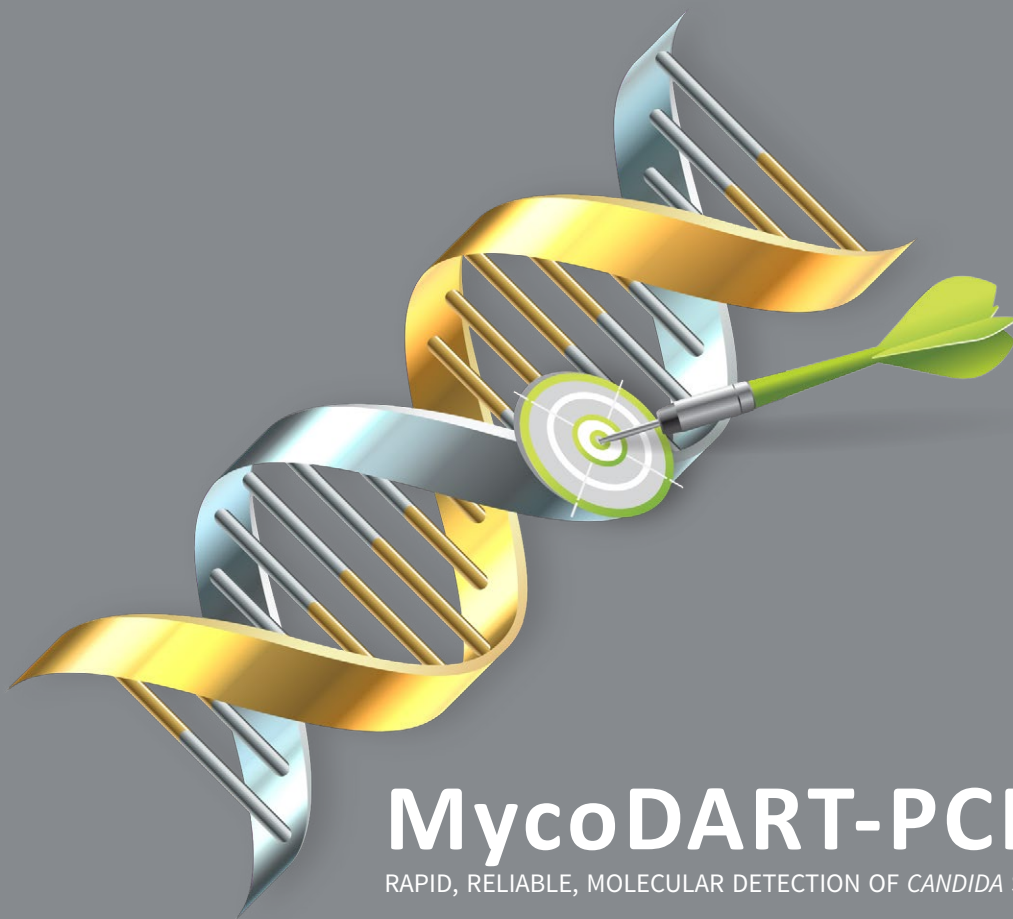


# Early and Rapid Detection of Invasive *Candidiasis* in Human Body Fluids



**MycoDART-PCR™**  
RAPID, RELIABLE, MOLECULAR DETECTION OF *CANDIDA* SPECIES

## The Problem

More than 1.6 million people in the U.S. alone are diagnosed with Sepsis each year. Sepsis is a condition in which the body has a severe inflammatory response to a bacterial or fungal infection. Mortality rates range from 30-35% and increase 8% for every hour that treatment is delayed. *Candida* is the most common and one of the most lethal fungal infections. Other fungal infections include *Aspergillus* and *Mucor*. Immunocompromised patients are most at risk for infection. This includes cancer patients, transplant patients and patients with central venous catheters.



## Many Populations with “Weak” or “Compromised” Immune Systems are at Risk for Developing Invasive *Candidiasis*

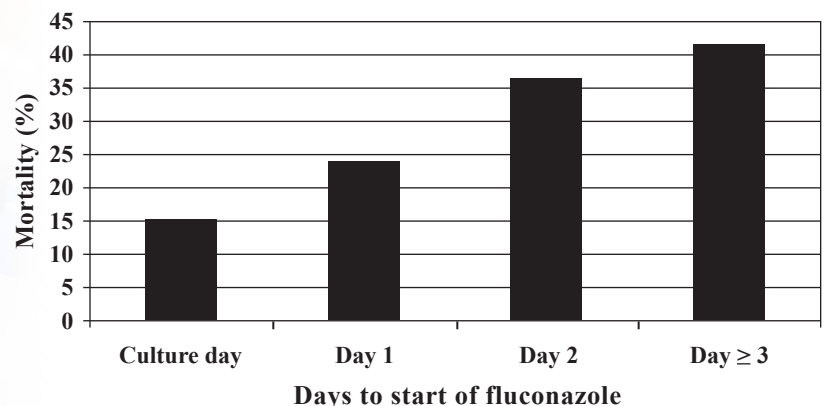
### POPULATIONS AT RISK FOR INVASIVE CANDIDIASIS

Patients who have a central venous catheter	8,000,000	<a href="http://www.who.int/patientsafety/implementation/bsi/en/">www.who.int/patientsafety/implementation/bsi/en/</a> <a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC387407/">www.ncbi.nlm.nih.gov/pmc/articles/PMC387407/</a>
Patients in the Intensive Care Unit	5,700,000	<a href="http://www.sccm.org/Communications/Pages/CriticalCareStats.aspx">www.sccm.org/Communications/Pages/CriticalCareStats.aspx</a>
Solid organ transplants	33,593	<a href="http://www.unos.org/data/">www.unos.org/data/</a>
Hemopoetic stem cell transplants	20,000+	<a href="http://www.cibmtr.org/pages/index.aspx">www.cibmtr.org/pages/index.aspx</a>
HIV/AIDS patients	1,200,000	<a href="http://www.cdc.gov/hiv/basics/statistics.html">www.cdc.gov/hiv/basics/statistics.html</a>
Patients on dialysis	400,000	<a href="http://www.niddk.nih.gov/health-information/health-statistics/">www.niddk.nih.gov/health-information/health-statistics/</a>
Patients with neutropenia	60,000	<a href="http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3621630/">www.ncbi.nlm.nih.gov/pmc/articles/PMC3621630/</a>
Cancer patients undergoing chemotherapy	650,000	<a href="http://www.cdc.gov/cancer/preventinfections/providers.htm">www.cdc.gov/cancer/preventinfections/providers.htm</a>

It is estimated that between 46,000 and 90,000 new cases of Invasive *Candidiasis* occur each year, with a Mortality Rate up to 40%.

## Rapid Diagnosis and Correct Treatment of *Candidiasis* is Critical to Reduce Mortality

Relationship between hospital mortality and the number of days to initiation of fluconazole therapy.



## Blood Culture, The Most Commonly Used Diagnostic Technique for *Candida* is Inadequate

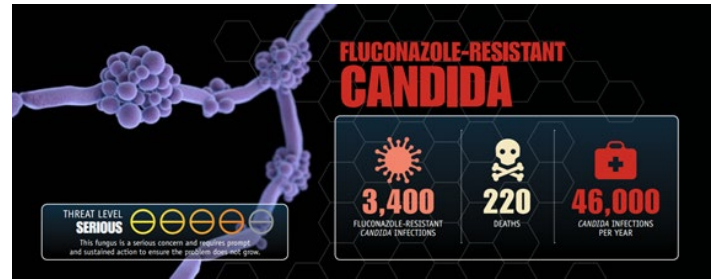
"Mortality among patients with candidemia and other invasive *Candida* infections is as high as 40%, despite antifungal therapy. The poor outcomes stem, at least in part, from the inadequate sensitivity of blood and sterile-site cultures, the current diagnostic gold standards."

*"Improved diagnostic tests for invasive candidiasis are among the most pressing needs in infectious diseases"\**

\*Clancy, C.J. and M.H. Nguyen. 2013. "Finding the "Missing 50%" of Invasive *Candidiasis*: How Nonculture Diagnostics Will Improve Understanding of Disease Spectrum and Transform Patient Care". Clin. Infect. Diseases.

## Some *Candida* Species are Resistant to Commonly Used Antibiotics. Therefore, Identification of Species is Required to Ensure Proper Treatment

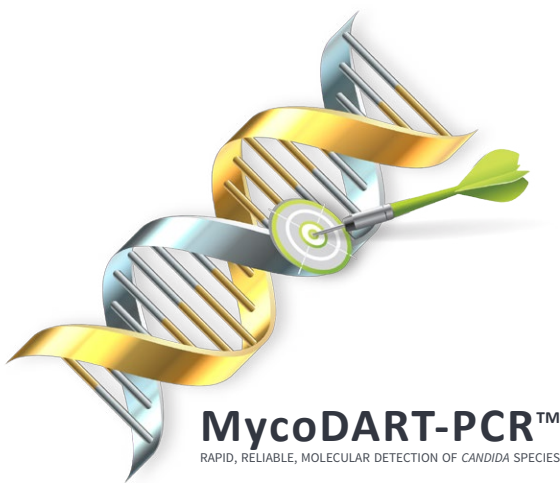
The fungus *Candida* is one of the most common cause of healthcare-associated bloodstream infections in the United States... Approximately 7% of all *Candida* bloodstream isolates tested at CDC are resistant to fluconazole, most of which are *Candida glabrata*.



[www.cdc.gov/fungal/antifungal-resistance.html](http://www.cdc.gov/fungal/antifungal-resistance.html)

## The Need

Fast and accurate method to identify the specific organism causing the patients fungal infection. This is critical to allow physicians to administer the proper anti-fungal drug as rapidly as possible, before the infection progresses. The current standard of care uses blood cultures which not only have low sensitivity but also take 2-5 days for results. This forces the physician to start the patient on an anti-fungal which may not be the right one for that species. It also can contribute to the growing problem with anti-fungal resistance.



## The Solution: MycoDART-PCR™

AdvaTect has patented DNA probes that can be used on most common hospital qPCR platforms. The patented **MycuDART-PCR™** allows for the reliable determination of species in 4-6 hours. *Candida* species include *C. albicans*, *C. krusei*, *C. parapsilosis*, *C. glabrata*, *C. tropicalis*, and *C. auris*. The patented *Aspergillus* probes are being developed into a diagnostic panel using the more sensitive **MycuDART-PCR™** technology, as are the *Mucor* probes.

### About the MycoDART-PCR™ Test

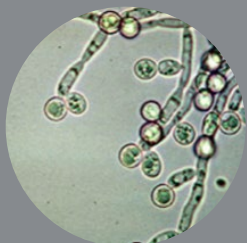
- Organisms (Fungi) to be Detected:
  - *Candida albicans*, *C. glabrata*, *C. krusei*, *C. tropicalis* and *C. parapsilosis*, and *C. auris*.
- Description: Qualitative
- Format: Dual Amplification Real-Time PCR
- Substance to be tested: DNA
- Matrix or specimen type: Whole Blood or Plasma, and Bronchial Alveolar Lavages (BALs), Tissue Samples and Culture Swabs.



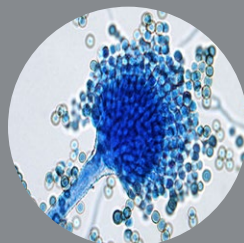
# Cutting Edge Technology

LIFE SAVING SOLUTIONS

**MycoDART-PCR™**  
CANDIDA DIAGNOSTIC PANEL



**MycoDART-PCR™**  
ASPERGILLUS DIAGNOSTIC PANEL



**MycoDART-PCR™**  
MUCOR DIAGNOSTIC PANEL

