



BioGX Lyophilized Control Template Beads (1 x 10⁵ copies/bead)

BioGX Product Number Series 720-XXXX

PRODUCT DESCRIPTION

BioGX Lyophilized Control Template Beads are formulated with quantified RNA (single stranded RNA) or DNA (amplicon cloned plasmid) at 1 x 10⁵ copies of RNA or DNA template sequence provided per tube in a lyophilized bead format. Each product package contains 1 pouch of 12 or 24 tubes with each tube containing 1 lyophilized control template bead.

INTENDED USE

BioGX Lyophilized Control Template Beads are for research 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

- 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: eu@biogx.com or 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 RNA and DNA template beads, refer to Recommended Use By Date stated on the pouch label.

Once rehydrated, aliquot the product into appropriate one-time use volumes and freeze the RNA aliquots at -80°C, freeze the DNA aliquots at -20°C. Standard precautions to avoid multiple freeze-thaw cycles should be observed.

Rehydrated RNA beads can be stored as single use aliquots for up to 12 months when stored at -80°C.

Rehydrated DNA beads can be stored as single use aliquots for up to 12 months when stored at -20°C.

INSTRUCTIONS FOR USE

Each bead contains the labeled approximate copy number of an amplicon region within the gene target corresponding to the target organism indicated. Copy number is provided on each tube label. Beads can be rehydrated and diluted to obtain the desired concentration of target copies per volume when diluted with molecular grade water.

Use of BioGX Rehydration Water (Part number: 800-0035) is recommended.

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INSTRUCTIONS FOR TEMPLATE CONTROL USE WITH BioGX ASSAY AND INSTRUMENTATION

BioGX template control Product No.: 720-XXXX

BioGX compatible assay Product No.: 400-XXX-X-MAX, 450-XXX-X-MAX

PCR Instrument: BD MAX

- Rehydrate the lyophilized bead with a minimum volume of 20 µL of molecular grade water.
- **DNA and RNA template beads:** Slowly pipette up and down 5 times to homogenize the rehydrated bead.
- Centrifuge the tube briefly to settle the liquid.
- Based on the desired copy number of nucleic acid, prepare appropriate dilutions and add 20-200 µL of diluted template to the BD MAX™ ExK™ Sample Buffer Tube.

BioGX template control Product No.: 720-XXXX

BioGX compatible assay Product No.: 450-XXX-LMP

PCR Instruments: Applied Biosystems™, Bio-Rad and pxi™

- Rehydrate the lyophilized bead with a minimum volume of 100 µL of molecular grade water.
- **DNA and RNA template beads:** Slowly pipette up and down 5 times to homogenize the rehydrated bead.
- Centrifuge the tube briefly to settle the liquid.
- Based on the desired copy number of nucleic acid, prepare appropriate dilutions and add 5 µL of the positive control to each positive control well position(s) containing the dispensed master mix.
- Visually examine the reaction mix pellet after mixing to ensure lyophilized reaction mix pellets are fully dissolved, no air bubbles are present and that all liquid is at the bottom of the tube.

BioGX template control Product No.: 720-XXXX

BioGX compatible assay Product No.: 450-Series-PXL

PCR Instrument: pxi™

- Rehydrate one BioGX lyophilized template control bead with 100 µL of molecular grade water.
- **DNA and RNA template beads:** Slowly pipette up and down 5 times to homogenize the rehydrated bead.
- **450-Series-E-PXL:** Rehydrate the BioGX lyophilized reaction mix by pipetting 30 µL of BioGX Rehydration Buffer E (BioGX catalog no. 800-0031-E-L) to one PCR strip tube containing the BioGX lyophilized reaction mix. Add 20 µL of the rehydrated BioGX lyophilized template control to the rehydrated BioGX reaction mix.
- **450-Series-H-PXL:** Rehydrate the BioGX lyophilized reaction mix by pipetting 30 µL of BioGX Rehydration Buffer H (BioGX catalog no. 800-0034-HL) to one PCR strip tube containing the BioGX lyophilized reaction mix. Add 20 µL of the rehydrated BioGX lyophilized template control to the rehydrated BioGX reaction mix.
- **450-Series-PXL:** Rehydrate the BioGX lyophilized reaction mix by pipetting 40 µL of molecular grade water to one PCR strip tube containing the BioGX lyophilized reaction mix. Add 10 µL of the rehydrated BioGX lyophilized template control to the rehydrated BioGX reaction mix.

- Visually examine the reaction mix pellet after mixing to ensure lyophilized reaction mix pellets are fully dissolved, no air bubbles are present and that all liquid is at the bottom of the tube.

BioGX template control Product No.: 720-0206 (SARS CoV-2 N1 gene)

BioGX compatible assay Product No.: 500-003-XMP

PCR Instruments: Applied Biosystems™, Bio-Rad and MIC

A single BioGX lyophilized SARS-CoV-2 (N1) control bead containing 100,000 copies/bead should be serially diluted to achieve a final concentration of 10,000 copies/mL (10 copies/µL):

- Rehydrate one BioGX lyophilized SARS-CoV-2 (N1) control bead (catalog no. 720-0206) with 100 µL of molecular grade water. Slowly pipette up and down 5 times to homogenize then discard the pipette tip. This will be the SARS-CoV-2 (N1) stock solution.
- With a fresh pipette tip, prepare two microcentrifuge tubes for serial dilution by adding 90 µL of molecular grade water to each.
- Label the tube caps with “N1-10” and “N1-100” to represent the 1/10 dilution and 1/100 dilution of SARS-CoV-2 (N1) stock solution, respectively.
- With a fresh pipette tip, transfer 10 µL of the SARS-CoV-2 (N1) stock solution to the first microcentrifuge tube labeled “N1-10”. Slowly pipette up and down 5 times to homogenize then discard the pipette tip.
- With a fresh pipette tip, transfer 10 µL of the “N1-10” dilution to the second microcentrifuge tube labeled “N1-100”. Slowly pipette up and down 5 times to homogenize then discard the pipette tip. The microcentrifuge tube labeled “N1-100” now contains SARS-CoV-2 (N1) control at 10,000 copies/mL.
- Add 5 µL of SARS-CoV-2 (N1) control (50 copies/PCR reaction) from the microcentrifuge tube labeled “N1-100” to each positive control well position(s) containing dispensed master mix.

BioGX template control Product No.: 720-0206 (SARS CoV-2 N1 gene)






BioGX compatible assay Product No.: 500-003-XMP

PCR Instrument: pxi™

- Rehydrate the lyophilized bead with 500 µL of molecular grade water.
- Mix by pipetting up and down 5 times.
- Add 5 µL of the positive control to each positive control well position(s) containing dispensed master mix.

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SYMBOLS

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

REVISION HISTORY

Rev. #	Effective Date	Summary of Changes
13	20 FEB 2024	Updated template control processing for use with pixl™ Real-Time PCR platform and 450-Series-PXL products
12	16 OCT 2023	Update of stability recommendations to "Use by date stated on pouch label".
11	24 MAR 2023	Updated template control processing for use with pixl™ Real-Time PCR platform and 450-XXX-E-PXL products
10	07 OCT 2022	Update dried RNA template control storage to 27 months when stored at 2-8C. Update dried DNA template control storage to 60 months when stored at 2-8C.
09	24 MAY 2022	Update dried DNA template control storage to 54 months when stored at 2-8C. Update rehydration steps for DNA and RNA template beads.
08	17 SEP 2021	Updated template control processing for use with ABI and Bio-Rad platforms, added procedure for 720-0206 for use with 500-003-XMP on ABI, Bio-Rad and pixl™ Real-Time PCR platforms
07	27 AUG 2021	Updated Branding.
06	07 MAY 2021	Updated RNA product stability
05	01 APR 2021	Include Research Use Only classification
04	20 OCT 2020	Update procedure for Xfree product line.
03	27 MAY 2020	Update recommended storage conditions and update product stability.
02	18 MAR 2020	Update product name and part number series, update product description section, update intended use section, update additional equipment but not provided section.
01	01 APR 2019	Initial Release.



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