



BioGX

Molecular Made Easy

Sample-Ready DNA Master Mix Lyophilized Open System Reagents

REF 450-051-XMM



16 Reactions (Direct Sample)

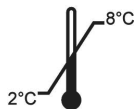


64 Reactions (Purified Nucleic Acid)

Product Insert

For Research Use Only: Not intended for In Vitro Diagnostic Use

For use with open system Real-Time PCR platforms



RUO



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For Research Use Only

Research use only reagents are not intended for human or animal diagnostic use. It is the responsibility of the end user to determine the performance of the reagents in an appropriately designed validation study for their intended use.

This product is manufactured and packaged as an open system reagent (OSR) for use with open system platforms and has to be validated by the user.

PLEASE READ ENTIRE PACKAGE INSERT BEFORE PROCEEDING TO USE THE OSR.

PRODUCT OVERVIEW

The BioGX Sample-Ready DNA Master Mix is a pre-mixed, pre-dispensed blend of reagents for performing PCR amplifications. The BioGX Sample-Ready DNA Master Mix is provided as a lyophilized reagent pellet and contains reagents necessary to perform PCR amplification, including DNA Polymerase, dNTPs, optimized PCR buffer, and salts. BioGX Sample-Ready DNA Master Mix lyophilized reagent pellets are compatible with direct and purified nucleic acid sample addition.

Reagents in each tube are sufficient to perform 1 x 50 µl PCR reaction with direct sample addition or 4 x 15 µl PCR reactions with purified nucleic acid sample addition.

The format for the lyophilized Sample-Ready OSR kit available is:

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- Each kit consists of one pouch containing 2 x 8-tube PCR strips.
- Each tube contains one lyophilized BioGX Sample-Ready DNA Master Mix reagent pellet sufficient for 1 x 50 µl PCR reaction for direct sample addition workflow or 4 x 15 µl PCR reactions for purified nucleic acid addition workflow.

EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- BioGX Molecular Grade Water or equivalent
 - BioGX Rehydration Water (Part number: 800-0035-12)
- Custom primer and probe or intercalating dye of choice
- Validated Nucleic Acid Extraction Kit (if extracted samples are used as template)
- PCR tubes and/or PCR plates compatible with the PCR instrument of choice
- Vortex Genie 2 Vortexer (VWR catalog no. 58815-234) or equivalent
- Microcentrifuge
- Micropipettes and pipette tips
- Disposable nitrile gloves

WARNINGS AND PRECAUTIONS

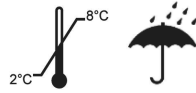


- For research use only. Not intended for human or animal diagnostics use.
- If handling biological samples, treat as if capable of transmitting infectious agents in accordance with safe laboratory procedures such as those described in CLSI Document M29¹ and in Biosafety in Microbiological and Biomedical Laboratories².
- Do not use the reagents if the protective pouches are open or torn upon arrival.
- Close reagent protective pouches promptly with the zip seal after each use. Remove any excess air in the pouches prior to sealing and store at 2-8 °C.
- Do not remove desiccant from the PCR master mix pouches.
- Do not use master mix if the desiccant is not present or is broken inside the pouches. Do not use reagent vials if they are opened or damaged.
- Do not mix reagents from different pouches and/or kits and/or lots.
- Do not use expired reagents and/or materials.
- Do not pipette by mouth.
- Do not smoke, drink, or eat in areas where samples or kits are being handled.
- Dispose of unused reagents and waste in accordance with country, federal, provincial, state, and local regulations.



- Clean and disinfect all surfaces with a 10% bleach solution followed by molecular grade water.
- Use clean gloves when handling PCR reagents.

STORAGE REQUIREMENTS AND RECOMMENDATIONS



Reagents are stable at a temperature range of 2-30°C during shipment for 5 days, but BioGX recommends long-term storage at 2-8°C. Reagents have been tested to demonstrate optimal performance when stored properly and consumed by the Manufacturer Recommended Use By Date. The end user may opt to extend the useful life for Research Use Only reagents upon completing performance validations. BioGX's guarantee of reagent integrity does not extend beyond the Manufacturer Recommended Use By Date. Avoid exposing the reagents (lyophilized or rehydrated) to direct sunlight or long-term ambient lighting. Store unused rehydrated master mix up to 24 hours at 2-8°C, protected from light. Tightly reseal the pouch with unused vials and immediately return to a refrigerator after opening. To mitigate reagent performance degradation from exposure to moisture, BioGX suggests using the entire contents of the opened and refrigerated pouch within 1 month; however, the user may choose to verify an extended working time (> 1 month) by performance testing with positive controls and an examination of the sample preparation control target.

QUALITY CONTROL TESTING

Quantified synthetic DNA at a concentration of 20 copies/reaction is used for quality control testing.

REAGENT PREPARATION

Please refer to the user manual of the PCR instrument of choice for the generation, import and installation of PCR run files.

1. Prepare reagents

- a. Keep reagents on ice during set-up.
- b. Remove sufficient tubes (1 tube sufficient for single direct sample addition or 1 tube sufficient for 4 samples of purified nucleic acid) of the lyophilized BioGX Sample-Ready DNA Master Mix from their mylar pouch. Return any unused tubes to the mylar pouch, re-seal pouch, and return to the appropriate storage location.
- c. The lyophilized funnel-shaped reagent pellet may be in any orientation (v, >, ^, <) and position. Gently tap the tube on the bench to bring the lyophilized reagent pellet to the bottom of the tube.
- d. Prepare primers/probe[s] or intercalating dye as per manufacturer's instructions. Protect fluorescent probes/intercalating dyes from sunlight or long term exposure to ambient lighting.
- e. Prepare template (direct or purified nucleic acid sample) as per manufacturer's instructions.
- f. Briefly vortex to thoroughly mix liquid reagents.
- g. Quickly centrifuge to collect solutions at the bottom of tubes.

2.1. Procedure for Direct Sample Addition (using liquid primers and probes)

- a. Prepare sufficient volume of master mix for the number of PCR reactions needed. **One tube of lyophilized BioGX Sample-Ready DNA Master Mix is sufficient for 1 x 50 μ l PCR reaction in direct sample workflow.**

If more than 1 PCR reaction is required, prepare the appropriate number of BioGX Sample-Ready DNA Master Mix tubes, e.g. if 8 PCR reactions are required, prepare 8 BioGX Sample-Ready DNA Master Mix tubes separately (**Table 1**).

Store unused rehydrated master mix up to 24 hours at 2-8°C, protected from light.

Note: It is recommended to include no template controls and/or positive controls.

- b. Rehydrate 1 PCR tube containing the BioGX Sample-Ready DNA Master Mix (lyophilized reagents) with molecular grade water and primers/probe[s] or intercalating dye stock mixture (**Table 1**).
- c. Thoroughly mix by slowly pipetting up and down.
- d. For each PCR reaction, dispense **30 μ l** of **prepared reaction mix (Table 1)** into PCR instrument compatible PCR tubes or plates.
- e. For each PCR reaction, add **20 μ l** of **direct sample template (Table 1)** to each PCR tube/plate well containing dispensed, prepared reaction mix.
- f. Seal PCR tubes/plates appropriately.
- g. Quickly centrifuge to collect solutions at the bottom of the tube and to remove air bubbles.

Sample-Ready DNA Master Mix Lyophilized Open System Reagents

Table 1: PCR Set-Up for use with Direct Sample^a addition.

Reagent	Final concentration	Volume per Sample-Ready DNA Master Mix tube (sufficient for 1 sample)
BioGX Sample-Ready DNA Master Mix	1 lyophilized reagent pellet	1 lyophilized reagent pellet
Primers, probe[s] or intercalating dye	Determined by User ^b	5 µL^b
Molecular grade water	N/A	25 µL
Direct Sample ^a	N/A	20 µL
Total Volume	N/A	50 µL^c

^aExamples of transport media that support direct sample addition include swab samples transported in Copan UTM, Copan Eswab, 0.85% saline and molecular grade water.

^b It is recommended to prepare a working concentration of primers, probe[s] or intercalating dye (recommended concentration range 100 nM to 600 nM each) into a final volume of 5 µL per Sample-Ready DNA Master Mix tube.

^cCalculations for final primers, probe[s] or intercalating dye consider a final volume per Sample-Ready DNA Master Mix of 50 µL.

2.2. Procedure for Purified Nucleic Acid Sample Addition (using liquid primers and probes)

- a. Prepare sufficient volume of master mix for the number of PCR reactions needed. **One tube of lyophilized BioGX Sample-Ready DNA Master Mix is sufficient for 4 x 15 μ L PCR reaction in purified nucleic acid sample workflow.**

If more than 4 PCR reactions are required, prepare the appropriate number of BioGX Sample-Ready DNA Master Mix tubes, e.g. if 8 PCR reactions are required, prepare 2 BioGX Sample-Ready DNA Master Mix tubes separately (**Table 2**).

Store unused rehydrated master mix up to 24 hours at 2-8°C, protected from light.

Note: It is recommended to include no template controls and/or positive controls.

- b. Rehydrate 1 PCR tube containing the BioGX Sample-Ready DNA Master Mix (lyophilized reagents) with molecular grade water and primer/probe stock mixture (**Table 2: Volume per Sample-Ready DNA Master Mix tube**).
- c. Thoroughly mix by slowly pipetting up and down.
- d. For each PCR reaction, dispense **10 μ L** of **prepared reaction mix (Table 2: Volume per PCR Reaction)** into compatible PCR tubes or plates.
- e. For each PCR reaction, add **5 μ L** of **purified nucleic acid sample template (Table 2: Volume per PCR Reaction)** to each PCR tube/plate well containing dispensed, prepared reaction mix.
- f. Seal PCR tubes/plates appropriately.
- g. Quickly centrifuge to collect solutions at the bottom of the tube and to remove air bubbles.

Sample-Ready DNA Master Mix Lyophilized Open System Reagents

Table 2: PCR Set-Up for use with Purified Nucleic Acid Sample Addition.

Reagent	Final concentration	Volume per Sample-Ready DNA Master Mix tube (sufficient for 4 reactions)	Volume per PCR Reaction
BioGX Sample-Ready DNA Master Mix	1 lyophilized reagent pellet	1 lyophilized reagent pellet	10 μL
Primers, probe[s] or intercalating dye	Determined by User ^a	5 μL^a	
Molecular grade water	N/A	35 μl	N/A
Purified Nucleic Acid	N/A	N/A	5 μL
Total Volume	N/A	40 μL^b	15 μL

^aIt is recommended to prepare a working concentration of primers, probe[s] or intercalating dye (recommended concentration range 100 nM to 600 nM each) into a final volume of 5 μ l per Sample-Ready DNA Master Mix tube.

^bCalculations for final primers, probe[s] or intercalating dye consider a final volume per Sample-Ready DNA Master Mix of 60 μ L.

3. Set-up PCR cycling program

- a. Program the appropriate PCR cycling protocol on the real-time PCR instrument of choice.

4. Run PCR

- a. If the PCR tube/plate was stored before PCR, centrifuge briefly.
- b. Place the plate in the real-time PCR instrument and start the PCR cycling program.

ASSAY PERFORMANCE

BioGX Sample-Ready DNA Master Mix is designed to detect 20 copies or less of the target nucleic acid per reaction when utilized in a properly optimized PCR.









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. Choosewood L.C. and Wilson D.E. (eds) (2009). HHS Publication No. (CDC) 21-1112.

Please call BioGX or email info@biogx.com with any questions you may have regarding this product.

Rev. #	Effective Date	Summary of Changes
03	05 NOV 2024	Product Name change from Xfree Master Mix DNA to Sample-Ready DNA Master Mix and streamlining of workflow.
02	05 APR 2024	Update workflow for direct sample processing.
01	19 NOV 2021	Initial Release.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
	Catalog number		Contains sufficient for <n> reactions
	Research Use Only		Manufacturer
	Keep dry		Temperature limitation
	Consult instructions for use		Biological Risks



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