BD MAX™ TNA MMK(SPC)

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REF 442830

P0142(03)
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(With Primer/Probe for Process Control)
For Laboratory Use
May be used with the BD MAX System or another PCR Amplification/Detection System.

PRODUCT DESCRIPTION

BD MAX TNA MMK(SPC) is a dried down PCR reagent mix containing dNTPs, Hot Start DNA polymerase with a reverse transcriptase function, buffers, as well as forward and reverse primers and a fluorophore labeled TaqMan® Probe (Excitation: 680 nm; Emission: 715 nm) which are used to amplify a Specimen Processing Control (SPC). BD MAX TNA MMK(SPC) contains primers and probe sequences from a proprietary armored RNA® Quant™ (Asuragen, Inc.)*.

REAGENTS

REF	COMPONENT NAME	QUANTITY
442830	BD MAX™ TNA MMK(SPC) Master Mix (C1) *Dried PCR Master Mix containing dNTPs, RT-polymerase, and Specimen Processing Control-specific molecular primers and probes.*	▽24
	BD MAX™ TNA Primers and Probes Diluent	0.6 mL

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BD MAX™ System: REF 441916 or 441927; or another PCR Amplification/Detection System
- Micropipettes (accurate between 2 and 1000 µL)
- Aerosol resistant micropipette tips
- Disposable gloves/lab coat
- BD MAX™ ExK™ TNA; or another TNA or RNA extraction method
- Molecular grade water

WARNINGS AND PRECAUTIONS

- The BD MAX TNA MMK(SPC) is for *Laboratory Use*.
- 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 is 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.

- Proceed with caution when using chemical solutions, as Master Mix barcode readability may be altered.
- Good laboratory technique is essential for the proper use of this product. 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 DNA MMK(SPC), 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.
- 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 reagents are being handled.
- Dispose of unused reagents and waste in accordance with local, state, provincial and/or federal regulations.
- Consult the user manual of the PCR amplification/detection system use for additional warnings, precautions and procedures.
- Consult the instructions for use of the DNA extraction kit for additional warnings, precautions and procedures.

STORAGE AND STABILITY

- The BD MAX TNA MMK(SPC) product is stable at 2 – 25 °C through the stated expiration date. Do not use if expired.
- The TNA MMK(SPC) Master Mix (C1) Tubes are provided in sealed pouches. To protect product from light and humidity, immediately re-seal after opening. The Master Mix Tubes are stable for up to 14 days at 2 - 25 °C after initial opening and re-sealing of the pouch. Unreconstituted Master Mix Tubes are stable for up to 4 hours at 2 – 25 °C after being removed from their protective pouch.

INSTRUCTIONS FOR USE

Note: The Hot Start DNA polymerase contained in the PCR reagent mix requires hot start activation. The following temperature and time ranges are recommended for activation and reverse transcription. Users must optimize the conditions below based on the desired application.

	Temperature Range	Time Range
Activation	80 - 90 °C	300-600s
RT	55 - 65 °C	900-1800s

BD MAX System Operation

Note: Refer to the BD MAX System User's Manual[1] for detailed instructions (Operation section). Refer to the BD MAX ExK TNA Product Insert for instructions.

For a Type 2: BD MMK or MMK (SPC) and Liquid Primers and Probes:

1. For each specimen to be extracted and amplified using a BD MAX ExK TNA product, assemble a Unitized Reagent Strip by snapping a Master Mix Tube into Position 2 and a BD MAX Conical Tube into position 3 of the Unitized Reagent Strip.
2. Prepare a 2X liquid primer and probe mixture for target(s) – For each specimen to be extracted and amplified, prepare:

COMPONENT	VOLUME
TNA Primer and Probe Diluent (5.88X)	4.25 µL
User Supplied Primers and Probes (in 1X TE)	Maximum 8.25 µL[1]
Sufficient Molecular Grade Water to a Final Volume of 12.5 µL	12.5 µL total

[1]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. Pipette 12.5 µL of the liquid primer and probe mixture into Position 3 of the Unitized Reagent Strip being careful to avoid bubble formation.
4. Continue with instructions for the BD MAX ExK TNA product.

PCR Only on BD MAX System or Use on Another PCR Amplification/Detection System

(Refer to other TNA or RNA Extraction Method Procedure or other PCR Amplification/Detection System User's Manual)

1. For each Master Mix Tube, combine with primers, probe, target TNA or RNA, Primer and Probe Diluent, Elution Buffer and sufficient Molecular Grade water to a final volume of 12.5 µL (1X).

COMPONENT	VOLUME
Primer and Probe Diluent (5.88X)	2.13 µL
User Supplied Primers and Probes (in 1X TE)[1]	Combined volume not to exceed 10.12 µL
TNA or RNA Target[1]	
6.25 µL of Elution Buffer	
Molecular Grade Water	Final volume of 12.5 µL total

[1]The user-supplied primer(s), probe(s) and target RNA and DNA or RNA only in the formulation above should be added at the final desired reaction concentration (1X). Primer(s), probe(s), and target RNA and DNA or RNA only volume determined by user based on desired final concentration.

REFERENCES

1. BD MAX™ System User's Manual (US Open System version 8089571 or International version 8089570 refer to the latest revision) BD Diagnostics, Sparks, MD USA.


Temperature limitations

Batch code (Lot)


Manufacturer


Use by / YYYY-MM-DD / YYYY-MM (MM = end of month)

Catalog number


Contains sufficient for <n> tests


Keep away from light


Consult Instructions for Use


Keep dry

H360 May damage fertility or the unborn child.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P308+**P313** IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/ international regulations.


Perforation

The purchase of this product allows the purchaser to use it for amplification and detection of nucleic acid sequences for diagnostic research purposes. 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, contact BD Technical Service and Support at 1.800.638.8663 or www.bd.com/ds.

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