



BAX® Prep *Aspergillus* Lysis Kit

Product No. KIT2044 (96 tests)

BAX® Prep *Aspergillus* Supplement Kit

Product No. KIT2045 (96 tests)

Revision A, September 2024

Introduction

Kit Contents

BAX Prep *Aspergillus* Lysis Kit Contents

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

BAX Prep *Aspergillus* Supplement Kit Contents

- 96 liquid-free Disruptor Tubes with beads (1 box of 96 tubes; green caps)
- 2 vials of DNA Stabilizer (1 mL; orange caps)

Intended Use

The BAX® Prep *Aspergillus* Lysis Kit is intended to be used with the foodproof® *Aspergillus* Detection LyoKit for the rapid detection of *Aspergillus flavus*, *A. terreus*, *A. niger* / *A. fumigatus* in hemp and cannabis flowers. The method is designed to report yes/no results at concentrations as low as 10⁴ CFU/mL after enrichment. With a processing time of approximately 120 minutes on the BAX® System Q7 instrument, the method returns results comparable to culture methods but with a significantly faster time to results. BAX Systems are designed for use by qualified lab personnel who follow standard microbiology laboratory practice, including the safe handling and disposal of potentially pathogenic materials.

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 to be used in conjunction with the user's regular quality assurance program. Not approved for clinical diagnosis. Use for research and development, quality assurance and quality control under supervision of technically qualified persons.

Principle

The BAX Prep *Aspergillus* Lysis Kit is designed for the rapid preparation of *Aspergillus* DNA for direct use in PCR testing. After an appropriate enrichment, the DNA extracted using the BAX Prep kit can be used directly on the BAX Q7 System. The BAX Prep *Aspergillus* Lysis kit prepares test samples with *Aspergillus* by aiding in the lysis of target fungal cells with a kit protocol consisting of the following: a DNA Stabilizer, disruptor tubes filled with beads, enzyme, buffer and two heat steps. The principle of this method is to release fungal DNA from samples using mechanical disruption. The added DNA stabilizer protects and preserves the genetic integrity of the sample. Heat lysis is then performed before hydration of foodproof *Aspergillus* Lyo PCR tablets. Samples are then placed on the BAX System Q7 instrument for processing.

Required Materials

BAX System Start-up Package

- BAX System cycler/detector and computer workstation
- Heating blocks with inserts* capable of maintaining 37 ± 2 °C and 95 ± 3 °C
- Cooling blocks with inserts*
- PCR tube holder
- Capping/decapping tools
- Adjustable mechanical pipettes (5-50 µL; 20-200 µL)
- Repeating pipette
- Multi-channel pipette (8 channels – 5-50 µL)
- Cluster tubes with caps and racks
- Pipette tips with barriers
- Powder-free nitrile gloves

Other Required Materials (not included):

- Sample bags (filter bags recommended, e.g., Whirl-Pak® Filter Sterilized Bags)
- Incubator capable of maintaining directed enrichment temperatures within ± 2 °C
- Cell disrupter device – Disruptor Genie® or equivalent
- Standard Solutions (such as Butterfield's phosphate buffer, 0.1% peptone buffer or other appropriate buffer for diluting samples)
- Buffered Peptone Water (BPW) with 100 mg/L chloramphenicol

*The Automated Thermal Block (Catalog No. MCH2023) may be used in place of heating and cooling blocks.

Test Protocol

1. Homogenize and Enrich Samples

- 1.1 Dried Hemp Flowers and Dried Cannabis Flowers (10 g): Add 90 mL BPW with 100 mg/L chloramphenicol to 10 g test portion. Hand mix for 30 seconds and incubate enrichments for 44 hours at 37 ± 2 °C.

2. Prepare Equipment

- 2.1 Turn on the heating blocks for 37 °C and 95 °C*.
- 2.2 Ensure cooling blocks are chilled to 2 to 8 °C*.

* If using the Automated Thermal Block, follow the instructions in the Automated Thermal Block User Guide for running the Gram-Negative Program.

- 2.3 Power on the Q7 instrument and launch the BAX System application.
- 2.4 Create a rack file (see User Guide for details).

3. Disrupt Samples

- 3.1 Add 1 mL of enrichment to a disruptor tube (green cap).
- 3.2 Add 20 µL DNA stabilizer (orange cap) to each disruptor tube.
- 3.3 Appropriately label the side (not cap) of each tube, then place tubes in disruptor device and agitate for 15 minutes.
- 3.4 Return tubes to the rack and repeat with the remaining disruptor tubes until all samples have been disrupted.

4. Perform Lysis

- 4.1 Break cluster tubes apart (Recommended to minimize risk of cross-contamination).
- 4.2 Label and arrange cluster tubes in rack according to the rack file.
- 4.3 Prepare lysis reagent by adding 150 µL protease to one 12 mL bottle of YM lysis buffer.
- 4.4 Transfer 200 µL lysis reagent to each cluster tube.
- 4.5 Transfer 20 µL disrupted sample to cluster tube filled with lysis reagent.
- 4.6 Heat at 37 °C for 20 minutes.
- 4.7 Heat at 95 °C for 10 minutes.
- 4.8 Cool at 2 to 8 °C for 5 minutes.

5. Hydrate Lyophilized Pellets

- 5.1 Initialize the instrument by selecting RUN FULL PROCESS from the OPERATION menu.
- 5.2 Place a PCR tube rack onto a chilled (2 to 8 °C) PCR cooling block.
- 5.3 Arrange strips of foodproof *Aspergillus* Detection LyoKit PCR tubes according to your rack file. Check that the reagent pellets are at the bottom of the tubes. If not, briefly flick the pellets to the bottom before proceeding.
- 5.4 Transfer 30 µL lysate into PCR tubes, then seal with flat optical caps. Repeat with the remaining strips of PCR tubes until all PCR tablets have been hydrated.

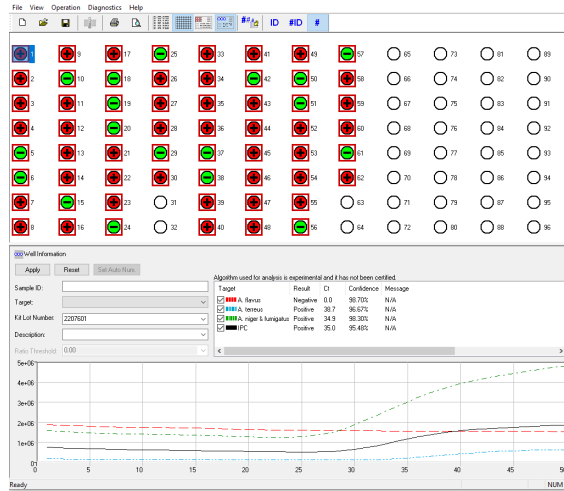
Note: PCR tablets must be hydrated and re-sealed immediately after removing the caps from the PCR tubes.

6 Amplify and detect

- 6.1 At the “Ready for Rack Load” prompt, click the NEXT button and open the instrument drawer.
- 6.2 Place the rack of PCR tubes over the wells in the drawer and check that the tubes are seated correctly.
- 6.3 Close the drawer and click the NEXT button to begin automated processing.

7 Review results

- 7.1 Qualitative results are displayed as a grid of color-cued icons in the top half of the screen.



- Green (-) = Negative for target organism
- Red (+) = Positive for target organism
- Yellow (?) = Indeterminate result*
- Yellow (?) with red slash = Signal error*

*Refer to the troubleshooting section in the BAX User Guide for assistance.

CONFIRMATION

If desired, BAX® System results can be confirmed using the recommended confirmation methods outlined in AOAC SMPR 2019.001.



Additional Information

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 addition of Protease to the Lysis Buffer, the shelf life of the solution is 2 weeks when stored at 2 to 8 °C.

Disposal

Decontaminate materials and dispose of biohazardous waste per your site practices and as required by federal, state and local regulations.

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.

Support

If you have any questions or need more information on our products, please contact us:

www.hygiena.com/support

Our aim is to provide you with a solution as quickly and effectively as possible. We would also like you to contact us if you have any suggestions for improving the product or in case you would like to use our product for a different application. We highly value your feedback.

Change Index

Revision A, September 2024

New product package insert.