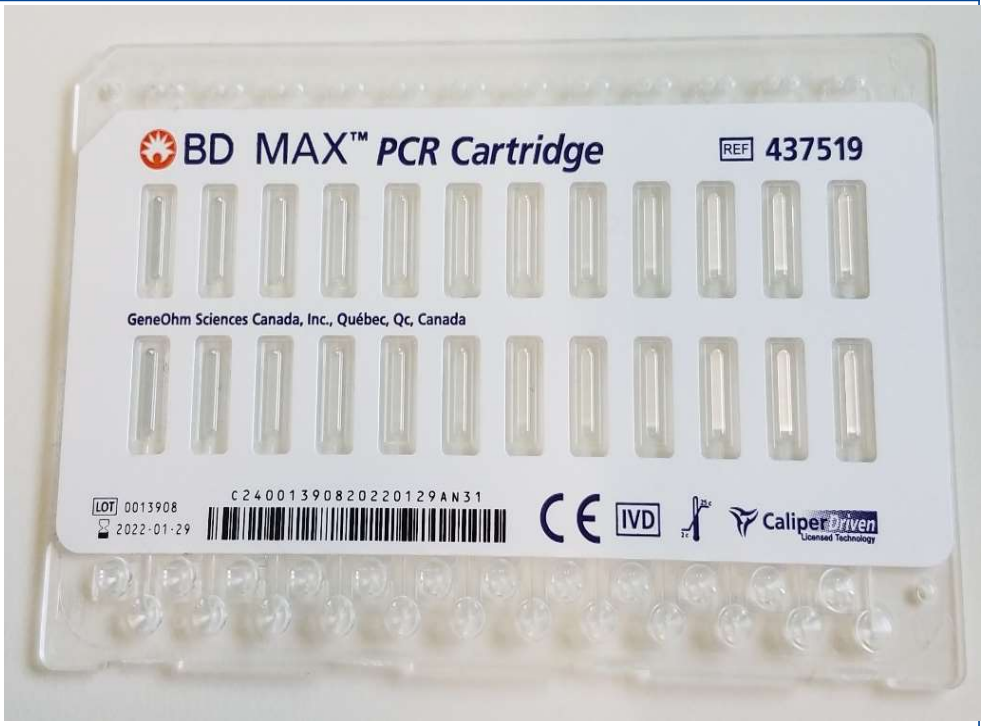
BD MAX Unitized Reagent Strip

- 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

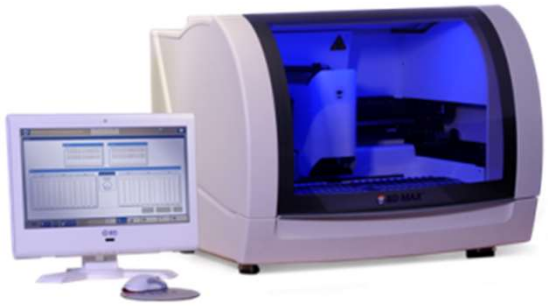
Simple and Efficient Reagent Design

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)

Add specimen to Sample Buffer Tube, then to Rack.

Load Unitized Reagent Strips with extraction and PCR reagents.

Place a PCR cartridge in the reader.

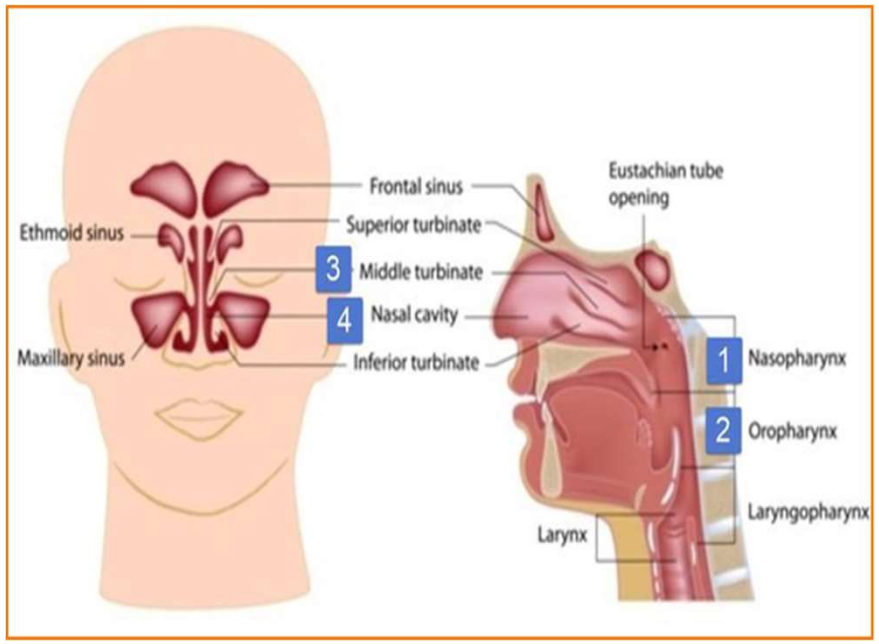
Run Test

<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**
  - 4^0C 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

Partner Developed

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

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.

	BD SARS-CoV-2 Reagents for BD MAX™ System
Manufacturer	Becton, Dickinson and Company
Catalog number	445003
Distributor	Becton, Dickinson and Company
Test type	Molecular (Real-time RT-PCR)
Platform	BD MAX™ System (441916)
Regulatory Status	FDA EUA (4/7/2020); CE-IVD (4/10/2020); Health Canada (In progress)
Primary use	Detection of SARS-CoV-2 by amplifying two unique regions of the N gene (i.e., N1 and N2).
Appropriate use case	Individuals suspecting active COVID-19 infection
Gene region	N1 and N2; human RNase Pgene
CLIA requirements	Moderate or High Complexity
Kit configuration	24 tests per kit
Specimen type(s)	Nasal, nasopharyngeal, or oropharyngeal swabs
Transport media	Copan Universal Transport Media or BD Universal Viral Transport
Time-to-result	~90 minutes (1-4 samples) / ~ 3 hours (24 samples)
Run capacity	Up to 24 samples
Reagent storage	Ambient
Materials required but not provided	442827 (BD MAX™ ExK™ TNA-3); 437519 (BD MAX™ PCR Cartridge); Sample Collection Device

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 2: Interpretation of Patient Specimen Results

N1 Region	N2 Region	Extraction Control (RNase P)	CoV-2	Result Interpretation[a,b]	Actions
Pos	Pos	Pos/Neg	Pos	Positive	Report as Positive
Pos	Neg	Pos/Neg	Pos	Positive	Report as Positive
Neg	Pos	Pos/Neg	Pos	Positive	Report as Positive
Neg	Neg	Pos	Neg	Negative	Report as Not Detected
Neg	Neg	Neg	UNR	UNR	Repeat Test[c]

[a]UNR = Unresolved

[b]Laboratories should report their diagnostic result as appropriate and in compliance with their specific reporting system.

[c]Repeat 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.

Results

- A positive tests 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.

Table 4. Clinical evaluation with contrived nasopharyngeal swab samples

Sample Concentration	Total Valid Results	% Positive Results	N1 Region		N2 Region		RNase P
			Agreement with Expected Results	Mean Ct	Agreement with Expected Results	Mean Ct	Mean Ct
~1-2x LoD	40	95% (38/40)	37/40[a]	33.9[a]	37/40[b]	33.9[b]	20.9
~3-5x LoD	10	100% (10/10)	10/10	32.6	10/10	32.3	20.1
Negative	29[c]	N/A (0/29)[c]	29/29[c]	N/A	29/29[c]	N/A	20.4

[a] One sample was positive for N1 detection but negative for N2 detection

[b] One sample was positive for N2 detection but negative for N1 detection

[c] During screening one retrospective nasopharyngeal swab clinical sample resulted in an UNR for N1 and N2 and as a result the sample was removed from data analysis.

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.

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]

IN DEVELOPMENT

1) COVID Tracking Project. https://covidtracking.com/data. Access 5 April 2020

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.

For more information, visit BD.com.
https://news.bd.com/2020-03-31-BD-BioMedomics-Announce-Launch-of-Rapid-Serology-Test-to-Detect-Exposure-to-COVID-19