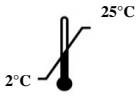
BD MAX™

BD MAX™ DNA MMK

REF 442848 

For Laboratory Use

May be used with the BD MAX™ System or another PCR Amplification/Detection System.

PRODUCT DESCRIPTION
BD MAX™ DNA MMK is a dried down PCR reagent mix containing dNTPs, $MgCl_2$, Hot Start DNA polymerase, and buffers.

MATERIALS PROVIDED

REF	COMPONENT NAME	QUANTITY
442848	(2) packages of 12 foil sealed Master Mix (B9) Tube (each tube contains a dried down pellet of PCR reagent mix) (1) Primer and Probe Diluent Tube (0.6 mL)	Σ 24

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED
1. Micropipettors
2. Aerosol resistant micropipette tips
3. Disposable gloves/lab coat
4. BD MAX™ ExK™ DNA or another DNA extraction method
5. BD MAX™ System: REF 441916 or 441927; or, another PCR Amplification/Detection System

WARNINGS AND PRECAUTIONS
- This product is *For Laboratory Use*.
- Do not use this product if the outer carton safety seal is broken.
- Do not use this product if the packaging is damaged upon arrival.
- Do not use reagents if their protective pouches are open or broken upon arrival.
- Do not use reagents if desiccant is not present or broken inside protective pouches.
- Do not remove desiccant from protective pouches.
- Close protective pouches promptly with the zip seal after each use. Remove any excess air in the pouches prior to sealing.
- Do not use reagents if their foil seal has been opened or damaged.
- The addition of user-provided sample processing control is recommended to monitor sample processing and inhibition.
- Proceed with caution when using chemical solutions, as Master Mix and Extraction Tube barcode readability may be altered.
- Protect reagents against heat and humidity. Prolonged exposure to humidity may affect product performance.
- Never pool reagents from different tubes even if they are from the same lot.
- Do not use reagents after expiration date.
- Avoid microbial and deoxyribonuclease (DNase) contamination of reagents at all times. The use of sterile DNase-free disposable filter-blocked or positive displacement pipette tips is recommended. Use a new tip for each specimen.
- Always handle specimens as if they are infectious and in accordance with safe laboratory procedures such as those described in *Biosafety in Microbiological and Biomedical Laboratories*[1] and in CLSI Document M29[2].
- Wear personal protective equipment and non-powdered disposable gloves while handling all reagents. Wash hands thoroughly after performing the test.
- Do not pipette by mouth, smoke, drink, or eat in areas where specimens or reagents are being handled.
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state and local regulations.
- Consult the user manuals of the DNA extraction system and/or PCR amplification/detection systems used for additional warnings, precautions and procedures.
- Consult the instructions for use of the DNA extraction kit used for additional warnings, precautions and procedures.

STORAGE AND STABILITY
- BD MAX™ DNA MMK is stable at 2-25°C through the stated expiration date. Do not use expired components. The expiration date applies only to unopened kit, stored as directed.
- BD MAX™ DNA MMK Master Mix Tubes are provided in sealed pouches. To protect product from humidity, immediately re-seal after opening. Master Mix Tubes are stable for up to 7 days at 2-8°C after initial opening and re-sealing.

INSTRUCTIONS FOR USE

BD MAX™ Operation
(Refer to BD MAX™ System User's Manual for programming and setup instructions; refer to BD MAX™ ExK™ DNA Product Insert for instructions)

1. For each sample to be extracted and DNA amplified, snap a Master Mix Tube into Position 2 of the DNA Strip.
2. Prepare Liquid Primer and Probe Mixture for target(s) – For each sample to be extracted and amplified, prepare:

COMPONENT	VOLUME
Primer and Probe Diluent (12.5X)	2 µL
User Supplied Primers and Probes (in 1X TE)	0.25 to 10.5 µL*
Sufficient Molecular Grade Water to a Final Volume of	12.5 µL

- the user-supplied primer(s) and probe(s) in the formulation above should be added at 2X the final desired reaction concentration. Primer and probe volume determined by user based on desired final concentration.

3. Add user-provided sample processing control to the Sample Buffer Tube.
4. Pipette 12.5 uL of the Liquid Primer and Probe mixture into Position 3 of the DNA Strip being careful to avoid bubble formation.
5. Continue with instructions for the BD MAX™ ExK™ DNA.
6. The Hot Start DNA polymerase contained in the PCR reagent mix requires hot start activation using a step hold for 600 to 900 seconds at 95°C to 98°C.

Other DNA Extraction Method and other PCR Amplification/Detection System
(DNA Extraction Method Procedure: refer to other PCR Amplification/Detection System's User's Manual)

1. For each Master Mix Tube, combine with primers, probe, target DNA, primer and probe diluent and sufficient Molecular Grade water to a final volume of 12.5 µL (1X).

COMPONENT	VOLUME
Primer and Probe Diluent (12.5X)	1 µL
User Supplied Primers and Probes (in 1X TE)	0.25 to 5.25 µL*
Target DNA	0.25 to 5.25 µL*
10mM Sodium Hydroxide	6.25 µL
Sufficient Molecular Grade Water to a Final Volume of	12.5 µL

- the user-supplied primer(s), probe(s) and target DNA in the formulation above should be added at the final desired reaction concentration (1X). Primer, probe, and target DNA volume determined by user based on desired final concentration. These volumes are **not to exceed** a combined total of 5.25 µL.

2. The Hot Start DNA polymerase contained in the PCR reagent mix requires hot start activation using a step hold for 600 to 900 seconds at 95°C to 98°C.

REFERENCES

[1] Centers for Disease Control and Prevention. *Biosafety in Microbiological and Biomedical Laboratories.* Richmond JY and McKinney RW (eds) (1993). HHS Publication number (CDC) 93-8395.

[2] Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline – Document M29 (Refer to the latest edition).

SYMBOL	MEANING
REF	**Catalog number**
	Use by
Σ	**Contains sufficient for "n" tests**
	Reseal pouch after use
LOT	**Batch code**
	Temperature limitation
	Consult instructions for use
	Protect from light
	Keep dry

THE PURCHASE OF THIS PRODUCT ALLOWS THE PURCHASER TO USE IT FOR AMPLIFICATION OF NUCLEIC ACID SEQUENCES FOR HUMAN *IN VITRO* DIAGNOSTICS IN ACCORDANCE WITH THE PATENTED METHOD DESCRIBED IN THE PACKAGE INSERT. NO GENERAL PATENT OR OTHER LICENSE OF ANY KIND OTHER THAN THIS SPECIFIC RIGHT OF USE FROM PURCHASE IS GRANTED HEREBY.

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Technical Information: In the United States, telephone Technical Services, toll-free (800) 638-8663.
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