BioGX
Molecular Made Easy

ABRM3 - vanA, vanB, mecA Open System PCR Reagents

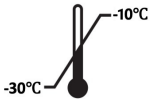
REF **450-081-LMP**

Σ 64 Reactions

Product Insert

For Research Use Only: Not for use in diagnostic procedures

For use with ABI QuantStudio™ 5, ABI 7500 Fast Dx, Bio-Rad CFX96 Touch™, Bio-Rad CFX384 Touch™, BioGX pixl.16 real-time PCR platform



RUO

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For Research Use Only

Research use only reagents are not for use in diagnostic procedures. It is the responsibility of the end user to implement for the intended use.

The vanA, vanB, mecA real-time PCR-based detection reagent is manufactured and packaged as an open system reagent (OSR) for use with open system platforms and has to be validated by the user. Examples of open system platforms are the Applied Biosystems QuantStudio™ 5 (Design & Analysis software version 1.5.1 or later), Applied Biosystems 7500 Fast Dx (SDS software version 1.4 or later), Bio-Rad CFX96 Touch™, CFX384 Touch™ (Maestro software version 1.1 or later) or BioGX pixl.16 (For Android® based software version 1.6.9 or later) real-time PCR platforms.

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

PRODUCT OVERVIEW

The BioGX OSR has been formulated in liquid format for the multiplex real-time PCR-based detection of DNA from antibiotic resistance gene(s) vanA[1], vanB[1], mecA[2] and RNaseP which serves as an endogenous extraction control. The assay format of the OSR kit is available for the ABI QuantStudio™ 5, ABI 7500 Fast Dx, Bio-Rad CFX96 Touch™, Bio-Rad CFX384 Touch™ and BioGX pixl.16 Platforms.

Note:

OSR for ABI, Bio-Rad and BioGX pixl.16 Platforms (450-081-LMP) contains all PCR primers, probes, enzymes, dNTPs, $MgCl_2$, buffers, and other components required for the PCR reaction. No exogenous addition of SPC is needed.

PACKAGE CONTENTS

BioGX REF: 450-081-LMP
Platform(s): ABI QuantStudio™ 5, ABI 7500 Fast Dx, Bio-Rad CFX96 Touch™, Bio-Rad CFX384 Touch™ and BioGX pixl.16

Each 64-reaction package consists of one pouch:
The pouch contains one 1.5 mL screw cap tube containing 640 uL of liquid master mix. Each tube is sufficient for 64 x 15 µL PCR reactions (10 µL PCR master mix + 5 µL purified DNA).

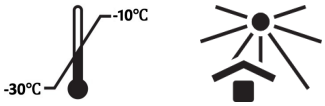
EQUIPMENT AND MATERIALS REQUIRED BUT NOT PROVIDED

- Lyophilized Positive Control Template DNA Beads (10^5 copies/bead)
  - BioGX vanA (Part number 720-0018)
  - BioGX vanB (Part number 720-0019)
  - BioGX mecA (Part number 720-0053)
  - BioGX RNaseP (DNA) (Part number 720-0009)
- BioGX Molecular Grade Water or equivalent
  - BioGX Rehydration Water (Part number: 800-0035-12)
- Vortex Genie 2 Vortexer (VWR catalog no. 58815-234) or equivalent
- Disposable nitrile gloves
- Applied Biosystems QuantStudio 5 (0.2 mL) consumables.
  - Thermo Fisher optical 8-tube strip (catalog no. 4316567)
  - Thermo Fisher ultra-clear optical caps, strips of 8 (catalog no. AB-0866)
  - Thermo Fisher 96-well optical clear reaction plates (catalog no. A36924)
  - Thermo Fisher 96-well qPCR plate seals (catalog no. AB-1170)
- Applied Biosystems 7500 Fast Dx (0.1 mL) consumables.
  - Thermo Fisher optical 8-tube strip (catalog no. 4358293)
  - Thermo Fisher ultra-clear optical caps, strips of 8 (catalog no. 4323032)
  - Thermo Fisher 96-well optical reaction plates (catalog no. 4346906)
  - Thermo Fisher 96-well qPCR plate seals (catalog no. 4311971)
- Bio-Rad CFX96 Touch consumables.
  - Bio-Rad 8-tube PCR strips without caps (catalog no. TLS0851)
  - Bio-Rad Optical flat 8-cap strips for PCR tubes (catalog no. TCS0803)
  - Bio-Rad 96-well plates (catalog no. HSP9655)
  - Bio-Rad 96-well plate sealing film, optical (catalog no. MSB1001)
- Bio-Rad CFX384 Touch consumables.
  - Bio-Rad 384-well plates (catalog no. HSP3905)
  - Bio-Rad 384-well plate sealing film, optical (catalog no. MSB1001)
- BioGX pixl.16 real-time PCR instrument (BioGX catalog no. 650-016-PXL-R)
- BioGX pixl.16 consumables.
  - TempAssure® PCR 8-Tube Strips, Att. Optical Caps (BioGX catalog no. 010-280-ETS) or
  - EasyStrip™ Plus Tube Strip with Attached Ultra Clear Caps (Thermo Fisher catalog no. AB2005) or
  - Axygen® 0.2 mL Polypropylene PCR Tube Strips and attached Flat Cap Strips, 8 Tubes/Strip, (Corning catalog no. PCR-0208-AF-C)

WARNINGS AND PRECAUTIONS

- For research use only. Not intended for use in diagnostic procedures.
- If handling biological samples, including used Extraction Kits and PCR Cartridges, treat as if capable of transmitting infectious agents in accordance with safe laboratory procedures such as those described in CLSI Document M29[3] and in Biosafety in Microbiological and Biomedical Laboratories[4].
- BioGX REF: 450-081-LMP has been quality control tested only with the ABI QuantStudio™ 5, ABI 7500 Fast Dx, Bio-Rad CFX96 Touch™, Bio-Rad CFX384 Touch™ and BioGX pixl.16 real-time PCR platforms.
- Do not use the reagents if the protective pouches are open or torn upon arrival.
- Upon arrival, thaw tube and aliquot in volumes appropriate for routine use and store at -30°C to -10°C. Do not freeze-thaw after aliquots are generated.
- 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.
- Use clean gloves when handling extraction kit components and PCR reagents and buffer tubes.

STORAGE REQUIREMENTS AND RECOMMENDATIONS



Reagents are stable at 0°C during shipment. Upon arrival, thaw tube and aliquot in volumes appropriate for routine use and store at -30°C to -10°C. Do not freeze-thaw after aliquots are generated. 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 their own performance validations. BioGX's guarantee of reagent integrity does not extend beyond the Manufacturer Recommended Use By Date when stored properly. Avoid exposing the reagents to direct sunlight or long-term ambient lighting.

SAMPLE TYPES UTILIZED FOR QUALITY CONTROL TESTING

-Swab samples collected in Copan Universal Transport Media (UTM) and Copan ESwab™
-Urine sample (neat urine or boric acid preserved urine)

REAGENT OPTICAL CONFIGURATION

Table 1. Optical Channel Configuration for REF 450-081-LMP.

Optical Channel (Fluorophore Equivalent)	**Target**
FAM	vanA
HEX	mecA
Texas Red	vanB
Cy5	RNase P
Cy5.5	Unused

QUALITY CONTROL AND EXTRACTION TESTING PARAMETERS

ABI, Bio-Rad and BioGX pixl.16 Platforms (BioGX REF: 450-081-LMP)

As a starting point, users can import and install a PCR run file onto:

1. Applied Biosystems QuantStudio™ 5 (Design & Analysis software version 1.5.1 or later)
2. ABI 7500 Fast Dx (SDS software version 1.4 or later)
3. Bio-Rad CFX96 Touch™ (Maestro software version 1.1 or later)
4. Bio-Rad CFX384 Touch™ (Maestro software version 1.1 or later)
5. BioGX pixl.16 real-time PCR platform (For Android® based software version 1.6.9 or later)

BioGX's most current ABI QuantStudio™ 5, ABI 7500 Fast Dx, Bio-Rad CFX96 Touch™, and Bio-Rad CFX384 Touch™ PCR run files utilized for quality control of this product can be obtained by sending an email to TS@biogx.com. Please refer to the Applied Biosystems QuantStudio™ 5 user manual[5] for uploading instructions. Please refer to the ABI 7500 Fast Dx user manual[6] for uploading instructions. Please refer to the Bio-Rad CFX96 Touch™ user manual[7] for uploading instructions. Please refer to the Bio-Rad CFX384 Touch™ user manual[7] for uploading instructions. Please refer to the BioGX pixl.16 user manual[8] for uploading instructions.

SAMPLE VOLUMES UTILIZED DURING QUALITY CONTROL TESTING

The end user may choose to validate a different pretreatment method or volume of sample to load other than the sample processing used by BioGX for QC testing as outlined below.

Urine collection (neat urine or boric acid preserved urine)

ABI, Bio-Rad and BioGX pixl.16 Platforms (validated magnetic bead or silica column extraction kits)
Thoroughly vortex the sample prior to processing. Follow manufacturer recommendations for extraction of appropriate sample volume. Transfer 5 µL of purified nucleic acid to master mix as described in Section: *BioGX Quality Control Setup Procedure for ABI, Bio-Rad and BioGX pixl.16 Platforms.*

Swab sample (Copan Universal Transport Media (UTM®) or Copan ESwab™)

ABI, and Bio-Rad and BioGX pixl.16 Platforms (validated magnetic bead or silica column extraction kits)
Thoroughly vortex the sample prior to processing. Follow manufacturer recommendations for extraction of appropriate sample volume. Transfer 5 µL of purified nucleic acid to master mix as described in Section: *BioGX Quality Control Setup Procedure for ABI, and Bio-Rad and BioGX pixl.16 Platforms.*

BioGX QUALITY CONTROL SETUP PROCEDURE

Quality Control Setup Procedure for: ABI, Bio-Rad and BioGX pixl.16 Platforms

Assembly of PCR Reactions

1. Prepare the appropriate number of 8-tube PCR strips, 96-well or 384-well PCR plates.

2. Thaw master mix, pipette up and down gently to thoroughly mix. IMPORTANT: Keep master mix in a cold block or on ice if setup can not be completed within 20 minutes. If the master mix cannot be used immediately, it can be stored for up to 12 hours at 2-8°C, protected from light.

3. Transfer 10 µL of master mix to the bottom of each empty well.

4. To each well containing 10 µL of master mix, add 5 µL of extracted sample.

5. Affix the appropriate optical caps or optical plate seals.

6. Pulse spin the sealed PCR plate or tube to mix and bring liquid to the bottom.

7. Load 8-tube PCR strips, 96-well or 384-well PCR plates into the real-time PCR platform and start the run. Avoid unnecessary delay once tubes/plates are loaded into the real-time PCR instrument.

ASSAY PERFORMANCE

All BioGX Research Use Only products are designed to detect 20 copies or less of the target nucleic acid per reaction.

INTERPRETATION OF RESULTS

Table 2. Multiplex PCR Results Interpretation for 450-081-LMP.

vanA	vanB	mecA	RNAse P	Interpretation
+	-	-	+/-	vanA POSITIVE
-	+	-	+/-	vanB POSITIVE
-	-	+	+/-	mecA POSITIVE
-	-	-	+	vanA, vanB, mecA NEGATIVE
-	-	-	-	Unresolved*

*Failed PCR due to inhibition, reagent failure or incorrect assembly of PCR reaction.

REFERENCES

1. Palladino, Silvano, et al. "Real-time PCR for the rapid detection of vanA and vanB genes." Diagnostic microbiology and infectious disease 45.1 (2003): 81-84.
2. Nijhuis, Roel HT, et al. "A rapid and high-throughput screening approach for methicillin-resistant Staphylococcus aureus based on the combination of two different real-time PCR assays." Journal of Clinical Microbiology 52.8 (2014): 2861-2867.
3. Clinical and Laboratory Standards Institute. Protection of laboratory workers from occupationally acquired infections; Approved Guideline. Document M29 (Refer to the latest edition).
4. 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.
5. QuantStudio™ Design and Analysis software User Guide, ThermoFisher Scientific, Waltham, Massachusetts, USA (Refer to the latest version).
6. Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument Instructions for Use (2012). Life Technologies Holdings Pte Ltd, Singapore. Publication Part Number 4406991 [Rev. E].
7. CFX96 Touch, CFX96 Touch Deep Well, CFX Connect, and CFX384 Touch Systems Instruction Manual (refer to the latest version), Bio-Rad Laboratories, Inc., Hercules, California, USA (Refer to the latest version).
8. BioGX pixl.16 Real-Time PCR Platform Instructions for Use (refer to the latest version), BioGX, Inc., Birmingham, Alabama, USA.

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

Rev. #	Effective Date	Summary of Changes
04	20 MAR 2026	Updated assay to liquid format, updated storage conditions and workflow
03	03 NOV 2025	Updated research use only text.
02	07 MAR 2025	Addition of product abbreviation code ABRM3 (Antibiotic Resistance Multiplex 3)
01	20 OCT 2022	Initial Release.

SYMBOLS

Symbol	Meaning	Symbol	Meaning
	Catalog number		Contains sufficient for <n> tests
	Research Use Only		Manufacturer
	Keep Away from Sunlight		Temperature limitation
	Consult instructions for use		Biological Risks

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