BAX® Prep Lysis Kit

Product No. KIT2047 (for 96 reactions)

Revision A, May 2025

Introduction

Kit Contents

- 2 bottles of Lysis Buffer (12 mL)
- 1 vial of Protease (400 µL)

Intended Use

The BAX® Prep Lysis Kit is intended to be used for the rapid extraction of DNA from gram-negative bacteria and some gram-positive bacteria (depending on the assay protocol) in various types of sample material for direct use in PCR testing. The extracted DNA can be used in combination with Hygiena's molecular diagnostics PCR kits on the BAX System Q7 and other real-time PCR instruments.

Field of Use

Data obtained from the BAX System should not be used for human diagnostic or human treatment purposes. Equipment is not approved by the United States Food and Drug Administration or any other US or non-US regulatory agency for use in human diagnostics or treatment. The BAX System should not be used as the sole basis for assessing the safety of products for release to consumers. The information generated is only for use in conjunction with the user's standard quality assurance program. Not approved for clinical diagnosis. Use for research and development, quality assurance and quality control under the supervision of technically qualified persons.

Storage and Shelf Life

- Reagents should be refrigerated at 2 to 8 °C. Do not freeze.
- Reagents should be used by the expiration date on the individual labels.
- After the addition of Protease to the Lysis Buffer, the shelf life of the solution is 2 weeks when stored at 2 to 8 °C.

Required Materials

- Heating blocks with inserts* capable of maintaining 37 ± 2 °C (or 55 ± 2 °C) and 95 ± 3 °C
- Cooling blocks with inserts*
- Capping/decapping tool (Product No. MIS2011)
- Adjustable mechanical pipettes (5 - 50 µL; 20 - 200 µL)
- Repeating pipette
- Cluster tubes with caps and racks
- Pipette tips with barriers
- Powder-free nitrile gloves

* The Automated Thermal Block (Product No. MCH2023) may be used in place of heating and cooling blocks. If using the Automated Thermal Block, follow the instructions in the *Automated Thermal Block User Guide*.

Test Protocol

1. Prepare Equipment

1.1 Turn on the heating blocks for the 37 °C (gram-negative, or 55 °C for gram-positive organisms) and the 95 °C incubations*.

1.2 Chill cooling blocks to 2 to 8 °C*.

2. Perform Lysis

2.1 Ensure the sample was enriched following appropriate incubation time and temperature protocols. If the enrichment has been shaken, let the suspension settle for 5-10 minutes before sampling.

2.2 Break the cluster tubes apart.

2.3 Label and arrange cluster tubes in a rack according to the rack file.

2.4 Prepare lysis reagent by adding 150 µL of Protease to one 12 mL bottle of Lysis Buffer.

2.5 Transfer 200 µL of lysis reagent to each cluster tube.

2.6 Transfer specified enriched sample volume listed below to a cluster tube filled with lysis reagent:

Name of assay(s)	Volume of Enriched Sample
BAX® System Standard and Real-Time Assays (except for *E. coli* O157:H7 and STEC)	5 µL
BAX® System *E. coli* O157:H7 MP	Refer to product instructions
BAX® System Real-Time *E. coli* O157:H7	20 µL
BAX® System Real-Time *E. coli* O157:H7 Exact	
BAX® System Real-Time STEC Screening	
BAX® System Real-Time STEC Panel 1	
BAX® System Real-Time STEC Panel 2	
foodproof® *Salmonella* plus *Cronobacter* Detection LyoKit	

2.7 Depending on the organism type, proceed as follows:

a. For gram-negative organisms, heat at 37 °C for 20 minutes.

b. For gram-positive organisms, heat at 55 °C for 60 minutes.

2.8 After the initial heat treatment in step 2.7, perform a second incubation by heating at 95 °C for 10 minutes.

2.9 Cool at 2 to 8 °C for 5 minutes.

2.10 Follow the relevant product instructions and proceed with the PCR steps. Otherwise, unopened processed lysates can be stored at 2 to 8°C for up to two weeks.
NOTE: For molecular colony confirmations, please use 5 µL of colony dilutions for all assays.

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Additional Information

Hygiena® Liability

Hygiena will not be liable to the user or others for any loss or damage, whether direct or indirect, incidental or consequential, from the use of this device. If this product is proven to be defective, Hygiena's sole obligation will be to replace the product, or at its discretion, refund the purchase price. Promptly notify Hygiena within 5 days of discovery of any suspected defect and return the product to Hygiena; please contact Customer Service for a Returned Goods Authorization Number.

Support

If you have questions or experience problems with this or any other Hygiena product, contact our Technical Support staff (for details, see www.hygiena.com/support). Our scientists commit themselves to providing rapid and effective help. Contact us if you have suggestions for enhancing our product performance or using our products in new or specialized ways. Such customer information has repeatedly proven invaluable to us and the worldwide research community.

Change Index

Revision A, November 2023/April 2025
New product package insert, with updated product name; added table of enriched sample volumes.