CandiDia

Antibody

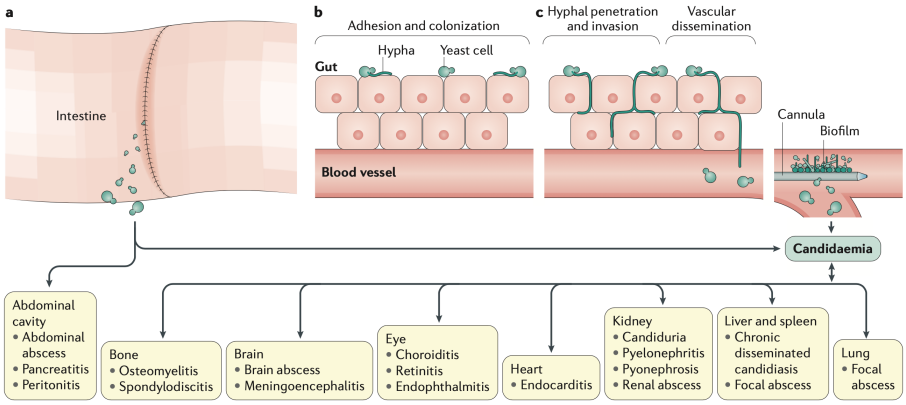
CE IVD

Candidemia and invasive candidiasis

Candida sp. is the most common fungal pathogen in intensive care unit (ICU), solid organ transplantation and bone marrow transplant (BMT) patients (Pfaller et al. 2006).
In ICU patients, colonization occurs in up to 80% and invasive candidiasis represents 15% of all ICU-acquired infection (Eggimann et al. 2011, Eggimann et al. 2014, Quindos et al. 2014)
On average, candidemia occurs after 14 to 22 days of hospitalization (Eggimann et al 2014).
In a large international prevalence survey in ICU, infections due to Candida represent 17% of all ICU-acquired infections (Vincent et al . 2009).

The major concerns with invasive candidiasis is the high mortality rate, the extension of hospital stay (3-30 days) and cost (Pfaller et al. 2006, Calandra et al. 2016, Pappas et al. 2018).

The overall mortality attributable to candidemia is ranged from 10-47%. (Eggimann et al. 2011; Pappas et al. 2018)



The attributable cost of candidemia is reported to be around US$ 40'000 per patient and an estimate of $ 1 billion per year in US (Pappas et al. 2018).

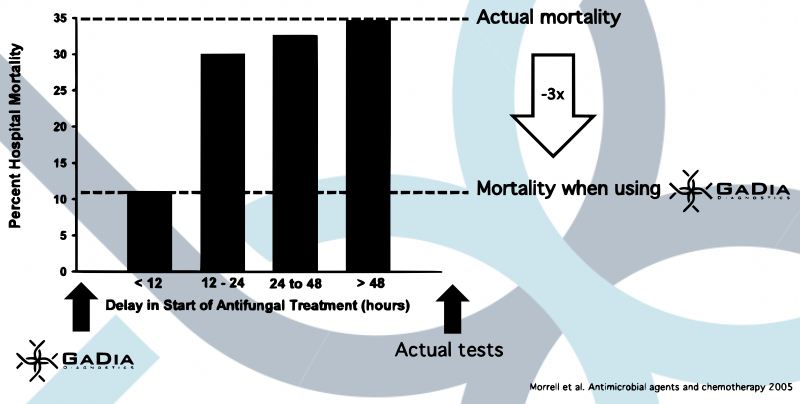
Diagnostic procedures

Actual diagnostic preocedures are time-consuming, require highly skilled staff and equiped laboratory. Moreover, these procedures are expensive.

Rapid tests are crucial to reduce the delay of treatment and reduce the mortality!

Diagnostic test	Specimen(s)	Advantages	Disadvantages
Fungal culture	Blood	• Enables species identification and subsequent susceptibility testing	• Slow (median detection time 2–3 days) • Sensitivity suboptimal, particularly if high volume (≥60 ml) and a fungal blood culture bottle are not employed
	Tissue and sterile body fluids	• Enables species identification and subsequent susceptibility testing	• Selective media, proper spreading of the sample and 3 days of incubation required for optimal performance
Microscopy	Cerebrospinal fluid, tissue and sterile body fluids	• Highly sensitive, particularly if using fluorescent brightener staining	• No species identification • Lower sensitivity in absence of fluorescent brightener staining
Histopathology	Tissue and sterile body fluids	• Enables evaluation of tissue invasion and inflammation	• No species identification • Lower sensitivity in absence of fluorescent brightener staining
Mannan antigen and antimannan antibody detection	Serum or plasma (EDTA) or cerebrospinal fluid	• Increased diagnostic sensitivity when combined antigen and antibody testing is performed (although in neonates (in any sample) and in cerebrospinal fluid, antigen testing suffices)	• Heavy colonization (many non-sterile body sites culture positive for *Candida* spp. and/or with heavy growth in semi-quantitative culture) could cause positivity for blood testing
β-D-glucan detection	Serum or plasma (EDTA)	• Pan-fungal marker	• No separation between *Candida* spp. and other fungi • Many sources for false positivity
PCR	Blood (EDTA)	• Rapid tests • Some commercial tests are FDA approved	• Commercial tests are expensive • May not detect all species

Pappas et al. 2018



Morrell et al. Antimicrobial agents and chemotherapy 2005

SWISS QUALITY

CandiDia

Antibody

CE IVD

CandiDia Rapid test kit

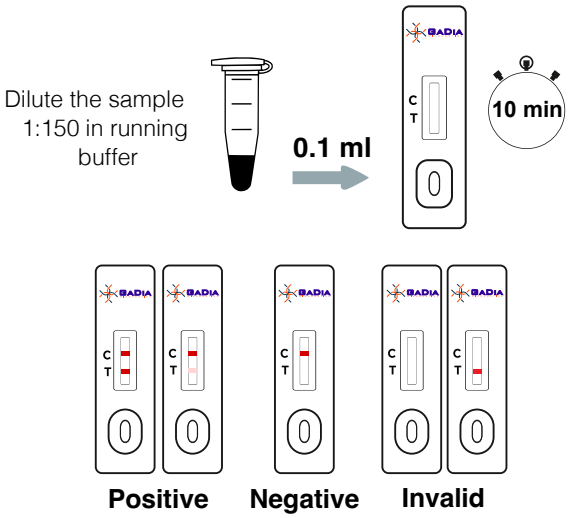
The First Rapid Diagnostic test detecting Candidemia and Invasive Candidiasis

Easy **Accurate** **Quick**

CandiDia is a rapid immunochromatographic test detecting IgG antibodies specific to a patented combination of biomarkers in blood, plasma/serum or Bronchoalveolar Lavage (BAL) of suspected patients affected by Invasive Candidiasis or Candidemia.

Early diagnostic is crucial to start quickly the right treatment and save lives

Test procedure



Diagnostic Performance

Serum Samples		Candida IgG ELISA	
		Positive	Negative
CandiDia Rapid test	Positive	30	10
	Negative	2	48
Sensitivity	93,8%	(CI95%: 77.8%-98.9%)	
Specificity	82,8%	(CI95%: 70.1%-91.0%)	
PPV	75,0%	(CI95%: 58.5%-86.8%)	
NPV	96,0%	(CI95%: 85.1%-99.3%)	

BAL		Candida culture	
		Positive	Negative
CandiDia Rapid test	Positive	9	2
	Negative	0	12
Sensitivity	100%	(IC95%: 63-100%)	
Specificity	86%	(IC95%: 56-98%)	
PPV	82%	(IC95%: 48-97%)	
NPV	100%	(IC95%: 70-100%)	

Order Information

CandiDia Rapid Test Kit

Catalog Number: CAN-020 -- 20 tests/kit

Content: 20 test devices in aluminum bag, 20 disposable pipettes, 1 bottle of running buffer, 1 Instruction for Use, 1 Quick Reference Guide

CONTACT: info@gadia.net

Product not available in all countries. Not available for sales in United States

www.gadia.net

GaDia SA is ISO13485:2016 certified

SWISS QUALITY