certest
IMMUNODIAGNOSTIC

Rapid test
Immunodiagnostic

Detection of antigens in stool, urine, and respiratory samples.

Ready to use
-No additional equipment required.
-Sample collection vial included

Immediate results, enabling **rapid decision-making.**

Validated according to **ISO 13485** standards and **CE-IVD/IVDR** marked.

Rapid Test

- Gastrointestinal infections
- Respiratory infections
- Tumor and inflammatory markers
- Antimicrobial resistance

Diagnostic reliability in a rapid and accessible format

Our rapid tests are developed using **lateral flow immunochromatography** technology, employing colored latex particles that enable clear and accurate result interpretation.

They provide an effective solution for the direct detection of antigens, biomarkers in clinical samples, and antimicrobial resistance, facilitating reliable presumptive diagnosis in the **early stages of disease**.

Designed for real laboratory settings, they combine **speed, ease of use, and high performance,** without the need for additional equipment.

Advantages

Multiple analytes detected in a single device.

Rapid results in **10 minutes.**

Very **easy** to use and interpret**.**

Multiple tests from a **single sample.**

Specific sample collection **vials included.**

Reduced cost throughout the entire process.

Clear and differentiated result interpretation

Control line – green

Test line – red

Option to include ***positive and negative controls.***

Certest Rapid Test

Antigens in faecal samples [1]

Format	Type	Reference	Description	
Single	Viruses	AD820001V	Adenovirus	IVDR
		AT820001V	Astrovirus	IVDR
		EV820001V	Enterovirus	
		NN820001V	Norovirus GI/GII	IVDR
		R820001V	Rotavirus	IVDR
	Bacteria	P820001V	*Helicobacter pylori*	IVDR
		GD820001V	*Clostridium difficile* GDH	IVDR
		E820001V	*Escherichia coli* O157	
		CA820001V	*Campylobacter*	IVDR
		SA820001V	*Salmonella*	
		ST820001V	*Salmonella typhi*	
		SP820001V	*Salmonella paratyphi*	
		YE820001V	*Yersinia O:3*	
		YC820001V	*Yersinia O:9*	
	Parasites	K820001V	Cryptosporidium parvum	IVDR
		GW820001V	Giardia lamblia	IVDR
		EH820001V	Entamoeba	IVDR
Combo	Viruses	XR882001V	Rotavirus + Adenovirus	IVDR
		NV882001V	Norovirus GI + Norovirus GII	IVDR
		RN882001V	Rotavirus + Norovirus	IVDR
	Bacteria	PT882001VF	*Helicobacter pylori* + Transferrin	
		GF882001VF	*Clostridium difficile* GDH + Lactoferrin	
		CD882001V	*Clostridium difficile* Toxin A + B	IVDR
		SX882001V	Enterohaemorrhagic *Escherichia coli (EHEC)* VT1 + VT2	
		TP882001V	*Salmonella typhi + Salmonella paratyphi*	
		YS882001V	*Yersinia enterocolitica O:3 + O:9*	
	Parasites	NW882001V	Crypto + Giardia	IVDR
Triple	Viruses	RT872001V	Rotavirus + Adenovirus + Astrovirus	IVDR
		RA872001V	Rotavirus + Adenovirus + Norovirus	IVDR
	Bacteria	GX872001V	*Clostridium difficile GDH* + Toxin A + Toxin B	IVDR
		EX872001V	*Escherichia coli* O157 + Enterohaemorrhagic *Escherichia coli (EHEC)* VT1 + VT2	
	Parasites	NE872001V	Crypto + Giardia + Entamoeba	IVDR
Quad	Viruses	RG862001V	Rotavirus + Adenovirus + Astrovirus + Norovirus	IVDR
	Bacteria	LX862001VF	*Clostridium difficile* GDH + Toxin A + Toxin B + Lactoferrin	

Tumor and inflammatory markers (1)

Format	Reference	Description
Single	F820001F	FOB (Haemoglobin)
	TF20001F	Transferrin
	CP820001F	Calprotectin
	LT820001F	Lactoferrin
Combo	FT882001F	FOB + Transferrin
	PT882001VF	*Helicobacter pylori* + Transferrin
	CC882001VF	Calprotectin 50 + 200
	CL882001F	Calprotectin + Lactoferrin
	GF882001F	*Clostridium difficile* GDH + Lactoferrin
Quad	FC862001F	FOB + Transferrin + Calprotectin + Lactoferrin
	LX862001VF	*Clostridium difficile* GDH + Toxin A + Toxin B + Lactoferrin

Antigens in respiratory samples (2)

Format	Type	Reference	Description	
Single	Viruses	Y820001PC	Influenza A (Flu A)	
		RV820001PC	Respiratory Syncytial Virus (RSV)	IVDR
		AP820001PC	Respiratory Adenovirus	IVDR
		SC820001PC	SARS-CoV-2	IVDR
	Bacteria	T820201PC	*Streptococcus pyogenes (Strep A)*	
Combo	Viruses	Z882001PC	Influenza A + Influenza B	IVDR
		VR882001PC	Respiratory Syncytial Virus + Respiratory Adenovirus	IVDR
Triple	Viruses	ZS872001PC	Influenza A + Influenza B + Respiratory Syncytial Virus	IVDR
		SS872001PC	SARS-CoV-2 + Influenza A+ Influenza B	IVDR
Quad	Viruses	ZV862001PC	Influenza A+ Influenza B + Respiratory Syncytial Virus + Respiratory Adenovirus	IVDR
		SV862001PC	SARS-CoV-2 + Influenza A+ Influenza B + Respiratory Syncytial Virus	IVDR

Antigens in urine samples (3)

Format	Type	Reference	Description
Single	Bacteria	LP820201PC	*Legionella*
		SN820201PC	*Streptococcus pneumoniae*
Combo	Bacteria	NL820201PC	*Streptococcus pneumoniae + Legionella*

Antimicrobial resistance

Format	Reference	Description	
Single	RB20001VC	Certest ResistCheck® Carbapenemases (KPC | NDM | VIM | OXA-48 | IMP)	IVDR

(1) Controls not included. Reference + C includes a positive control. Reference + CC includes a positive control and a negative control.
(2) Includes a positive control. Reference + C includes a positive control and a negative control.
(3) Includes a positive control and a negative control.

Optimized for real-world diagnostic settings

Designed to improve laboratory operational efficiency, reduce costs, and support rapid decision-making in clinical settings.

Operational efficiency

- **Simplified workflow**
  One sample, a single process, and rapid results.
- **Lower risk of error** thanks to reduced handling and simple, easy result interpretation.

Cost-effectiveness

- **Optimized total cost per test**
  no additional equipment or investment in instrumentation required.
- **Higher productivity**
  reduced technical time per sample and improved throughput.

Flexibility

- **Multi-analyte panels tailored to different clinical needs:** Available in single, combo, triple, and quad formats.
- **Portfolio scalability**
  Expand the diagnostic menu without increasing operational complexity.

Ease of use

- **Ready-to-use kits** with all necessary components included.
- **Specific collection vials** provided to facilitate sample collection.
- **Clear interpretation** with differentiated control and test lines.

Simplified workflow

01 Sample Collection

02 Sample Extraction and Preparation

03 Sample Application to the Cassette

04 Test execution

05 Result Reading and Interpretation

Results in approximately 10 minutes with easy visual interpretation and high diagnostic reliability.

Certest ResisCheck® Carbapenemases

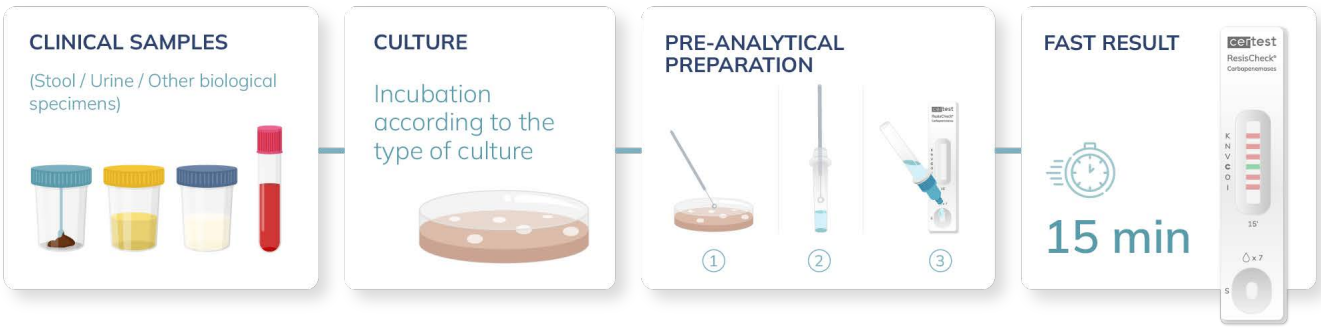
IVDR CERTIFIED

5 enzymes on a single strip: **KPC | NDM | VIM | OXA-48 | IMP**

Advantages

- **IVDR** Certification
- **European** manufacturing
- **High signal intensity** across all 5 lines
- **Clear results,** with a clear membrane background
- **Larger reading window** for results interpreation
- **Differential control line** in green
- **Sample type:** Bacterial isolates from any biological specimen.
- **Lyophilized positive control** included

Workflow



Technical specifications

» Demonstrates proven performance under real laboratory conditions, with an overall agreement of 98.9% compared to other established assays.

- **PPA:** 97,3%
- **NPA:** 99,3%
- **κ** = 0,97

- **Sensitivity:** >95% (1)
- **Specificity:** 100%

» Robust results, comparable to established and validated methods used in routine practice:

- Samples previously analyzed in routine diagnostics.
- Discrepancies resolved by qPCR and sequencing.
- Formal statistical analysis (PPA, NPA, kappa).

(1) *Approximate mean value calculated from the clinical sensitivities obtained for each target. Refer to the IFUs for detailed information.*

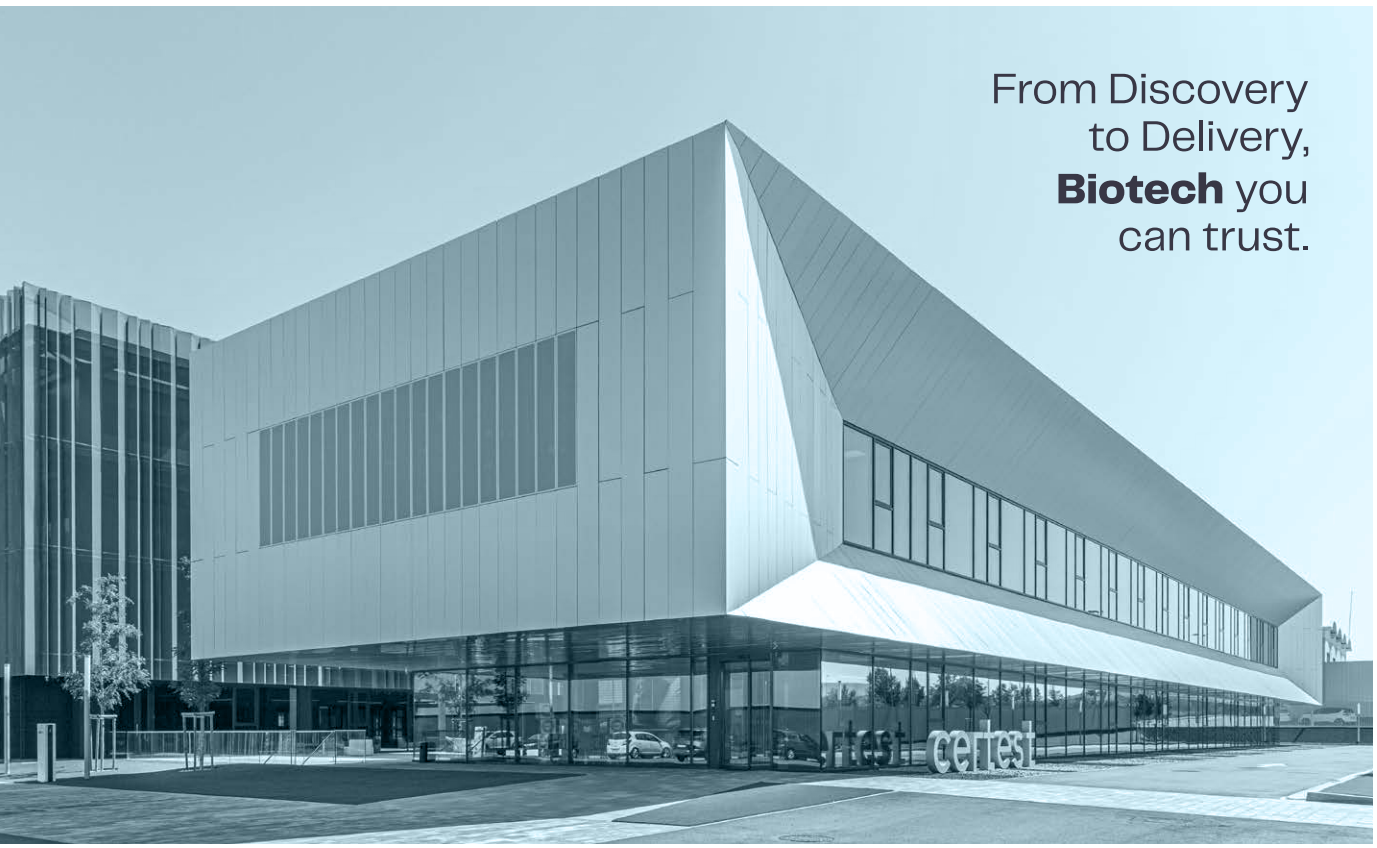
Accelerating Immuno-diagnostics

Non-invasive diagnosis

All-inclusive kit, no additional equipment required.

Immediate results

ISO 13485 certified CE-IVD/IVDR marked



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