



## Statement of Inactivation of Moulds by Sample Processing

Viability studies for moulds were performed by the bioMérieux Research and Development Department to assess and verify that there is no biological risk to the user when handling test samples or slides, once the inactivation process has been performed.

Fresh cultured strains from a panel of different mould species (listed in the table below) were inactivated using the method developed by bioMérieux. The test panel included strains from 11 different genera. Testing encompassed both BSL2 and BSL3 moulds.

The strains were tested at 2 days, 8 days, and 17 days of growth. After the inactivation process, the resulting supernatant was inoculated onto an appropriate solid medium for detection and recovery. The cultures were incubated at the appropriate temperature and monitored for growth from 8 days to 8 weeks depending on the species.

Results obtained during this study demonstrate that the final supernatant obtained from sample preparation contains no viable moulds.

<b>Species tested</b>	<b>Age of culture</b>
<i>Alternaria alternata</i>	2 & 8 days
<i>Aspergillus niger</i>	2 & 8 days
<i>Aspergillus flavus</i>	2 & 8 days
<i>Aspergillus fumigatus</i>	2 & 8 days
<i>Aspergillus versicolor</i>	2 & 8 days
<i>Blastomyces dermatitidis</i>	17 days
<i>Cladosporium cladosporioides</i>	2 & 8 days
<i>Coccidioides immitis</i>	17 days
<i>Coccidioides posadasii</i>	17 days
<i>Fusarium oxysporum</i>	2 & 8 days
<i>Histoplasma capsulatum</i>	17 days
<i>Lecythophora hoffmanii</i>	2 & 8 days
<i>Paecilomyces variotii</i>	2 & 8 days
<i>Paracoccidioides brasiliensis</i>	17 days
<i>Penicillium chrysogenum</i>	2 & 8 days

Inactivation studies were performed at two ages of cultures, or at least when conidia (sometimes referred to as spores) were present, to assess that the inactivation process works on both conidia and hyphae.

Due to the highly pathogenic nature of the thermally dimorphic fungi, safe handling practices are recommended prior to inactivation. These steps are described in detail in the package insert for the VITEK<sup>®</sup> MS Mould Kit. Based on the bioMérieux R&D studies, this preparation procedure has been shown to repeatedly inactivate mould species if followed exactly as described. Once the moulds are no longer viable, the user can perform any subsequent steps including the spotting and handling of the VITEK<sup>®</sup> MS-DS target slide.

In conclusion, these inactivation studies show that moulds are no longer viable after performing the inactivation steps if the user adheres to the protocol provided by bioMérieux. As a general safety precaution, all users should wear protective powder-free gloves when handling the VITEK<sup>®</sup> MS-DS target slide.