



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

REF 444213

For Emergency Use Authorization (EUA) Only
For *In Vitro* Diagnostic Use
For use with the BD MAX™ System

P0251(05)
2020-09
English



Rx Only

INTENDED USE

The BioGX 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 nasopharyngeal, nasal, mid-turbinate, and oropharyngeal swab specimens, nasopharyngeal wash/aspirate or nasal aspirates obtained from individuals suspected of COVID-19 by their health care provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definitive cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The BioGX SARS-CoV-2 Reagents for BD MAX System is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR, *in vitro* diagnostic procedures, and use of the BD MAX System. The BioGX SARS-CoV-2 Reagents for BD MAX System is only for use under the Food and Drug Administration's Emergency Use Authorization.

EXPLANATION OF THE TEST

Total nucleic acid (TNA) is isolated and purified using BD MAX™ ExK™ TNA-3 kit from nasopharyngeal and/or oropharyngeal swabs collected in BD Universal Viral Transport System (UVT) or Copan Universal Transport Media System (UTM). Patient sample is transferred to the Sample Buffer Tube (SBT) provided in the BD MAX ExK TNA-3 kit and placed in the BD MAX System. The final eluate is used to rehydrate BioGX SARS-CoV-2 Reagents, which contains all reagents necessary for RT-PCR including primers and probes. This rehydrated master mix is subsequently transferred to a BD MAX PCR cartridge.

The BD SARS-CoV-2 Reagents for BD MAX System utilizes multiplexed primers and probes targeting RNA from the nucleocapsid phosphoprotein gene (N1 and N2 regions) of the SARS-CoV-2 coronavirus, and the human RNase P gene. The primer and probe sets are based on the United States Centers for Disease Control and Prevention (US CDC) assay for specific detection of SARS-CoV-2 by amplifying two unique regions of the N gene (i.e., N1 and N2).

An internal control targeting the human RNase P gene will be co-amplified along with N1 and N2 gene targets (if present) and will serve as an endogenous nucleic acid extraction control present in all properly collected patient samples. This control serves as both an extraction control and an internal amplification control.

PRINCIPLES OF THE PROCEDURE

A combination of lytic and extraction reagents is used to perform cell lysis and DNA/RNA extraction. Nucleic acids released from the target organisms are captured on magnetic affinity beads. The beads, together with the bound nucleic acids, are washed and the nucleic acids are eluted by a combination of heat and pH variation. The final eluate is used to rehydrate BioGX SARS-CoV-2 Reagents, which contains all reagents necessary for RT-PCR including primers and probes. After reconstitution, the BD MAX System dispenses a fixed volume of RT-PCR-ready solution containing extracted nucleic acids into the PCR Cartridge. Microvalves on the cartridge are sealed by the system prior to initiating PCR in order to contain the amplification mixture and thus prevent evaporation and contamination.

The amplified cDNA targets are detected using hydrolysis (TaqMan®) probes, labeled at one end with a fluorescent reporter dye (fluorophore), and at the other end, with a quencher moiety. Probes labeled with different fluorophores are used to detect the target analytes in different optical channels of the BD MAX System. When the probes are in their native state, the fluorescence of the fluorophore is quenched due to its proximity to the quencher. However, in the presence of target cDNA, the probes hybridize to their complementary sequences and are hydrolyzed by the 5'–3' exonuclease activity of the DNA polymerase as it synthesizes the nascent strand along the cDNA template. As a result, the fluorophores are separated from the quencher molecules and fluorescence is emitted. The amount of fluorescence detected in the optical channels is directly proportional to the quantity of the corresponding probe that is hydrolyzed. The BD MAX System monitors these signals at each cycle of the PCR and interprets the data at the end of the reaction to provide qualitative test results for each analyte.

REAGENTS AND MATERIALS

REF	CONTENTS	QUANTITY
444213	BioGX SARS-CoV-2 Reagents for BD MAX System Lyophilized reagents for multiplexed detection of N1 and RNase P. Each tube is sufficient for a 12.5 µL reaction, sealed in BD MAX 0.3 mL conical tubes	24 tests
	BioGX SARS-CoV-2 Reagents for BD MAX System Lyophilized reagents for multiplexed detection of N2 and RNase P. Each tube is sufficient for a 12.5 µL reaction, sealed in BD MAX 0.3 mL conical tubes	24 tests
	BioGX Rehydration Buffer Sealed in BD MAX 0.3 mL conical tubes. Each tube contains 25 µL of buffer	24 tests

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BD MAX System (BD Cat. No. 441916)
- BD MAX Sample Rack (BD Cat. No. 441935, 443550, 443551, 444807, or 444808)
- BD MAX ExK TNA-3 (BD Cat. No. 442827)
- BD MAX PCR Cartridges (BD Cat. No. 437519)
- SARS-CoV-2 Controls
- Copan UTM Collection Kit
- BD UVT Collection Kit
- Vortex Genie 2 (VWR Cat. No. 58815-235 or equivalent)
- Multi-Tube Vortex Mixer (VWR Cat. No. 58816-115 or equivalent)
- Rack compatible with a multi-tube vortexer (e.g., Cryogenic Vial Holder or equivalent)
- Variable Volume Calibrated Pipettor (750 µL volume capability)
- Aerosol resistant micropipette tips
- Disposable gloves, powderless

WARNINGS AND PRECAUTION

- For *in vitro* diagnostic use under Emergency Use Authorization only.
- For Prescription Use only.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.
- Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- All patient samples should be handled as if infectious, using good laboratory procedures as outlined in the CLSI Document M29-A4¹ and in Biosafety in Microbiological and Biomedical Laboratories.² Only personnel proficient in handling infectious materials and the use of BioGX SARS-CoV-2 and BD MAX System should perform this procedure.
- All human-sourced materials should be considered potentially infectious and should be handled with universal precautions. If spillage occurs, follow appropriate site procedures.
- Closely follow procedures and guidelines provided to ensure that the test is performed correctly. Any deviation from the procedures and guidelines may affect optimal test performance.
- Do not use expired reagents and/or materials.
- Do not use the kit if the label that seals the outer box is broken upon arrival.
- Do not use reagents if the protective pouches are open or broken upon arrival.
- Do not use reagents if desiccant is not present or broken inside reagent pouches.
- Do not remove desiccant from reagent pouches.
- Close protective pouches of reagents promptly with the zip seal after each use. Remove any excess air in the pouches prior to sealing.
- Protect reagents against heat and humidity. Prolonged exposure to humidity may affect product performance.
- Do not use reagents if the foil has been broken or damaged.
- Do not mix reagents from different pouches and/or kits and/or lots.
- Do not interchange or re-use caps, as contamination may occur and compromise test results.

- Check Unitized Reagent Strips for proper liquid fills (ensure that the liquids are at the bottom of the tubes).
- Check Unitized Reagent Strips to ensure that all pipette tips are present.
- Proceed with caution when using chemical solutions, as Extraction Tube barcode readability may be altered.
- Good laboratory technique is essential to the proper performance of this assay. Extreme care should be taken to preserve the purity of all materials and reagents.
- In cases where other PCR tests are conducted in the same general area of the laboratory, care must be taken to ensure that the BD MAX ExK TNA-3 components, any additional reagents required for testing, and the BD MAX System are not contaminated. Avoid microbial and ribonuclease (RNase)/deoxyribonuclease (DNase) contamination of reagents at all times. The use of sterile RNase/DNase-free disposable aerosol resistant or positive displacement pipette tips is recommended. Use a new tip for each specimen. Gloves must be changed before manipulating reagents and cartridges.
- To avoid contamination of the environment by amplicons, do not break apart the BD MAX PCR Cartridge after use. The seals of the BD MAX PCR Cartridges are designed to prevent contamination.
- The laboratory should routinely perform environmental monitoring to minimize the risk of cross-contamination.
- Wear protective clothing and disposable gloves while handling all reagents.
- Wash hands thoroughly after performing the test.
- Do not pipette by mouth.
- Do not smoke, drink, chew or eat in areas where specimens or kit reagents are being handled.
- Dispose of unused reagents and waste in accordance with local, state, provincial and/or federal regulations.
- Consult the BD MAX System User's Manual³ for additional warnings, precautions, and procedures.

STORAGE AND STABILITY

BioGX SARS-CoV-2 Reagents for BD MAX System

BioGX SARS-CoV-2 Reagents for BD MAX System components are provided in sealed pouches and ships at ambient temperature. To protect the product from humidity, immediately re-seal after opening. Open pouch stability for similar products has been established for 1 month at ambient temperature and closed pouch for 6 months at ambient temperature.

INSTRUCTIONS FOR USE

Swab Specimen Collection/Transport

Note: Wear gloves when handling Universal Viral Transport (UVT) or Universal Transport Media (UTM) specimens. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens.

1. Nasopharyngeal / oropharyngeal swab specimens should be collected and expressed directly into the BD Universal Viral Transport System or the Copan Universal Transport Media System according to their respective package insert instructions.
2. Transport the UVT/UTM specimen according to the manufacturer's instructions for use.

BD MAX Sample Buffer Tube Preparation

Note: Wear gloves when handling Universal Viral Transport (UVT) or Universal Transport Media (UTM) specimens. If gloves come in contact with the specimen, immediately change them to prevent contamination of other specimens.

Note: If frozen, allow Universal Transport Media (UTM) specimen to come to room temperature before proceeding.

1. Uncap the BD MAX TNA-3 Sample Buffer Tube and transfer (using a calibrated, variable pipette) 750 µL from the UVT/UTM specimen directly into the BD MAX TNA-3 Sample Buffer Tube.
2. Recap the tube with a septum cap and vortex or mix by inversion 5 times.
3. Label the BD MAX TNA-3 Sample Buffer Tube with patient information.

Note: Do not obscure the barcodes on the tube. Obscuring the barcode may result in BD MAX System catalog failure and inability to test the sample.

4. Repeat Steps 1 to 3 for each UVT/UTM sample that will be tested on the BD MAX System.
5. Proceed directly with the BD MAX System Operation.

BD MAX System Operation

Note: Refer to the BD MAX System User's Manual³ for detailed instructions (Operation section).

1. Power on the BD MAX System (if not already done) and log in by entering <user name> and <password>.
2. Gloves must be changed before manipulating reagents and cartridges.
3. Remove the required number of Unitized Reagent Strips from the BD MAX ExK TNA-3 kit. Gently tap each Unitized Reagent Strip onto a hard surface to ensure that all the liquids are at the bottom of the tubes. Remove the required number of Extraction Tube(s) from the protective pouch. Remove excess air, and close pouch with the zip seal.
4. From the BioGx SARS-CoV-2 kit, remove the required number of Master Mix Tube(s) and rehydration buffer tubes from the protective pouches. Remove excess air, and close pouch with the zip seal.

- For each specimen to be tested, place one (1) Unitized Reagent Strip on the BD MAX System Rack. Assemble the strip as in Figure 1:

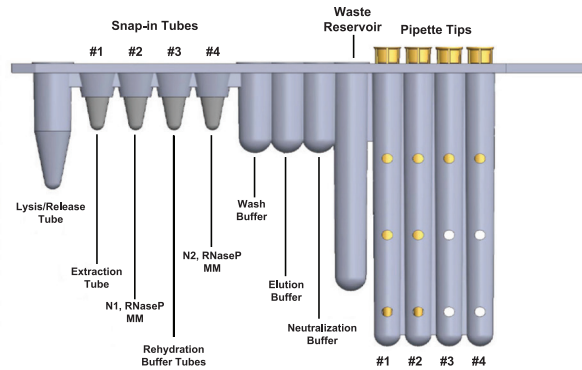


Figure 1: Snap Extraction Tubes and Master Mix Tubes into Unitized Reagent Strip

Note: Failure to add extraction tube and master mix tubes may result in instrument contamination.

Note: A conical snap-in tube is fully seated in the strip when a ‘click’ is heard. Refer to above for reagent placement in the Unitized Reagent Strip.

- Position 1= Snap the BD MAX TNA-3 Extraction Tube into Position 1.
 - Position 2= Snap the BioGX “N1, RNaseP” lyophilized master mix into Position 2.
 - Position 3= Snap the BioGX Rehydration Buffer tube into Position 3.
 - Position 4= Snap the BioGX “N2, RNaseP” lyophilized master mix into Position 4.
- Create the User Defined Protocol (UDP) as follows:
 - Navigate to Run > Test Editor tab.
 - Click “Create”.
 - Complete each section of the user protocol as outlined in the screen shots below.

Basic Information Section

Parameter	Value	Default	Value Range
Lysis Heat Time	10	10	10 - 10 ± 1 mins
Lysis Temperature	37	37	30 - 80 ± 1 °C
Sample Tip Limit	1600	1600	1200 - 1600 ± 1 steps
Sample Volume	32.5	32.5	250 - 950 ± 2.5 µL
Wash Volume	500	500	187.5 - 500 ± 2.5 µL
Neutralization Volume	--	--	--
DNase Heat Time	--	--	--

PCR Setting Section Snap2

Run > Test Editor > Edit > PCR Settings: Snap-In 2 (green)

Test Name: 350093CMAX Extraction Type: ExK TNA-3 Master Mix Format: Dual Master Mix: Lyophilized MM with Rehydration Buffer (Type 4)

PCR Settings

Channel	Wavelength	Alias	PCR Gain	Threshold (Cross)	Ct Min	Ct Max
	475/520	CoV N1	80	150	0	42
	530/565		0	0	0	0
	585/630		0	0	0	0
	630/665		0	0	0	0
	680/715	RNase P	60	100	0	35

Color Compensation

Excitation Channel	Wavelength	475/520	530/565	585/630	630/665	680/715
	475/520	--	0	0	0	0
	530/565	0	--	0	0	0
	585/630	0	0	--	0	0
	630/665	0	0	0	--	0
	680/715	0	0	0	0	--

Buttons: Save, Cancel, Back to Test List

Navigation: Worklist, PCR Only, Test Editor, Inventory

System: BD, Log Out, Unlock Door, Start, Run, Status, Results, Configuration, Reports, Maintenance

3/18/2020 8:39:40 AM Instrument: 1 User: ADMIN

Melt Settings Section Snap2

Run > Test Editor > Edit > Melt Settings: Snap-In 2 (green)

Test Name: 350093CMAX Extraction Type: ExK TNA-3 Master Mix Format: Dual Master Mix: Lyophilized MM with Rehydration Buffer (Type 4)

Melt Settings

Channel	Wavelength	Alias	Melt Gain	Direction	Sensitivity	Melt Bins
	475/520	CoV N1	0	Peak	Medium	Edit Melt Bins
	530/565		0	Peak	Medium	Edit Melt Bins
	585/630		0	Peak	Medium	Edit Melt Bins
	630/665		0	Peak	Medium	Edit Melt Bins
	680/715	RNase P	0	Peak	Medium	Edit Melt Bins

Color Compensation

Excitation Channel	Wavelength	475/520	530/565	585/630	630/665	680/715
	475/520	--	0	0	0	0
	530/565	0	--	0	0	0
	585/630	0	0	--	0	0
	630/665	0	0	0	--	0
	680/715	0	0	0	0	--

Buttons: Save, Cancel, Back to Test List

Navigation: Worklist, PCR Only, Test Editor, Inventory

System: BD, Log Out, Unlock Door, Start, Run, Status, Results, Configuration, Reports, Maintenance

3/18/2020 8:39:42 AM Instrument: 1 User: ADMIN

Test Steps Section Snap2

Run > Test Editor > Edit > Test Steps: Snap-In 2 (green)

Test Name: 350093CMAX Extraction Type: ExK TNA-3 Master Mix Format: Dual Master Mix: Lyophilized MM with Rehydration Buffer (Type 4)

Test Steps

Step Name: RT Profile Type: Hold Cycles: 1

Type	Time (s)	Temp (°C)	Detect
	900	43	

Step Name: Denaturation Profile Type: Hold Cycles: 1

Type	Time (s)	Temp (°C)	Detect
	120	99	

Step Name: PCR Profile Type: 3 - Temperature Cycles: 45

Type	Time (s)	Temp (°C)	Detect
	5	99	
	16	60	
	25.6	72	<input checked="" type="checkbox"/>

Basic Information

- PCR Settings: Snap-In 2 (green)
- Melt Settings: Snap-In 2 (green)
- Test Steps: Snap-In 2 (green)
- PCR Settings: Snap-In 4 (blue)
- Melt Settings: Snap-In 4 (blue)
- Test Steps: Snap-In 4 (blue)

Result Logic

Save Cancel Back to Test List

BD Log Out Unlock Door Start Run Status Results Configuration Reports Maintenance

PCR Setting Section Snap4

Run > Test Editor > Edit > PCR Settings: Snap-In 4 (blue)

Test Name: 350093CMAX Extraction Type: ExK TNA-3 Master Mix Format: Dual Master Mix: Lyophilized MM with Rehydration Buffer (Type 4)

PCR Settings

Channel	Wavelength	Alias	PCR Gain	PCR Temp	Ct Min	Ct Max
Channel	475/520	CoV N2	80	150	42	
	530/565		0	0	0	
	585/630		0	0	0	
	630/665		0	0	0	
	680/715	RNase P	60	100	0	35

Color Compensation

Excitation Channel	Wavelength	False Excitation Channel			
		475/520	530/565	585/630	630/665
Excitation Channel	475/520	--	0	0	0
	530/565	0	--	0	0
	585/630	0	0	--	0
	630/665	0	0	0	--
	680/715	0	0	0	0

Save Cancel Back to Test List

BD Log Out Unlock Door Start Run Status Results Configuration Reports Maintenance

Melt Settings Section Snap4

Run > Test Editor > Edit > Melt Settings: Snap-In 4 (blue)

Test Name: 350093CMAX Extraction Type: ExK TNA-3 Master Mix Format: Dual Master Mix: Lyophilized MM with Rehydration Buffer (Type 4)

Channel	Wavelength	Alias	Melt Gain	Peak Direction	Sensitivity	Melt Bins
Melt	475/520	CoV N2	- 0 +	Peak	Medium	Edit Melt Bins
	530/565		- 0 +	Peak	Medium	Edit Melt Bins
	585/630		- 0 +	Peak	Medium	Edit Melt Bins
	630/665		- 0 +	Peak	Medium	Edit Melt Bins
	680/715	RNase P	- 0 +	Peak	Medium	Edit Melt Bins

Excitation Channel	Wavelength	475/520	530/565	585/630	630/665	680/715
False Receiving Channel	475/520	--	- 0 +	- 0 +	- 0 +	- 0 +
	530/565	- 0 +	--	- 0 +	- 0 +	- 0 +
	585/630	- 0 +	- 0 +	--	- 0 +	- 0 +
	630/665	- 0 +	- 0 +	- 0 +	--	- 0 +
	680/715	- 0 +	- 0 +	- 0 +	- 0 +	--

Basic Information
 PCR Settings: Snap-In 2 (green)
 Melt Settings: Snap-In 2 (green)
 Test Steps: Snap-In 2 (green)
 PCR Settings: Snap-In 4 (blue)
 Melt Settings: Snap-In 4 (blue)
 Test Steps: Snap-In 4 (blue)
 Result Logic

Save Cancel Back to Test List

Worklist PCR Only Test Editor Inventory

BD Log Out Unlock Door Start Run Status Results Configuration Reports Maintenance

PCR Setting Section Snap4

Run > Test Editor > Edit > Test Steps: Snap-In 4 (blue)

Test Name: 350093CMAX Extraction Type: ExK TNA-3 Master Mix Format: Dual Master Mix: Lyophilized MM with Rehydration Buffer (Type 4)

Step Name: RT Profile Type: Hold Cycles: 1

Type	Time (s)	Temp (°C)	Detect
	900	43	

Step Name: Denaturation Profile Type: Hold Cycles: 1

Type	Time (s)	Temp (°C)	Detect
	120	99	

Step Name: PCR Profile Type: Temperature Cycles: 45

Type	Time (s)	Temp (°C)	Detect
	5	99	
	16	60	
	25.6	72	✓

Basic Information
 PCR Settings: Snap-In 2 (green)
 Melt Settings: Snap-In 2 (green)
 Test Steps: Snap-In 2 (green)
 PCR Settings: Snap-In 4 (blue)
 Melt Settings: Snap-In 4 (blue)
 Test Steps: Snap-In 4 (blue)
 Result Logic

Save Cancel Back to Test List

Worklist PCR Only Test Editor Inventory

BD Log Out Unlock Door Start Run Status Results Configuration Reports Maintenance

Result Logic Section

Run > Test Editor > Edit > Result Logic

Test Name: 350093CMAX Extraction Type: ExK TNA-3 Master Mix Format: Dual Master Mix: Lyophilized MM with Rehydration Buffer (Type 4)

Result Logic Steps

Target:	CoV N1	CoV N2	RNaseP1
Master Mix:	Snap-In 2 (green)	Snap-In 4 (blue)	Snap-In 2 (green)
Wavelength	475/520	475/520	680/715
Alias	CoV N1	CoV N2	RNase P
Type	PCR	PCR	PCR
Analyze	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Buttons: Edit Logic, Move, Add

Target: CoV N1

Result	CoV N1 (475/520) PCR	RNase P (680/715) PCR
POS	Valid	Valid
NEG	Invalid	Invalid

Buttons: OK

Target: CoV N2

Result	CoV N2 (475/520) PCR	RNase P (680/715) PCR
POS	Valid	Valid
NEG	Invalid	Invalid

Buttons: OK

Target: RNaseP1

Result	RNase P (680/715) PCR	CoV N1 (475/520) PCR
POS	Valid	Valid
NEG	Invalid	Invalid

Buttons: OK

Run > Test Editor > Edit > Result Logic

Test Name: 350093CMAX Extraction Type: ExK TNA-3 Master Mix Format: Dual Master Mix: Lyophilized MM with Rehydration Buffer (Type 4)

Result Logic Steps

Target:	CoV N2	RNaseP1	RNaseP2
Master Mix:	Snap-In 4 (blue)	Snap-In 2 (green)	Snap-In 4 (blue)
Wavelength	475/520	680/715	680/715
Alias	CoV N2	RNase P	RNase P
Type	PCR	PCR	PCR
Analyze	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Buttons: Edit Logic, Move, Add

Target: RNaseP2

Result	RNase P (680/715) PCR	CoV N2 (475/520) PCR
POS	Valid	Valid
NEG	Invalid	Invalid

Buttons: OK

Note: Click on the scroll bar to scroll right.

7. Click **<SAVE>** after all information has been entered into the Test Editor. The UDP only needs to be created once, and steps 6 and 7 do not need to be repeated for subsequent runs.
8. Click on the Run tab, then Inventory. Enter the kit lot number for the BD MAX ExK TNA-3 (for lot traceability) by either scanning the barcode with the scanner or by manual entry and then save.
Note: Repeat step 8 each time a new kit lot is used.
9. Navigate to the Worklist (RUN > WORKLIST). Using the pull down menu select the UDP previously created in Step 6 (example: 350093CMAX).
10. Enter the Sample Buffer Tube ID, Patient ID and Accession Number (if applicable) into the Worklist, either by scanning the barcode with the scanner or by manual entry.
11. Select the appropriate kit lot number (found on the outer box) from the pull down menu.
12. Repeat Steps 9 to 11 for all remaining Sample Buffer Tubes.
13. Place the Sample Buffer Tubes into the BD MAX System Rack(s) corresponding to the Unitized Reagent Strips previously assembled.
14. Place the required number of BD MAX PCR Cartridge(s) into the BD MAX System (refer to Figure 2).



Figure 2: Load BD PCR Cartridges

15. Load rack(s) onto the BD MAX System (refer to Figure 3).



Side A Side B

Figure 3: Load Rack(s) onto the BD MAX System

16. Close the BD MAX System lid and click **<Start>** to begin the processing.

QUALITY CONTROL

Quality control procedures monitor the performance of the assay. Laboratories must establish the number, type, and frequency of testing of control materials according to guidelines or requirements of local, provincial, state, and federal and/or country regulations or accreditation organizations in order to monitor the effectiveness of the entire analytical process. For general Quality Control guidance, the user may wish to refer to CLSI MM3 and EP12.^{1,2}

External Control materials are not provided by BD. External Positive and Negative Controls are not used by the BD MAX System software for the purpose of sample test result interpretation. External Controls are treated as if they were patient samples. (Refer to the table in the Results Interpretation section for the interpretation of External Control assay results.)

It is recommended that one (1) External Positive Control and one (1) External Negative Control be run at least daily until adequate process validation is achieved on the BD MAX System in each laboratory setting. All test controls should be examined prior to interpretation of patient results. If controls are not valid, the patient results cannot be interpreted. Reduced frequency of control testing should be in accordance with applicable regulations.

The External Positive Control is intended to monitor for substantial reagent failure. The External Negative Control is intended to detect reagent or environmental contamination (or carry-over) by target nucleic acids.

Various types of External Controls are recommended to allow the user to select the most appropriate for their laboratory quality control program.

External Negative Control: A previously characterized sample known to be negative or an SBT with RNase P external control added. BD recommends that the External Negative Control be prepared prior to the External Positive Control in order to reduce the potential for contamination as a result of control preparation.

External Positive Control: Commercially available control material from BioGX or other authorized control material may be used. For the preparation of External Control suspensions, it is recommended that RNA suspensions be prepared in the Sample Buffer Tube (SBT) according to manufacturer's instructions.

All External Controls should yield the expected results (positive for External Positive Control, negative for External Negative Control).

An External Negative Control that yields a positive result is indicative of sample handling and/or contamination. An External Positive Control that yields a negative result is indicative of a specimen handling/preparation problem. Review the specimen handling/preparation technique.

An External Control that yields an Unresolved, Indeterminate or Incomplete result is indicative of a reagent or a BD MAX System failure. Check the BD MAX System monitor for any error messages. Refer to the System Error Summary section of the BD MAX System User's Manual³ for interpretation of warning and error codes. If the problem persists, use reagents from an unopened pouch or use a new assay kit.

RESULT INTERPRETATION

Results are available on the results tab in the Results window on the BD MAX System monitor. The BD MAX System automatically interprets the test result when the SARS-CoV-2 User Defined Protocol (UDP) is used.

External Negative and Positive Controls

If the positive or negative controls are processed in the run and do not exhibit the expected performance as described in the Control Interpretations table below, the assay may have been set up/or executed improperly, or reagent or equipment malfunction could have occurred. In this case, invalidate the run and re-test samples in that run.

The RNase P gene serves as both a sample extraction control (EC) and an internal amplification control (IAC). In the event that both N1 and N2 region results are negative, an RNase P result must be positive for the BD BioGX SARS-CoV-2 result to be a valid negative result. When either N1 or N2 target results positive, the RNase P result is ignored.

If any of the above controls do not exhibit the expected performance as described, the assay may have been set up/or executed improperly, or reagent or equipment malfunction could have occurred. Invalidate the run and re-test.

Table 1: External Control Interpretations

Control Type		Used to Monitor	Expected Results			
			BioGX “N1, RNase P” master mix		BioGX “N2, RNase P” master mix	
			N1	RNase P	N2	RNase P
External Negative Control	Known Negative Sample	Reagent and/or environmental contamination and reagent failure including primer and probe integrity	NEG	POS	NEG	POS
	RNase P Positive Control					
External Positive Control	N1 and N2 Positive Control	Substantial reagent failure including primer and probe integrity	POS	NEG	POS	NEG

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. If the controls are not valid, the patient results cannot be interpreted.

The table below lists the expected results. If results are obtained that do not follow the guidelines, re-extract and re-test the sample. If repeat testing yields similar results, collect a fresh sample from the patient for testing.

Table 2: Interpretation of Patient Specimen Results

BioGX “N1, RNase P” master mix		BioGX “N2, RNase P” master mix		Result Interpretation ^{a,b}	Actions
N1 Target	RNase P	N2 Target	RNase P		
+	+/-	+	+/-	Positive	Report as Positive
+	+/-	-	+	Positive	Report as Positive
+	+/-	UNR	-	Positive	Report as Positive
-	+	+	+/-	Positive	Report as Positive
UNR	-	+	+/-	Positive	Report as Positive
UNR	-	-	+	UNR	Repeat Test ^c
-	+	UNR	-	UNR	Repeat Test ^c
UNR	-	UNR	-	UNR	Repeat Test ^c
-	+	-	+	Negative	Report as Negative

^aIn the absence of target detection in both of the master mix reactions, the external control (RNase P) must be detected in that master mix reaction in order for the result to be valid.

^bLaboratories should report their diagnostic result as appropriate and in compliance with their specific reporting system. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

^cRepeat Test by preparing a fresh sample buffer tube from the original primary UVT or UTM sample.

UNRESOLVED, INDETERMINATE, AND INCOMPLETE RESULTS

When an Indeterminate (IND), Unresolved (UNR), or Incomplete (INC) result is obtained a repeat test from the Patient Sample must be performed (see Repeat Test Procedure). If an External Control fails, repeat testing of all specimens conducted on the same day using freshly prepared External Controls (see Quality Control).

Unresolved Result

Unresolved results may be obtained in the event that specimen-associated inhibition or reagent failure prevents proper target or RNase P amplification. Sample(s) can be repeated from the original Patient Sample. Uncap the BD MAX TNA-3 Sample Buffer Tube and transfer (using a calibrated, variable pipette) 750 µL from the UVT/UTM specimen directly into the BD MAX TNA-3 Sample Buffer Tube. Restart from the BD MAX System Operation section.

Indeterminate Result

Indeterminate results may be obtained in the event that a System failure occurs. Sample(s) can be repeated from the original Patient Sample. Uncap the BD MAX TNA-3 Sample Buffer Tube and transfer (using a calibrated, variable pipette) 750 µL from the UVT/UTM specimen directly into the BD MAX TNA-3 Sample Buffer Tube. Restart from the BD MAX System Operation section.

Incomplete Result

Incomplete results may be obtained in the event that Specimen Preparation or the PCR did not reach its expected time points. Sample(s) can be repeated from the original Patient Sample. Uncap the BD MAX TNA-3 Sample Buffer Tube and transfer (using a calibrated, variable pipette) 750 µL from the UVT/UTM specimen directly into the BD MAX TNA-3 Sample Buffer Tube. Restart from the BD MAX System Operation section.

External Control Failure

External Controls should yield expected results when tested. If samples have to be repeated due to an incorrect External Control result, the samples should be repeated from the original Patient Sample along with freshly prepared External Controls. Restart from the BD MAX System Operation section.

LIMITATIONS OF THE PROCEDURE

- BioGX SARS-CoV-2 Reagents for BD MAX System has been evaluated only for use in combination with the BD MAX TNA-3 kit and BD MAX System.
- Reliable results depend on 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.
- Nasopharyngeal wash/aspirates, nasal aspirates, and nasal/mid-turbinate nasal swabs (self-collected under supervision of a healthcare provider or healthcare provider-collected) are additional acceptable upper respiratory specimens that can be tested with BioGx SARS-CoV-2 Reagents for BD MAX System; however, performance with these specimen types have not been determined.
- Detection of SARS-CoV-2 RNA may be affected by sample collection methods, patient factors (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 differences. One hundred percent agreement between the results should not be expected due to aforementioned differences 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 substances that may interfere with nucleic acid isolation and PCR amplification.
- Good laboratory practices and careful adherence to the procedures specified in this Instructions For Use document are necessary to avoid contamination of reagents.
- For the BD MAX TNA extraction: Tobramycin at 1.1×10^{-3} g/SBT interferes with the assay. Lower concentrations of Tobramycin have not been evaluated.
- The effect of homeopathic medications for respiratory symptoms on the assay performance was not tested.
- BioGX SARS-CoV-2 Reagent and BD MAX TNA-3 extraction have not been evaluated for patients receiving intranasally administered influenza vaccine.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The BioGX SARS-CoV-2 Reagents for BD MAX System Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

To assist clinical laboratories running the BioGX SARS-CoV-2 Reagents for BD MAX System, the relevant Conditions of Authorization are listed below, and are required to be met by laboratories performing the EUA test.

- Authorized laboratories* using the BioGX SARS-CoV-2 Reagents for BD MAX System will include with result reports of the BioGX SARS-CoV-2 for BD MAX System test, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- Authorized laboratories using the BioGX SARS-CoV-2 Reagents for BD MAX System will perform the BioGX SARS-CoV-2 Reagents for use with the BD MAX System as outlined in the BioGX SARS-CoV-2 Reagents for BD MAX System Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized ancillary reagents, and authorized material required to perform the BioGX SARS-CoV-2 Reagents for BD MAX System test are not permitted.
- Authorized laboratories that receive the BioGX SARS-CoV-2 Reagents for BD MAX System test must notify the relevant public health authorities of their intent to run the test prior to initiating testing.
- Authorized laboratories using the BioGX SARS-CoV-2 Reagents for BD MAX System test will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- All laboratory personnel using the BioGX SARS-CoV-2 Reagents for BD MAX System test must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.
- Becton, Dickinson and Company, authorized distributors, and authorized laboratories using the BioGX SARS-CoV-2 Reagents for BD MAX System will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

- Authorized laboratories will collect information on the performance of the BioGX SARS-CoV-2 Reagents for BD MAX System test and report to DMD/OHT7-OIR/OPEQ/ CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Becton, Dickinson and Company Customer Technical Support 1.800.638.8663 any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the BioGX SARS-CoV-2 Reagents for BD MAX System test of which they become aware.

* For ease of reference, the letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate and high complexity tests" as "authorized laboratories".

NON-CLINICAL PERFORMANCE EVALUATION

Limit of Detection (LoD)

LoD studies determine the lowest detectable concentration of the SARS-CoV-2 at which approximately 95% of all (true positive) replicates test positive.

To determine the LoD, quantified genomic viral RNA from SARS-CoV-2, obtained from BEI Resources (Cat. No. NR-52285), was serially diluted into pooled negative nasopharyngeal clinical matrix, a total of 5 concentrations levels, with 2-fold serial dilutions between each level. Confirmation of the estimated LoD was performed with one reagent lot in replicates of 20 prepared in pooled nasopharyngeal swab clinical matrix. The LoD is the lowest concentration (reported as genome equivalents/mL, GE/mL) of genomic RNA from SARS-CoV-2 that can be reproducibly distinguished from negative samples $\geq 95\%$ of the time. The LoD for the assay is 40 GE/mL.

Table 3. LoD determination using genomic RNA from SARS-CoV-2 USA WA1/2020 strain

RNA from strain	Concentration (GE/mL)	Total Valid Results	Positives			Mean Ct.score			
			SARS-CoV-2	N1	N2	N1	RNase P	N2	RNase P
SARS-CoV-2 USA WA1/2020 (Stock 4.8e+07 GE/mL)	40	20	20	20	20	33.8	22.6	34.3	22.7

Reactivity/ Inclusivity

The nCoV N1 and nCoV N2 primers and probes utilized within the BioGX SARS-CoV-2 Reagents for BD MAX System are identical in sequence to those reported in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel.

An *in silico* comparison of the N1 and N2 primer sets was performed using all 111 available SARS-CoV-2 sequences in the NCBI nt database (Genbank) as of April 1, 2020. Multiple sequence alignment revealed 100% sequence identity (0 mismatches) across the entire 72 base-pair region of the N1 primer/probe set for all sequences. Multiple sequence alignment showed 100% sequence identity (0 mismatches) across the entire 67 base-pair region of the N2 primer/probe set with one exception. Sequence accession MT159720.1 indicates a "T" instead of a "C" at the 5' end of the N2 reverse primer.

In a separate analysis on April 9, 2020, 634 full-length SARS-CoV-2 genomes were retrieved from the GISAID EpiCoV database, only including human isolates marked as "high coverage". Multiple alignment of the N gene showed that 98.0% of the sequences were a perfect match to the N1 primer set region, and 99.5% were a perfect match to the N2 primer set region.

All variants have a perfect match to either the N1 region or the N2 region primer set.

Cross-Reactivity

The nCoV N1 and nCoV N2 primers and probes utilized within the BioGX SARS-CoV-2 Reagents for BD MAX System are identical in sequence to those reported in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. The CDC reported an *in silico* analysis of primer and probe sequences within their IFU (CDC-006-0019, Rev 02), and has been copied below for reference:

BLASTn analysis queries of the 2019-nCoV rRT-PCR assays primers and probes were performed against public domain nucleotide sequences. The database search parameters were as follows: 1) The nucleotide collection consists of GenBank+EMBL+DDBJ+PDB+RefSeq sequences, but excludes EST, STS, GSS, WGS, TSA, patent sequences as well as phase 0, 1, and 2 HTGS sequences and sequences longer than 100Mb; 2) The database is non-redundant. Identical sequences have been merged into one entry, while preserving the accession, GI, title and taxonomy information for each entry; 3) Database was updated on 10/03/2019; 4) The search parameters automatically adjust for short input sequences and the expect threshold is 1000; 5) The match and mismatch scores are 1 and -3, respectively; 6) The penalty to create and extend a gap in an alignment is 5 and 2 respectively.

2019-nCoV_N1 Assay:

Probe sequence of 2019-nCoV rRT-PCR assay N1 showed high sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. However, forward and reverse primers showed no sequence homology with SARS coronavirus and Bat SARS-like coronavirus genome. Combining primers and probe, there is no significant homologies with human genome, other coronaviruses or human microflora that would predict potential false positive rRT-PCR results.

2019-nCoV_N2 Assay:

The forward primer sequence of 2019-nCoV rRT-PCR assay N2 showed high sequence homology to Bat SARS-like coronaviruses. The reverse primer and probe sequences showed no significant homology with human genome, other coronaviruses or human microflora. Combining primers and probe, there is no prediction of potential false positive rRT-PCR results.

In summary, the 2019-nCoV rRT-PCR assay N1 and N2, designed for the specific detection of 2019-nCoV, showed no significant combined homologies with human genome, other coronaviruses, or human microflora that would predict potential false positive rRT-PCR results.

CLINICAL EVALUATION

The performance of BioGx SARS-CoV-2 Reagents for BD MAX System with retrospective collected nasopharyngeal swab clinical samples was evaluated using 30 individual negative clinical samples and 30 contrived positive clinical samples collected from patients with signs and symptoms of an upper respiratory infection.

Clinical samples were collected by qualified personnel according to the package insert of the collection device. Samples were handled as described in the package insert of the collection device and stored frozen until use.

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 approximately ~1–2x LoD (20 samples) and ~3–5x LoD (10 samples), respectively.

All low positive and moderate positive samples were positive and all negative samples were negative in the background of individual clinical sample matrix.

Table 4. Clinical evaluation with contrived nasopharyngeal swab samples

Sample Concentration	Total Valid Results	Agreement with the expected results	BioGX "N1, RNase P" master mix			BioGX "N2, RNase P" master mix		
			% Positive	Mean Ct. score		% Positive	Mean Ct. score	
				N1	RNase P		N2	RNase P
~1–2x LoD	19/20 ^a	19/19	100 (19/19 ^a)	33.8	23.2	100 (19/19 ^a)	33.7	23.0
~3–5x LoD	10	10/10	100 (10/10)	33.1	21.6	100 (10/10)	33.6	21.4
Negative	30	30/30	0 (N/A)	N/A	22.5	0 (N/A)	N/A	22.3

^aDuring screening one retrospective nasopharyngeal swab clinical sample resulted in an UNR for N1 and as a result was removed from data analysis.

FDA SARS-CoV-2 REFERENCE PANEL TESTING

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples, and a standard protocol provided by the FDA. The study includes a range-finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The extraction method and instrument used were the BD MAX System. The results are summarized in Table 5.

Table 5. Summary of LoD confirmation result using the FDA SARS-CoV-2 reference panel

Reference Material	Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2		Nasopharyngeal matrix	1,800 NDU/mL	N/A
MERS-CoV			N/A	ND

NDU/mL = RNA NAAT detectable units/mL

N/A = Not applicable

ND = Not detected

REFERENCES

1. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (refer to the latest edition).
2. Centers for Disease Control and Prevention, and National Institutes of Health. Biosafety in microbiological and biomedical laboratories. Chosewood L.C. and Wilson D.E. (eds) (2009). HHS Publication No. (CDC) 21–1112.
3. BD MAX System User's Manual (refer to the latest revision) BD Life Sciences, Sparks, Maryland 21152 USA.

Change History

Revision	Date	Change Summary
(03)	2020-04	Updates made to reflect FDA authorization. Added additional BD MAX Sample Rack catalog numbers. Clarified Instructions For Use. Updated Result Interpretation, Limit of Detection, and Clinical Evaluation information. Added information on interfering substances. Made typographical edits.
(04)	2020-05	Updated Intended Use and Limitations of the Procedure to include details about nasal and mid-turbinate swabs. Made minor clarifications to MAX System Operation, Quality Control, and Result Interpretation. In Quality Control section the definition of external negative control was changed. Table 1 was updated. Reactivity/Inclusivity was updated.
(05)	2020-09	Added FDA SARS-CoV-2 Reference and Testing section.

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary



Manufacturer / Производител / Výrobce / Fabrikant / Hersteller / Κατασκευαστής / Fabricante / Tootja / Fabricator / Proizvođač / Склад / Fabbrikante / Atқарушы / 제조업체 / Gamintojas / Ražotājs / Tilvirker / Producent / Producător / Производитель / Výrobca / Proizvođač / Tilverker / Üretici / Виробник / 製造元



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YYYY-MM-DD / YYYY-MM (MM = end of month)
 ГТГГ-ММ-ДД / ГТГГ-ММ (ММ = края на месеца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 AAAA-MM-DD / AAAA-MM (MM = slutning af måned)
 JJJJ-MM-TT / JJJJ-MM (MM = Monatsende)
 EEEE-MM-HH / EEEE-MM (MM = τέλος του μήνα)
 AAAA-MM-DD / AAAA-MM (MM = fin del mes)
 AAAA-KK-PP / AAAA-KK (KK = kuu lõpp)
 AAAA-MM-JJ / AAAA-MM (MM = fin du mois)
 GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
 ÉÉÉÉ-HH-NN / ÉÉÉÉ-HH (HH = hónap utolsó napja)
 AAAA-MM-GG / AAAA-MM (MM = fine mese)
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 MMMM-MM-DD / MMMM-MM (MM = mēnesio pabaiga)
 GGGG-MM-DD/GGGG-MM (MM = mēneša beigas)
 JJJJ-MM-DD / JJJJ-MM (MM = einde maand)
 AAAA-MM-DD / AAAA-MM (MM = sluttet av måneden)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 AAAA-MM-DD / AAAA-MM (MM = fim do mês)
 AAAA-LL-ZZ / AAAA-LL (LL = sfârșitul lunii)
 ГТГГ-ММ-ДД / ГТГГ-ММ (ММ = край месеца)
 RRRR-MM-DD / RRRR-MM (MM = koniec miesiąca)
 GGGG-MM-DD / GGGG-MM (MM = kraj mjeseca)
 AAAA-MM-DD / AAAA-MM (MM = sluttet månaden)
 YYYY-AA-GG / YYYY-AA (AA = fin sonu)
 PPPP-MM-DD / PPPP-MM (MM = finec mēnesī)
 YYYY-MM-DD / YYYY-MM (MM = 月末)



Catalog number / Каталоген број / Brojovno číslo / Katalognummer / Αριθμός καταλόγου / Número de catálogo / Katalooginumber / Numéro catalogue / Kataloški broj / Katalógusszám / Número do catálogo / Каталог номер / 카탈로그 번호 / Katalog / numeris / Kataloga numurs / Catalogus nummer / Numer katalogowy / Numár de catalog / Номер по каталогу / Brojovno číslo / Kataloški broj / Katalog numarası / Номер за каталогом / 目录号



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In Vitro Diagnostic Medical Device / Медицински уред за диагностика ин витро / Lékařské zařízení určené pro diagnostiku in vitro / In vitro diagnostisk medicinsk anordning / Medizinisches In-vitro-Diagnostikum / In vitro diagnostickej iatrickj oviskuj / Dispositivo médico para diagnóstico in vitro / In vitro diagnostika meditsiniaparatuur / Dispositif médical de diagnostic in vitro / Medicinska romagala za In Vitro Dijagnostiku / In vitro diagnostikai orvosi eszköz / Dispositivo medicale per diagnostica in vitro / Жасанды жағдайда жүргізілетін медициналық диагностика аспабы / In Vitro Diagnostik 의료 기기 / In vitro diagnostikos prietaisais / Medicinas ierces, ko lieto in vitro diagnostika / Medisch hulpmiddel voor in-vitro diagnostiek / In vitro diagnostisk medisinsk utstyr / Urządzenie medyczne do diagnostyki in vitro / Dispositivo médico para diagnóstico in vitro / Dispositiv medical pentru diagnostic in vitro / Медицинский прибор для диагностики in vitro / Medicinska rombodka na diagnostiku in vitro / Medicinski uređaj za in vitro dijagnostiku / Medicinteknik produkt för in vitro-diagnostik / In Vitro Diagnostik Tibbi Cihaz / Медицинский пристрій для діагностики in vitro / 体外诊断医疗设备



Temperature limitation / Температурни ограничения / Teplotní omezení / Temperaturbegrænsning / Temperaturbegrenzung / Περιορισμοί θερμοκρασίας / Limitación de temperatura / Temperaturri piirang / Limites de température / Dozvoljena temperatura / Hörmérsékleti határ / Limiti di temperatura / Температураны шектеу / 온도 제한 / Laikumo temperatūra / Temperatūras ierobežojumi / Temperaturulimiet / Temperaturbegrenzung / Ograniczenie temperatury / Limites de temperatura / Limite de temperatură / Ограничение температуры / Ograničenje teploty / Ograničenje temperature / Temperaturgräns / Sıcaklık sınırlaması / Обмеження температури / 温度限制



Batch Code (Lot) / Код на партидата / Kód (číslo) šarže / Batch-kode (lot) / Batch-Code (Charge) / Κωδικός παρτίδας (παρτίδα) / Código de lote (lote) / Partii kood / Numéro de lot / Lot (kod) / Tétel száma (lot) / Codice batch (lotto) / Топтама коды / 배치 코드(로트) / Partijos numeris (LOT) / Partijas kods (laidiens) / Lot number / Batch-kode (parti) / Kod partii (seria) / Código do lote / Cod de serie (lot) / Код партии (лот) / Kód série (šarža) / Kod serije / Partinummer (lot) / Parti Kodu (lot) / Код партії / 批号 (亚批)



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For IVD Performance evaluation only / Само за оценка качеството на работа на IVD / Pouze pro vyhodnocení výkonu IVD / Kun til evaluering af IVD ydelse / Nur für IVD-Leistungsbewertungszwecke / Μόνο για αξιολόγηση απόδοσης IVD / Solo para la evaluación del rendimiento en diagnóstico in vitro / Ainult IVD seadme hindamiseks / Réservé à l'évaluation des performances IVD / Samo u znanstvene svrhe za In Vitro Dijagnostiku / Kizárólag in vitro diagnosztikához / Solo per valutazione delle prestazioni IVD / Жасанды жағдайда «пробирка ішінде» диагностикада тек жұмысты бағалау үшін / IVD 성능 평가에 대해서만 사용 / Tik IVD prietaisų veikimo charakteristikoms tikrinti / Vienigi IVD darbības novērtēšanai / Uitsluitend voor doeltreffendheidsonderzoek / Kun for evaluering av IVD-ytelse / Tylko do oceny wydajności IVD / Exclusivo para avaliação de IVD / Numai pentru evaluarea performanței IVD / Только для оценки качества диагностики in vitro / Určeno iba na diagnostiku in vitro / Samo za namenu účinka u in vitro dijagnostici / Endast för utvärdering av diagnostisk användning in vitro / Yalnızca IVD Performans değerlendirilmesi için / Тільки для оцінювання якості діагностики in vitro / 仅限 IVD 性能评估



Lower limit of temperature / Долен лимит на температурата / Dolní hranice teploty / Nedre temperaturgrænse / Temperaturuntergrenze / Κατώτερο όριο θερμοκρασίας / Limite inferior de temperatura / Alumine temperatuuripiiri / Limite inférieure de température / Najnižja dovoljena temperatura / Alsó hőmérsékleti határ / Limite inferiore di temperatura / Температураның төменгі рұқсат шегі / 하한 온도 / Žemiausia laikymo temperatūra / Temperatūras zemākā robeža / Laagste temperatuurilimiet / Nedre temperaturgrænse / Dolna granica temperature / Limite minimo de temperatura / Limită minimă de temperatură / Нижний предел температуры / Snižná hranica teploty / Donja granica temperature / Nedre temperaturgräns / Sicaklık alt sınırı / Мінімальна температура / 温度下限



Control / Контроль / Kontrola / Kontrol / Kontrolle / Μάρτυρας / Kontroll / Contrôle / Controllo / Бақылау / Контроль / Kontrolle / Kontrolle / Controle / Controllo / Контроль / kontroll / Контроль / 对照



Positive control / Положителен контрол / Pozitivní kontrola / Positiv kontrol / Positive Kontrolle / Θετικός μάρτυρας / Control positivo / Positiivne kontroll / Contrôle positif / Pozitivna kontrola / Pozitiv kontroll / Controllo positivo / Оң бақылау / 양성 컨트롤 / Teijiamia kontrolė / Pozitivā kontrola / Positiveve controle / Kontrola dodatnia / Controllo positivo / Control pozitiv / Положительный контроль / Pozitif kontrol / Позитивный контроль / 阳性对照试剂



Negative control / Отрицателен контрол / Negativní kontrola / Negativ kontrol / Negative Kontrolle / Αρνητικός μάρτυρας / Control negativo / Negatiivne kontroll / Contrôle négatif / Negativna kontrola / Negativ kontroll / Controllo negativo / Негативтік бақылау / 음성 컨트롤 / Negijama kontrolė / Negativā kontrola / Negativeve controle / Kontrola ujemna / Controllo negativo / Control negativ / Отрицательный контроль / Negatif kontrol / 阴性对照试剂



Method of sterilization: ethylene oxide / Метод на стерилизация: етилен оксид / Zpracování: etylenoxid / Steriliseringmetode: ethylenoxid / Sterilisationsmethode: ethylenoxid / Μέθοδος αποστείρωσης: αιθυλενοξείδιο / Método de esterilización: óxido de etileno / Steeriliseringsmetode: etylenoksidi / Méthode de stérilisation: oxyde d'éthylène / Metoda sterilizacije: etilen oksid / Sterilizálás módszer: etilén-oxid / Metoda di sterilizzazione: ossido di etilene / Sterilizacija eđici – етилен тотығы / 소독 방법: 에틸렌옥사이드 / Sterilizavimo būdas: etileno oksidas / Sterilizācijas metode: etilēnoksīds / Steriliseerd met behulp van ethyleenoxide / Steriliseringmetode: etylenoksid / Metoda sterylizacji: tlenek etylu / Método de esterilização: óxido de etileno / Metoda de sterilizare: oxid de etilenă / Metoda sterylizacji: etylenoksid / Metoda sterilizacije: etylenoxid / Metoda sterilizacije: etilen oksid / Steriliseringmetode: etenoxid / Sterilizasyon yöntemi: etilen oksit / Метод стерилизації: етиленоксидом / 灭菌方法: 环氧乙烷



Method of sterilization: irradiation / Метод на стерилизация: ирадиация / Zpracování: záření / Steriliseringmetode: bestråling / Sterilisationsmethode: Bestrahlung / Μέθοδος αποστείρωσης: ακτινοβολία / Método de esterilización: irradiación / Steriliseringsmetode: kirguss / Méthode de stérilisation: rayonnement / Metoda sterilizacije: zračenje / Sterilizálás módszer: besugárzás / Metoda di sterilizzazione: irradiazione / Sterilizacija eđici – сәулә түсірі / 소독 방법: 방사 / Sterilizavimo būdas: radiacija / Sterilizācijas metode: apstarošana / Gesteriliseerd met behulp van ioniserende straling / Steriliseringmetode: bestråling / Metoda sterylizacji: napromienianie / Método de esterilização: irradiação / Metoda de sterilizare: iradiere / Метод стерилизації: об'ємне опромінення / Metoda sterilizacije: ožiarzenie / Metoda sterilizacije: ozračavanje / Steriliseringmetode: stråling / Sterilizasyon yöntemi: irradyasyon / Метод стерилизації: опромінення / 灭菌方法: 放射



Biological Risks / Биологични рискови / Biologické rizika / Biologisk fare / Biogefährdung / Βιολογικοί κίνδυνοι / Riesgos biológicos / Biologilised riskid / Risques biologiques / Biološki rizik / Biologiailgal veszély / Rischio biologico / Биологиялык тауекелдер / 생물학적 위험 / Biologinis pavojus / Biologiskie riski / Biologisch risico / Biologisk risiko / Zagrożenia biologiczne / Perigo biológico / Rischi biologice / Биологическая опасность / Biologické riziko / Biološki rizici / Biologisk risk / Biolojisk Riskler / Биологічна небезпека / 生物学风险



Caution, consult accompanying documents / Внимание, направете справка в придружаващите документи / Pozor! Prostudujte si přiloženou dokumentaci! / Forsigtigt, se ledsagende dokumenter / Achtung, Begleitdokumente beachten / Προσοχή, συμβουλευτείτε τα συνοδευτικά έγγραφα / Precaución, consultar la documentación adjunta / Ettevaatusti! Lugege kaasnevat dokumentatsiooniga / Attention, consulter les documents joints / Urozorenje, koristi prateću dokumentaciju / Figyelem! Olvassa el a mellékelt tájékoztatót / Attenzione: consultare la documentazione allegata / Абайлаңыз, тиісті құжаттармен танысыңыз / 주의, 동봉된 설명서 참조 / Dămesio, zăiurkete pridedamus dokumentus / Priežiģdzba, skatiet lidoģakojamie dokumentus / Voorzichtig, raadpleeg bijgevoegde documenten / Forsiktigt, se vedlagt dokumentasjon / Naleyż zapoznać się z dołączonymi dokumentami / Cuidado, consulte a documentação fornecida / Atenție, consultați documentele însoțitoare / Внимание: см. прилагаемую документацию / Výstraha, pozri sprievodné dokumenty / Poznaj! Pogledajte priložena dokumenta / Obs! Se medföljande dokumentation / Dikkat, birlikte verilen belgelere başvurun / Увага: див. супутню документацию / 小心, 请参阅附带文档。



Upper limit of temperature / Долен лимит на температурата / Horní hranice teploty / Øvre temperaturgrænse / Temperaturobergrenze / Ανώτερο όριο θερμοκρασίας / Limite superior de temperatura / Ülemine temperatuuripiiri / Limite supérieure de température / Gornja dovoljena temperatura / Felső hőmérsékleti határ / Limite superiore di temperatura / Температураның рұқсат етілген жоғарғы шегі / 상한 온도 / Aukščiausia laikymo temperatūra / Augšējā temperatūras robeža / Hoogste temperatuurilimiet / Øvre temperaturgrænse / Górná granica temperature / Limite máximo de temperatura / Limită maximă de temperatură / Верхний предел температуры / Horná hranica teploty / Gornja granica temperature / Övre temperaturgräns / Sicaklık üst sınırı / Максимальна температура / 温度上限



Keep dry / Пазете сухо / Skladujte v suchém prostředi / Orbevares tørt / Trocklagern / Φυλάξτε το στεγνό / Mantener seco / Hoida kuivas / Conserver au sec / DrŽati na suhom / Száraz helyen tartandó / Tenere all'asciutto / Құрғақ күйінде ұста / 건조 상태 유지 / Laikykite sausiai / Uzglabāt sausu / Droog houden / Holdes tørt / Przechowywać w stanie suchym / Manter seco / A se feri de umezeală / Не допускать попадания влаги / Uchovávať v suchu / DrŽite na suvom mestu / Förvaras torrt / Kuru bir şekilde muhafaza edin / Берегти від вологи / 请保持干燥



Collection time / Време на събиране / Čas odběru / Orsamlingsstidspunkt / Entnahmezeit / Ώρα συλλογής / Hora de recogida / Kogumisaeg / Heure de prélèvement / Sati prikupljanja / Mintavétel időpontja / Ora di raccolta / Жиная уақыты / 수집 시간 / Paėmimo laikas / Savākšanas laiks / Verzameltijd / Tid prøvetaking / Godzina pobrania / Hora de colheita / Ora colectării / Време прикупляња / Uppsamlingsstid / Toplama zamanı / Час забору / 采集时间



Peel / Обелете / Otevířte zde / Ábn / Abziehen / Αποκολλήστε / Desprender / Koorida / Décoller / Otvoriti skini / Húzza le / Staccare / Υστίρηι қабатын алып таста / 벗기다 / Plēřti ģia / Attimēt / Schillen / Trekk av / Oderwać / Destacar / Se dezipeřte / Откпеить / Odrhните / Oljūřti / Dra isår / Ayırma / Відкпеити / 撕下



Perforation / Перфорация / Perforace / Perforering / Διείρση / Perforación / Perforatsioon / Perforacija / Perforálás / Perforazione / Tesik tescy / 절취선 / Perforacija / Perforăcija / Perforatie / Perforacja / Perforação / Perforare / Перфорация / Perforăcia / Perforasyon / Перфорация / 穿孔



Do not use if package damaged / Не използвайте, ако опаковката е повредена / Ne používejte, je-li obal poškozený / Må ikke anvendes hvis emballagen er beskadiget / Inhal beschädigter Packung nicht verwenden / Μη χρησιμοποιείτε εάν η συσκευασία έχει υποστεί ζημιώ. / No usar si el paquete está dañado / Mitte kasutada, kui pakend on kahjustatud / Ne pas l'utiliser si l'emballage est endommagé / Ne koristite ako je oštećeno pakiranje / Ne használja, ha a csomagolás sérült / Non usare se la confezione è danneggiata / Егер пакет бязълган болса, пайдаланба / Пакети지가 손상된 경우 사용 금지 / Jei pakuočių pažeista, nenaudoti / Nelietot, ja iepakojums bojāts / Niet gebruiken indien de verpakking beschadigd is / Må ikke brukes hvis pakke er skadet / Nie używać, jeśli opakowanie jest uszkodzone / Não usar se a embalagem estiver danificada / A nu se folosi dacă pachetul este deteriorat / Не използвайте при повреждени опаковки / Ne používať, ak je obal poškodený / Ne koristite ako je pakovanje oštećeno / Använd ej om förpackningen är skadad / Ambalaj hasar görmüşse kullanmayın / Не використовувати за пошкодженої упаковки / 如果包装破损, 请勿使用



Keep away from heat / Παζετε οτ τοπλινα / Nevystavujte přilišnému teplu / Må ikke udsættes for varme / Vor Wärme schützen / Κρατήστε το μακριά από τη θερμότητα / Mantener alejado de fuentes de calor / Hoida eemal valgusest / Protéger de la chaleur / Držati dalje od izvora topline / Óvja a melegtől / Tenere lontano dal calore / Саққын жерде сақта / 열을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no karstuma / Beschermen tegen warmte / Må ikke utsettes for varme / Przechowywać z dala od źródeł ciepła / Manter ao abrigo do calor / A se feri de căldură / He нагревать / Uchovávať mimo zdroja tepla / Držite dalje od toplote / Får ej utsättas för värme / Isidan uzak tutun / Беретти від дії світла / 请远离热源



Cut / Срежете / Odstřihněte / Klip / Schneiden / Κόψτε / Cortar / Lõigata / Découper / Reži / Vágja ki / Tagliare / Keciңиз / 잘라내기 / Kirpti / Nogriez / Knippen / Kutt / Odciać / Cortar / Decupați / Отрезать / Odstrihnite / Iseći / Klipp / Kesme / Розрізати / 剪下



Collection date / Дата на събиране / Datum odběru / Opsamlingsdato / Entnahmedatum / Ημερομηνία συλλογής / Fecha de recogida / Kogumiskuupäev / Date de prélèvement / Dani prikupljanja / Mintavétel dátuma / Data di raccolta / Жинаган тизбекүні / 수집 날짜 / Paémimo data / Savākšanas datums / Verzameldatum / Dato prøvetaking / Data pobrania / Data de colheita / Data colectării / Дата сбора / Dátum odberu / Datum prikupljanja / Uppsamlingsdatum / Toplama tarihi / Дата забору / 采集日期



Keep away from light / Παζετε οτ светлина / Nevystavujte světlu / Må ikke udsættes for lys / Vor Licht schützen / Κρατήστε το μακριά από το φως / Mantener alejado de la luz / Hoida eemal valgusest / Conserver à l'abri de la lumière / Držati dalje od svjetla / Fény nem érheti / Tenere al riparo dalla luce / Қаpaңғыланған жерде ұста / 빛을 피해야 함 / Laikyti atokiau nuo šilumos šaltinių / Sargāt no gaismas / Niet blootstellen aan zonlicht / Må ikke utsettes for lys / Przechowywać z dala od źródeł światła / Manter ao abrigo da luz / Feriti de lumina / Хранить в темноте / Uchovávať mimo dosahu svetla / Držite dalje od svetlosti / Får ej utsättas för ljus / Isidan uzak tutun / Беретти від дії світла / 请远离光线



Hydrogen gas generated / Образуван е водород газ / Možnost úniku plynného vodíku / Frembringer hydrogengas / Wasserdampf erzeugt / Ηυδρογία αερίου υδρογόνου / Producción de gas de hidrógeno / Vesinikgaasi tekitatud / Produit de l'hydrogène gazeux / Sadrží hydrogen vodík / Hidrogeen gázt fejleszt / Produzione di gas idrogeno / Газтөктөс сүгері пайда болды / 수소 가스 생성됨 / Išskiria vandenilio dujas / Rodas ūdeņradis / Waterstofgas gegenereerd / Hydrogeen gas generert / Powstaje powstawanie wodoru / Produção de gás de hidrogénio / Generare gaz de hidrogen / Выделение водорода / Vyrobené použitím vodíka / Għobada s'hydroġen / Generare di vătgas / Açığa çıkan hidrojen gazı / Реакция з виділенням водню / 会产生氢气



Patient ID number / ИД номер на пациента / ID pacienta / Patientens ID-nummer / Patienten-ID / Αριθμός αναγνώρισης ασθενούς / Número de ID del paciente / Patsiendi ID / No d'identification du patient / Identifikacijski broj pacijenta / Beteg azonosító száma / Numero ID paziente / Пациент идентификационный номер / 환자 ID 번호 / Paciento identifikavimo numeris / Pacienta ID numurs / Identificatienummer van de patiënt / Pasientens ID-nummer / Numer ID pacijenta / Número da ID do doente / Număr ID pacient / Идентификационный номер пациента / Identifikačné číslo pacienta / ID broj pacijenta / Patientnummer / Número / Klinik numarası / Идентификатор пациента / 患者标识号



Fragile, Handle with Care / Чупливо, Работете с необходимото внимание. / Křehké. Při manipulaci postupujte opatrně. / Forngil, kan gá i stykker. / Zerbrechlich, vorsichtig handhaben. / Εύθραυστο. Χειριστείτε το με προσοχή. / Frágil. Manipular con cuidado. / Öm, käsitlege ettevaatlikult. / Frágil, manipuler avec précaution. / Lomljivo, rukujte pažljivo. / Törékeny! Óvatosan kezelendő. / Fragile, maneggiare con cura. / Сыңғыш, абайлап пайдаланыңыз. / 조심히 다뤄주세요. / 쉬운 처리 / Trapu, elkítés atsargiai. / Trausis; rikoties uzmanīgi / Breekbaar, voorzichtig behandelen. / Ømtålig, håndter forsigtig. / Kolay zawaatlaşır. / przenieść ostrożnie. / Frágil, Manuseie com Cuidado. / Frágil, manipulați cu atenție. / Хрупкое! Обращаться с осторожностью. / Křehké, vyžaduje sa opatrná manipulácia. / Forngil, kan gá i stykker. / Bräckligt. Hantera försiktigt. / Kolay Kırılır, Dikkatli Taşıyın. / Тендітна, звертатися з обережністю / 易碎, 小心轻放




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