

MycoReal[®] Kit *Candida* & *A. fumigatus*

Kit version 1.1



For *in vitro* diagnostic use only

MycoReal[®] Kit *Candida* & *A. fumigatus*

Order no.	Reactions	Pathogen	Internal positive control
DHUF00153	50	FAM + VIC channel	Cy5 channel

Kit contents:

- Detection assay 1 for *C. parapsilosis* group (FAM) and *C. glabrata*, *C. krusei* (VIC) and internal DNA positive control (IPC) (Cy5)
- Detection assay 2 for *C. albicans*, *C. tropicalis*, *C. dubliniensis* (FAM) and *A. fumigatus* (VIC) and internal DNA positive control (IPC) (Cy5)
- IPC-Target DNA (control of DNA extraction and of PCR amplification)
- DNA reaction mix (contains a highly purified Taq Polymerase for rapid hot-start PCR, dNTPs with dUTP and Uracil-N glycosylase (UNG) to eliminate amplicon carryover, ROX[™] dye (passive reference) and buffer components – additives optimized to handle PCR inhibitors)
- Positive control for *C. parapsilosis*, *C. glabrata*, *C. albicans*, *A. fumigatus*
- Nuclease-free water



Pathogen information: Candidiasis is a yeast infection caused by different *Candida* species. *Candida* can cause opportunistic infections of the skin and mucosa as well as invasive infections. Aspergilli are ubiquitous molds that can cause allergies as well as infections (aspergilloses). Invasive candidiasis and aspergillosis are increasingly recognized as a primary cause of morbidity and mortality especially in immunocompromised patients, patients with severe underlying disorders or intensive care patients. The pathogen can be detected in biopsies from the affected organ or in the blood. The rapid and early diagnosis of a fungal infection is of particular importance with regard to survival and cure rates. Not only the detection, but also the exact identification of the fungal species is important.

Intended purpose: MycoReal[®] Kit *Candida* & *A. fumigatus* is a non-automated CE-certified IVD real-time PCR test for the qualitative detection of DNA (ITS2-region) of *Candida albicans*, *C. dubliniensis*, *C. glabrata*, *C. krusei* (= *Pichia kudriavzevii*, *Issatchenkia orientalis*), *C. parapsilosis* group, *C. tropicalis* and *Aspergillus fumigatus*.

Proper specimens are DNA extracts isolated from samples of human EDTA-blood, aspirates, punctates, cerebrospinal fluid (CSF), bronchoalveolar lavage (BAL), tissue and paraffin-embedded tissue.

This test is suitable for patients with suspected infection with *Aspergillus* or *Candida* and is intended as an aid in the diagnosis of infection with this pathogen in combination with patient history and additional clinical information.

The test is intended for professional use and is limited to qualified personnel instructed in the procedures of real-time PCR and *in vitro* diagnostic procedures.

The analysis is performed with 2 different assay mixes in two parallel PCR reactions. *Candida glabrata*, *C. krusei*, *C. parapsilosis* and *A. fumigatus* can be differentiated from other *Candida* species, enabling targeted antifungal therapy. A probe-specific amplification-curve in FAM and/or VIC channel indicates amplification of *Candida* or *A. fumigatus* specific DNA. The internal DNA Positive Control (IPC) is detected in the fluorescence channel Cy5 and serves as a control for DNA extraction and possible real-time PCR inhibition. The target for the DNA IPC (artificial target DNA) is added during sample extraction.

PCR-platforms: This test has been validated with the ABI[®] 7500 Fast instrument (Thermo Fisher Scientific) and tested with a cobas z 480 Analyzer (Roche). The test is also compatible with other real-time PCR instruments which detect and differentiate fluorescence in FAM, VIC and Cy5 channel (e.g., QuantStudio[™] 5, QuantStudio[™] 7 real-time PCR system (Thermo Fisher Scientific), qTOWER³G (Analytik Jena), Mic instrument (bio molecular systems), cobas z 480 Analyzer (Roche)).

Specificity and sensitivity: This kit detects the medically important species *C. albicans*, *C. dubliniensis*, *C. glabrata*, *C. krusei* (= *Pichia kudriavzevii*, *Issatchenkia orientalis*), *C. parapsilosis* group, *C. tropicalis*, *Aspergillus fumigatus* and furthermore *Candida africana*, *Candida sojae* and *Candida neerlandica*. MycoReal® Kit *Aspergillus* has a LoD95% (defined as the concentration, where 95% of 20 PCR repeats were positive) between 3-32 target copies/PCR, depending on the species.

Results of clinical validation:

	Blood + other samples (n=70)	Blood samples (n=39)	Other samples (n=31)
Sensitivity	90.91%	85.29%	100.00%
Specificity	93.33%	100.00%	90.00%
NPV	73.68%	50.00%	100.00%
PPV	98.04%	100.00%	95.45%
Prevalence	78.57%	87.18%	67.74%
Accuracy	91.43%	87.18%	96.77%

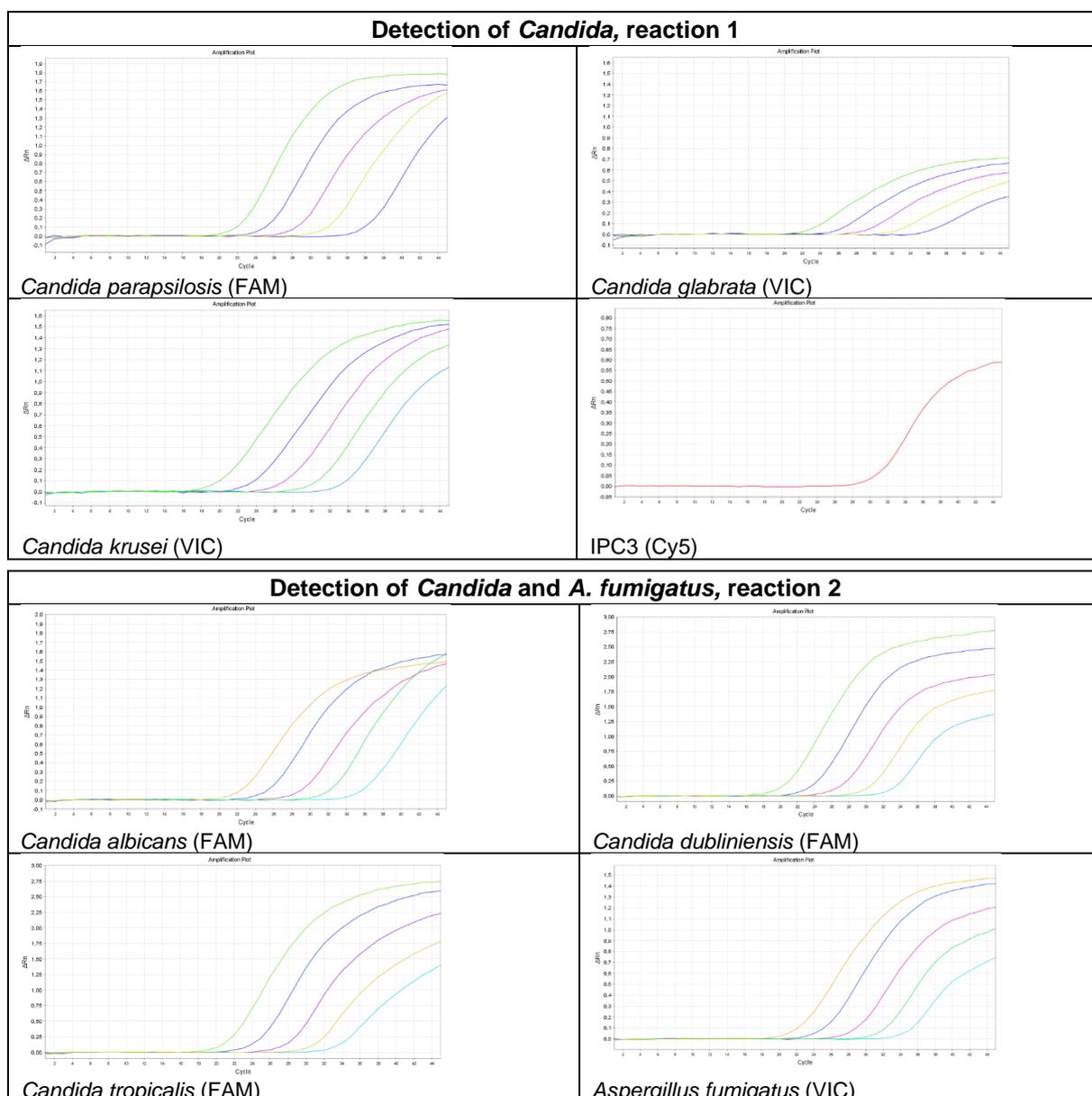


Figure 1 Performance of MycoReal® Kit *Candida* & *A. fumigatus*.