

BioGX SARS-CoV-2 & RNase P Synthetic RNA Control Templates

BioGX Product no. 720-0678/BD Part no. 444214

SARS-CoV-2 Nucleocapsid Phosphoprotein gene (N1) - Product no. 720-0206

SARS-CoV-2 Nucleocapsid Phosphoprotein gene (N2) - Product no. 720-0207

RNase P - Product no. 720-0208

PRODUCT DESCRIPTION

BioGX Lyophilized Control Template Beads are formulated with quantified RNA (single stranded RNA) at 1×10^5 copies per tube in a lyophilized bead format. Each color coded [(720-0206 (Red), 720-0207 (Green), 720-0208 (Yellow))] product package contains 1 pouch of 12 tubes with each tube containing 1 lyophilized control template bead.

INTENDED USE

BioGX Lyophilized Control Template Beads are for Emergency Use Only and designed to be used only with real-time PCR reagents manufactured by BioGX. Each template control part number in the 720-series corresponds to a specific amplicon region within the gene target for a BioGX manufactured real-time PCR reagent.

ADDITIONAL EQUIPMENT REQUIRED BUT NOT PROVIDED

- BD MAX™ ExK™ TNA-3 [BD Cat. No. 442827 (US) or BD Cat. No. 442828 (ex-US)]
- Molecular grade water
 - BioGX Rehydration Water (Part number: 800-0035)
- Personal Protective Equipment (PPE)
- Biological Safety Cabinet
- Corresponding BioGX real-time PCR reagent
 - Appropriate control template and corresponding PCR reagent part numbers can be confirmed by contacting BioGX at: info@biogx.com
- Bench vortex
- Micro-centrifuge
- Calibrated pipettes and sterile barrier filter tips

PRECAUTIONS

- For Research Use Only
- Product does not contain infectious material but should be handled using aseptic technique as if it is potentially infectious.
- Use Universal Precautions when handling this product.
- To avoid cross-contamination, use separate pipette tips for all reagents.
- All residual materials must be treated as potentially hazardous and disposed of accordingly. This must be carried out according to the established procedures of the laboratory and in accordance with national and international regulations.
- Do not pipette by mouth.
- Do not eat, drink, or smoke when handling this product or within laboratory spaces.

RECOMMENDED STORAGE

BioGX Lyophilized Control Template Beads are shipped at ambient temperature but are recommended to be stored long-term at 2-8 °C prior to bead rehydration.

For lyophilized template beads, refer to Recommended Use By Date stated on the pouch label.






For rehydrated template beads, the Recommended Use by Date must be established by the user.

INSTRUCTIONS FOR USE

For BioGX Lyophilized Controls Template Beads, spike 100 µL of the rehydrated bead into the BD MAX ExK TNA-3 Sample Buffer Tube (SBT) as follows:

1. Add 650 µL of water to the SBT.
2. Rehydrate the positive control beads individually with 100 µL of nuclease free water.
3. Pipette the entire volume of the rehydrated positive control into the SBT tube; N1 and N2 rehydrated control beads are spiked into the same SBT.
4. To prepare the RNase P positive control bead, repeat the steps above with a **new** BD MAX ExK TNA-3 SBT. The rehydrated RNase P positive control bead is added to a separate SBT.

SYMBOLS

	Temperature Limitation
	Keep Dry
	For Research Use Only
	Batch Code / Lot Number
	Manufacture Date



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Rev. #	Effective Date	Summary of Changes
09	16 OCT 2023	Update of stability recommendations to "Use by date stated on pouch label".
08	07 OCT 2022	Updated stability to 27 months when stored at 2-8°C.
07	27 AUG 2021	Updated Branding.
06	07 MAY 2021	Updated stability to 21 months when stored at 2-8°C.
05	01 APR 2021	Include Research Use Only Classification
04	17 MAR 2021	Updated stability to 12 months when stored at 2-8°C.
03	07 APR 2020	Indication of tube color coding, storage conditions and BioGX contact information
02	03 APR 2020	Kit part number addition. TNA-3 kit part numbers for ex-US
01	18 MAR 2020	Initial Release



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