

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.

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