

Rapid mold detection in as little as one day

QUICK TO SPREAD and difficult to detect, molds can compromise a facility in the time it takes to confirm their presence. RMBNucleus™ Mold Alarm allows investigations to begin in as little as one day with automated alerts triggered by detection of molds during the early stages of incubation.

RMBNucleus™ Mold Alarm for the Growth Direct® System is our latest innovation in the Pharma 4.0™ space – encompassing automation and further customisation for notifications, reporting and workflows to support the speed and quality needed in manufacturing critical medicines to improve patients' lives. Users can improve data integrity (DI) compliance and time to result (TTR) in their quality control microbiology processes through the implementation and routine use of an automated incubation and colony counting technology, yielding rapid microbial detection of mold and bacteria. Rapid Micro Biosystems® Growth Direct® System can be validated for environmental monitoring (EM), bioburden and water

testing in a current good manufacturing practice (cGMP) environment.


The licensed software offering, together with our standard software and validation services, ensures enumeration speed and provides faster differentiation of mold. This level of differentiation allows microbiology analysts to direct attention (or labour) from visual plate checks to higher value tasks within the laboratory environment. The software also maintains data integrity to a higher level, providing a presence/absence assessment of mold directly to laboratory information management systems (LIMS) via easy integration.

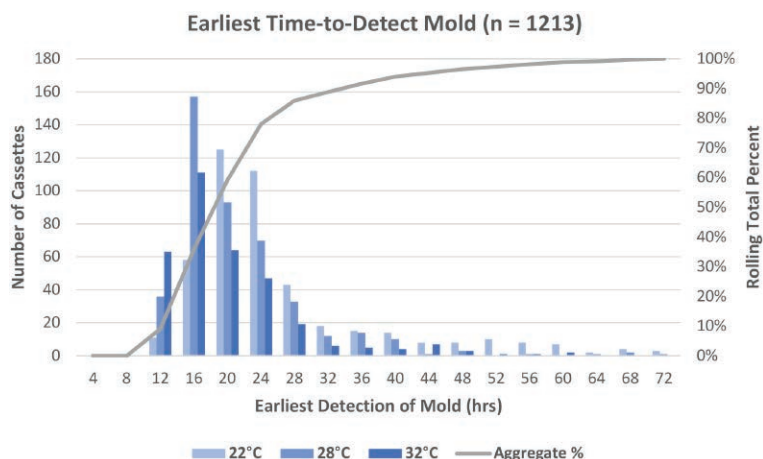
This novel offering enhances the existing Growth Direct® technology, providing a validated-total count in up to half the time of the manual method and detecting molds in as little as 24 hours. In a recent study, RMBNucleus™ Mold Alarm delivered an accuracy detection level for mold of ≥ 95 percent across the common EM incubation temperatures of 22°C, 28°C and

32.5°C and utilising 16 of the most common EM-reported mould species, including *Alternaria sp.*, *Aspergillus sp.*, *Cladosporium sp.*, *Curvularia sp.*, *Fusarium sp.*, *Penicillium sp.*

The high accuracy rates of RMBNucleus™ Mold Alarm reduce labour-intensive assessment of plates and facilitate earlier remediation of mold contaminations to suit any workflow. The verification study results shown in **Figure 1** indicate that approximately 78 percent of all the mold species tested provided an alert within the first 24 hours of initial incubation.

This means that before a manual-read assessment can be performed at 22°C, the RMBNucleus™ Mold Alarm has provided the current count of microcolonies and has alerted the user to the presence of mold. While incubation can continue until a colony has grown large enough for sub-culture identification, the remediation can begin, depending on the risk-assessment and mold-handling procedures unique to each customer site.

RMBNucleus™ Mold Alarm has been verified to rapidly differentiate molds from other microorganisms – in up to half the time of the traditional compendial method. This reduces or eliminates dependence on manual-subjective methods and moves the industry closer to achieving Pharma 4.0™. 



For further information, visit:

www.rapidmicrobio.com

Figure 1

Real-Time **Mold Detection** Matters

RMBNucleus™ **Mold Alarm**

RMBNucleus™ Mold Alarm signals at the first sign of mold detection. This allows for intervention and remediation to start in as little as one day, upholding compliance and reducing risk.

- **Automated alerts** signaling the presence of mold at incubation
- **Detection** of molds that commonly cause microbial contamination
- **Rapid detection** in as little as 1 day
- **Enhanced data integrity**
- **Easy implementation** as part of your Growth Direct® System software

Learn more at:
www.rapidmicrobio.com

