Product Catalog

2022

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

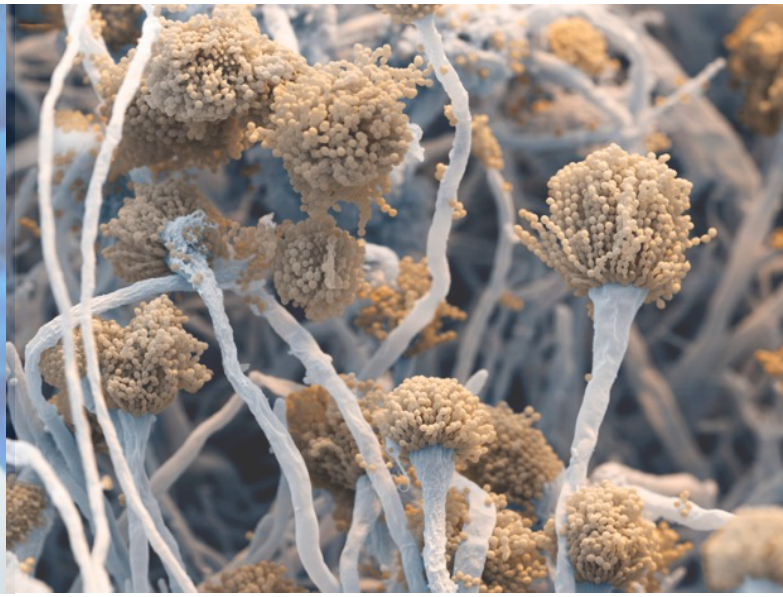
GaDia SA
Route de l'ile aux bois 1A
1870 Monthey (Switzerland)

CE IVD

SWISS QUALITY

Fungal Diagnostics

2022



Aspergillus Galactomannan ELISA

Aspergillus Galactomannan Rapid Test

Candidemia Rapid Test

CONTACT: info@gadia.net

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SWISS QUALITY

FUNGADIA

Aspergillus Antigen ELISA

GaDia Diagnostics

CE IVD

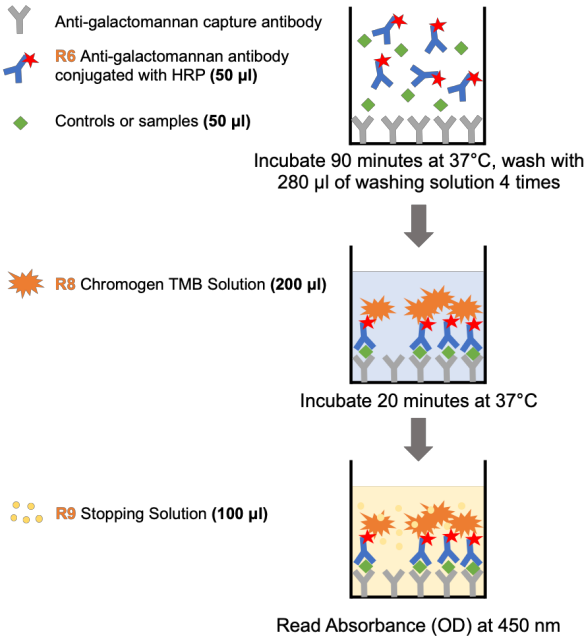
Aspergillosis Diagnostic Guidelines

Aspergillosis is a common infection caused by a mold called Aspergillus. Several stages of infection can be present, including invasive aspergillosis, aspergiloma and Chronic pulmonary Aspergillosis. Without a rapid diagnostic and treatment, the mortality rate can be high.

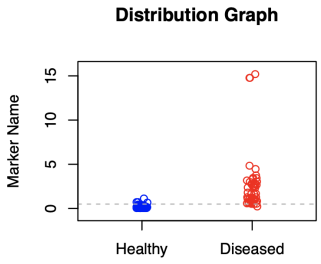
Galactomannan detection in BAL is recommended to diagnose pulmorary invasive Aspergillosis. The detection of Galactomannan in serum or blood is recommended only in certain cases (neutropenic and cancer patients)

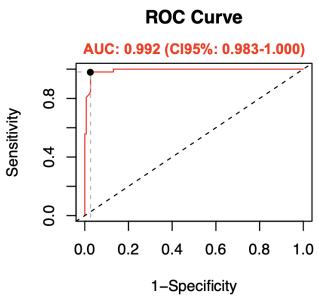
Ullmann et al., Diagnosis and management of Aspergillus diseases: executive summary of the 2017 ESCMID-ECMM-ERS guideline, Clinical Microbiology and Infection 24 (2018) e1ee38

Test procedure



Diagnostic Performance





Platelia (BioRad)/Clinical diagnostic

		+	-
FungaDia ELISA	+	49	1
	-	1	152
Sensitivity:	98,0%	(CI95%: 87.8-100%)	
Specificity:	99,3%	(CI95%: 95.9-100%)	
PPV:	98,0%	(CI95%: 88.4-99.9%)	
NPV:	99,3%	(CI95%: 95.9-100%)	

- High Sensitivity
- More Specific than Platelia (BioRad)
- Validated in a French CHU

Test time: 2 hours
CE-IVD approved
Sample types: Serum/plasma, BAL
Storage: 2-8°C (transport at room temperature)

Order Information

FungaDia - Aspergillus Antigen ELISA Kit

Catalog Number: ASPE-096 -- 96 tests per kit

Content: 1 x 96-well plate, 1 x positive control, 1 x cut-off control, 1 x negative control, 1 x washing solution, 1 x HRP conjugated antibody, 1 x sample treatment solution, 1 x TMB solution, 1 x stop solution, 1 x Instruction for use, 5 x plate sealer

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SWISS QUALITY

FUNGADIA

Aspergillus Antigen

CE IVD

Aspergillosis Diagnostic Guidelines

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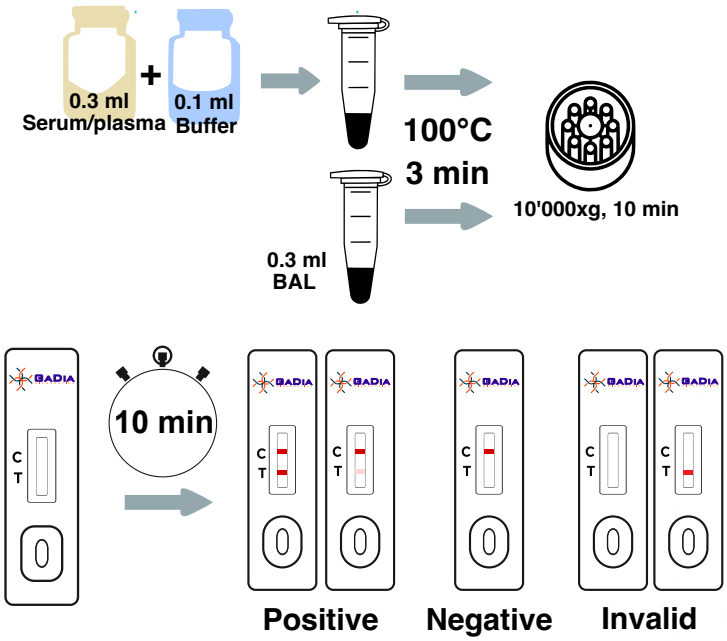
Ullmann et al., Diagnosis and management of Aspergillus diseases: executive summary of the 2017 ESCMID-ECMM-ERS guideline, Clinical Microbiology and Infection 24 (2018) e1ee38

Test procedure



Diagnostic Performance

BAL	ELISA		
FungaDia Aspergillus Antigen		Positive	Negative
	Positive	102	15
	Negative	11	186

Sensitivity: 90.3% (CI95%: 82.9%-94.8%)
Specificity: 92.5% (CI95%: 87.8%-95.6%)
PPV: 87.2% (CI95%: 79.4%-92.4%)
NPV: 94.4% (CI95%: 90.0%-97.0%)

Serum	ELISA		
FungaDia Aspergillus Antigen		Positive	Negative
	Positive	112	30
	Negative	18	241

Sensitivity: 86.2% (CI95%: 78.7%-91.3%)
Specificity: 88.9% (CI95%: 84.4%-92.3%)
PPV: 78.9% (CI95%: 71.1%-85.1%)
NPV: 93.1% (CI95%: 89.1%-95.7%)

Test time: 10-15 minutes
CE-IVD approved
Sample types: Serum/plasma, BAL
Storage: 5°C-30°C

Clinical evaluation by CHU GRENOBLE ALPES

Order Information

FungaDia - Aspergillus Antigen Test Kit
Catalog Number: ASP-025 -- 25 tests/kit
Content: 25 tests in pouch, 1 positive control, 1 negative control, 1 sample treatment solution, 1 Instruction for Use

CONTACT: info@gadia.net

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www.gadia.net

GaDia SA is ISO13485:2016 certified

SWISS QUALITY

CANDIDIA

GADIA DIAGNOSTICS

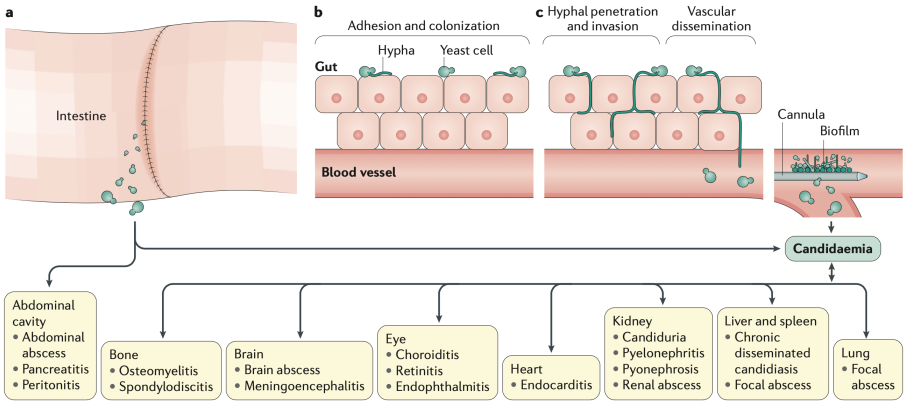
CE IVD

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).

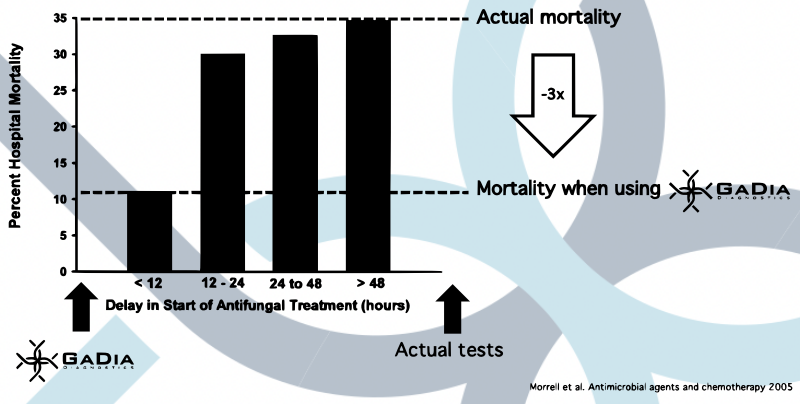
Diagnostic procedures

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

GADIA DIAGNOSTICS

CE IVD

CandiDia Rapid test kit

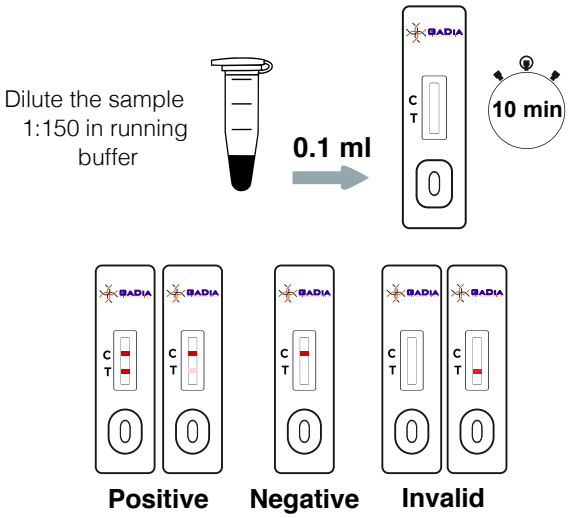
The First Rapid Diagnostic test detecting Candidemia and Invasive Candidiasis

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/plasma		ELISA	
		Positive	Negative
CandiDia Rapid test	Positive	30	10
	Negative	3	47
Sensitivity	**91%**	(IC95%: 75-98%)	
Specificity	**83%**	(IC95%: 70-91%)	
PPV	**75%**	(IC95%: 59-87%)	
NPV	**94%**	(IC95%: 83-98%)	

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

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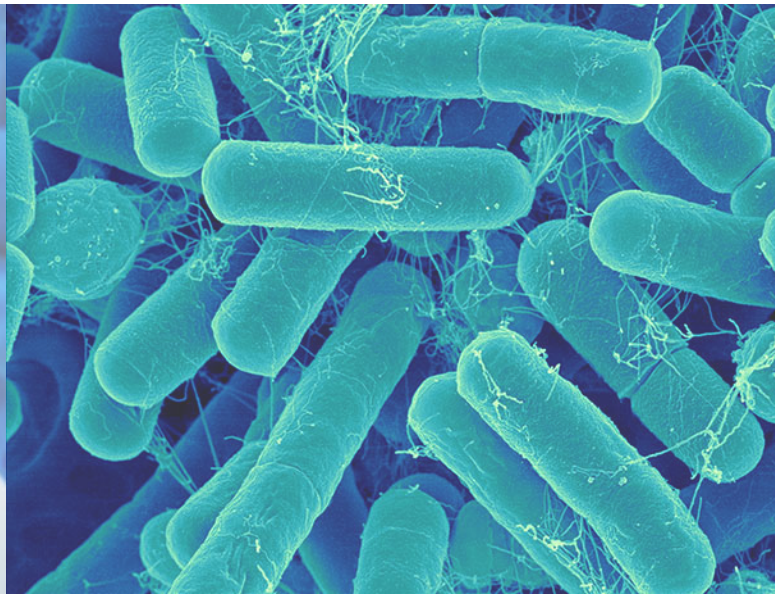
www.gadia.net

GaDia SA is ISO13485:2016 certified

SWISS QUALITY

Bacterial Diagnostics

2022



Carbapenemase Rapid Test

Bacterial Sepsis Rapid Test

Vaginal Infections

CONTACT: info@gadia.net

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www.gadia.net

GaDia SA is ISO13485:2016 certified

GaDia SA
Route de l'ile-au-Bois 1A
1870 Monthey (Switzerland)

CE IVD

SWISS QUALITY

KarbaDiag

GaDia Diagnostics

IVD

Carbapenem-resistant Enterobacterales (CRE)

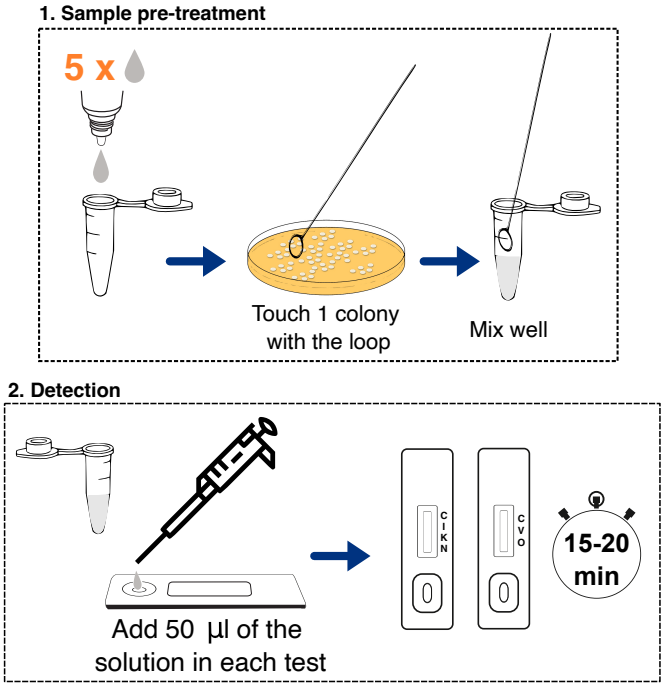
Carbapenem-resistant Enterobacteriaceae (CRE) are strains of bacteria that are resistant to an antibiotic class (carpabenem) used to treat severe infections. CRE are also resistant to most other commonly used antibiotics and in some cases to all available antibiotics.
CRE-related infections are associated with high mortality. CRE-related infections have often caused outbreaks in health care settings. Actual Minimum Inhibitory Concentration (MIC) assay are long and require specific laboratory

Rapid and easy tests are needed to diagnose quickly these infections.

Our KarbaDiag rapid test detects in 15 minutes only the 5 types of Carbapenem resistances directly in bacterial colonies with high accuracy at point of care.

Gupta et al., Carbapenem-Resistant Enterobacteriaceae: Epidemiology and Prevention, Clinical Infectious Diseases 2011, 53, 1,

Test Procedure



Diagnostic Performance

Clinical evaluation by ihma

KarbaDiag vs genetic testing and MIC

KPC	+	-	Sensitivity	100%	(CI95%: 87-100%)
+	32	0	Specificity	100%	(CI95%: 97-100%)
-	0	180	PPV	100%	(CI95%: 87-100%)
			NPV	100%	(CI95%: 97-100%)
OXA	+	-	Sensitivity	98%	(CI95%: 90-100%)
+	58	2	Specificity	99%	(CI95%: 95-100%)
-	1	149	PPV	97%	(CI95%: 87-99%)
			NPV	99%	(CI95%: 96-100%)
NDM	+	-	Sensitivity	97%	(CI95%: 89-99%)
+	65	1	Specificity	99%	(CI95%: 95-100%)
-	2	139	PPV	98%	(CI95%: 91-100%)
			NPV	99%	(CI95%: 94-100%)
IMP	+	-	Sensitivity	93%	(CI95%: 66-100%)
+	14	0	Specificity	100%	(CI95%: 98-100%)
-	1	190	PPV	100%	(CI95%: 73-100%)
			NPV	99%	(CI95%: 97-100%)
VIM	+	-	Sensitivity	100%	(CI95%: 85-100%)
+	29	0	Specificity	100%	(CI95%: 97-100%)
-	0	183	PPV	100%	(CI95%: 85-100%)
			NPV	100%	(CI95%: 97-100%)

KarbaDiag - Rapid diagnostic test Kit

Catalog Number: KAR-025 -- 25 tests per kit

Content: 25 tests in pouch (Cassette A & B), 2 positive controls, 1 sample treatment solution
1 Instruction for Use, 1 Quick guide

CONTACT: info@gadia.net

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

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1870 Monthey (Switzerland)

SWISS QUALITY

PapilloDia

GaDia Diagnostics

CE IVD

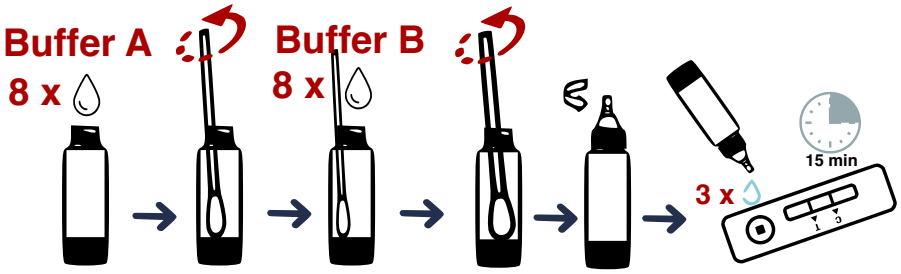
Cervical Cancer

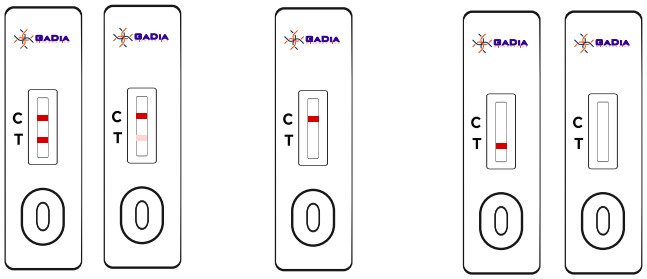
Cervical cancer is the fourth most common cancer in women. In 2018, an estimated 570 000 women were diagnosed with cervical cancer worldwide and about 311 000 women died. Almost all cervical cancer cases (99%) are linked to infection with high-risk human papillomaviruses (HPV), an extremely common virus transmitted through sexual contact. Effective primary (HPV vaccination) and secondary prevention approaches (screening for, and treating precancerous lesions) will prevent most cervical cancer cases.

Rapid and easy tests are needed to screen quickly cancer and improve treatment.

Our PapilloDia rapid test detects specific HPV 16/18 E6 & E7 oncoproteins in cervical swab samples to help healthcare professional to diagnose and screen quickly cervical cancer.

Test Procedure





Positive **Negative** **Invalid**

Diagnostic Performance

		Immunohistochemistry (IHC)		
		+	-	Total
PapilloDia Rapid test	+	58	21	79
	-	13	169	182
	Total	71	190	261

Sensitivity	**81.7%**	(CI95%: 70.4-89.5%)
Specificity	**88.9%**	(CI95%: 83.4-92.9%)
PPV	**73.4%**	(CI95%: 62.1-82.4%)
NPV	**92.9%**	(CI95%: 87.8-96.0%)

PapilloDia - Rapid diagnostic test Kit

Catalog Number: CER-020 -- 20 tests per kit

Content: 20 tests in pouch, 1 extraction Buffer A, 1 extraction Buffer B, 20 extraction tubes, 1 workstation, 1 Instruction for Use, 1 Quick guide

CONTACT: info@gadia.net

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

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