

GALACTOMANNAN EXTERNAL CONTROL

External control containing *Aspergillus fumigatus* galactomannan in human serum, specifically designed to monitor both sample preparation and analytical performance in galactomannan antigen detection assays.

VIRCELL® ASPERGILLUS GALACTOMANNAN Ag CONTROL

In many clinical laboratories, the lack of **standardized external controls** for galactomannan testing can compromise result consistency, particularly in processes involving complex sample pretreatment. The Vircell® **Aspergillus Galactomannan** Ag Control addresses this gap by providing a robust, independent control specifically designed to:

- **Serve as an independent, third-party external control for *Aspergillus* galactomannan antigen detection, covering both sample pretreatment and analytical detection phases.**
- **Promote consistent lab performance by monitoring assay reliability and reducing the risk of inaccurate or variable results.**
- **Support reproducibility across instruments, operators, and testing batches, reinforcing confidence in routine diagnostics.**

PRODUCT INFORMATION

- Each kit will contain 3 freeze-dried negative control vials and 3 freeze-dried positive control vials.
- In addition, the kit contains 4 screw-top tubes with 1.5 ml of Braun® distilled water for reconstituting the freeze-dried vials.



Ref. VEC001

INFORMATION AND RELATED PRODUCTS

Description	Reference	CE Mark	Content / Capacity
VIRCELL® ASPERGILLUS GALACTOMANNAN AG CONTROL	VEC001	CE IVDR	6 tests
ASPERGILLUS GALACTOMANNAN Ag VIRCLIA® MONOTEST	VMC073	CE	24 tests

GALACTOMANNAN EXTERNAL CONTROL

WHY IT MATTERS?

Monitors the Full Analytical Process

Vircell's external control is subjected to the same pre-analytical treatment as Clinical samples (heating and centrifugation), allowing full validation of the entire workflow, including the most error-prone step in galactomannan testing.

Independent control

Designed as a third-party, unassayed control, it is compatible with any *Aspergillus* galactomannan diagnostic method (ELISA, CLIA, rapid tests), making it ideal for both VirClia® users and laboratories using Bio-Rad Platelia® or other platforms.

Addresses a Known Gap in Quality Control

Internal controls provided in some kits bypass the sample preparation step, leaving laboratories blind to potential pre-analytical errors. Vircell's control fills this gap.

Support ISO 15189 Accreditation

Enables clinical labs to meet critical requirements for independent quality control and continuous performance verification, as required by ISO 15189 and similar accreditation frameworks.

Validated Precision and Lot Consistency

Demonstrated coefficient of variation <20% and minimal lot-to-lot variability ensure reliable performance over time.

Safe and Realistic Training Material

Ideal for training new laboratory staff or assessing technical competency using a non-infectious, human serum-based material that mimics real patient samples.

Practical Use Scenarios

Recommended for daily quality monitoring, kit or lot change verification, post-maintenance requalification of platforms, and assay troubleshooting.

Part of a Complete *Aspergillus* Diagnostic Solution

The Vircell *Aspergillus* Galactomannan Ag Control can be used as part of a comprehensive and integrated diagnostic workflow for laboratories adopting or expanding *Aspergillus* diagnostics—particularly for existing VirClia users.

Not for general supply unless first included in the Australian Register of Therapeutic Goods.

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