Bacterial GE

CarbaR+VRE

CarbaR+MCR

H. pylori+ClariR

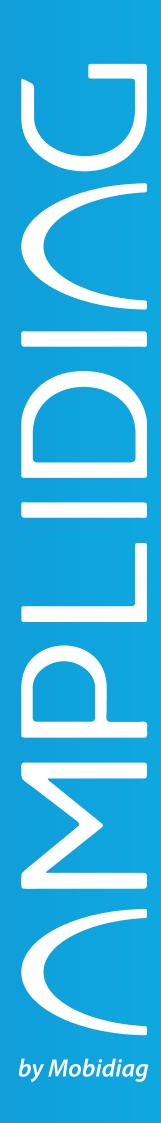
**Stool Parasites** 

C. difficile+027

Viral GE

# EACH UNIQUE. TOGETHER COMPLETE.

Molecular diagnostic solutions for detection of most common gastrointestinal infections and antibiotic resistances



# Fast and reliable molecular diagnostics for detection of most common gastrointestinal infections and antibiotic resistances

Based on well-established **multiplex qPCR** technology, the Amplidiag® test panels allow the detection of most clinically relevant gastrointestinal **bacteria**, **parasites**, **viruses** and **antibiotic resistances**. The qPCR technology gives you wider access to rapid, reliable and comprehensive information in one single test compared to conventional methods (e.g. culture). This ensures optimal performance and cost-effectiveness in **mid-sized to large laboratory** settings.

Each Amplidiag test is delivered with the Amplidiag® Analyzer, a **dedicated software** eliminating the need for time-consuming manual interpretation of results by automating the necessary processes.

The Amplidiag® Easy system brings the Amplidiag® test panels further by enabling process **automation from nucleic acid extraction to PCR set-up** to ensure seamless transfer of information from sample to results.



Product no AD-BGE-100 96 tests

# Detects eight bacterial pathogens in one single test

Sample type: DNA extracted from stool (without any preculture)

Time to result: <2 hours

Target	Sensitivity	Specificity
Campylobacter	98,9%	99,3%
Salmonella	100%	99,7%
Shigella/EIEC	98,0%	99,9%
Yersinia	100%	99,9%
EHEC*	100%	99,9%
ETEC	93,5%	99,7%
EPEC	99,1%	98,7%
EAEC	100%	99,8%
Total	98,7%	99,6%

N=1360 patient samples

<sup>\*</sup> Discrimination between eae, Stx1 and Stx2 variants



Product no AD-CD-300 288 tests

#### Detects pathogenic Clostridium difficile and its hypervirulent 027 ribotype in one single test

Sample type: DNA extracted from stool (without any preculture)

Time to result: <2 hours

Target	Sensitivity	Specificity		
Toxin B gene	97,8%	100%		
Ribotype 027	94,1%	100%		



Product no AD-HP-80 96 tests

# Detects *Helicobacter pylori* and its clarithromycin resistance directly from stool samples or gastric biopsies

Sample type: DNA extracted from stool or gastric biopsies

Time to result: <2 hours

		Stool		Gastric biopsies	
Target	Identified gene/mutation	Sensitivity	Specificity	Sensitivity	Specificity
Helicobacter pylori	23S rRNA	96%	100%	100%	96,2%
Clarithromycin resistance	SNPs at sites 2142 and 2143 of 23S rRNA gene	93,2%	100%	100%	100%

N=301 patient samples (stool) N=200 patient samples (gastric biopsies)



Product no AD-SP-100 96 tests

# Detects most frequent gastroenteric parasites in one single test

Sample type: DNA extracted from stool

Time to result: <2 hours

Target	Sensitivity	Specificity
Cryptosporidium spp.*	100%	100%
Giardia lamblia	100%	98,6%
Entamoeba histolytica	100%	100%
Dientamoeba fragilis	87,5%	99%

N=227 patient samples

<sup>\*</sup> Including: C. andersoni, C. canis, C. chipmunk genotype 1, C. felis, C. cuniculus, C. hominis, C. horse, C. meleagridis, C. muris, C. parvum, C. ubiquitum



C E IVD
Product no AD-VGE-100
96 tests

# Detects most frequent gastroenteric viruses in one single test

Sample type: RNA extracted from stool (without any preculture)

Time to result: <2,5 hours

Target	Sensitivity	Specificity
Norovirus GI	100%	100%
Norovirus GII	100%	98,9%
Rotavirus A	100%	99,1%
Sapovirus	95,8%*	95,7%*
Astrovirus	100%	100%
Adenovirus 40 and 41	93,3%	99,2%

N=164 patient samples; \*N=347





# Detects clinically most relevant carbapenemases and vancomycin resistances in one single test

Sample type: DNA extracted from stool samples, rectal swabs or pure culture

Time to result: <2 hours

		Combined stool & rectal swabs		Culture	
Target	Variant	Sensitivity	Specificity	Sensitivity	Specificity
KPC	KPC-1 through KPC-24	96%	100%	100%	99%
NDM	NDM-1 through NDM-16	93%	100%	92%	100%
VIM	VIM-1 through VIM-21; VIM-23 à VIM-46	100%	100%	100%	100%
IMP	IMP-1 through IMP-35; IMP-37; IMP-38; IMP-40 through IMP-45; IMP-47; IMP-48; IMP-51; IMP-53	100%	99%	100%	99%
OXA-48, OXA-181	OXA-48; OXA-162; OXA-181; OXA-204; OXA-232; OXA-244; OXA-245; OXA-405	100%	100%	100%	99%
Acinetobacter OXA	ISAbal-OXA-51*, OXA-23*, OXA-24/40*, OXA-58*	92%	97%	96%	97%
vanA	VanA gene	100%	100%	100%	100%
vanB	vanB1, vanB2 and vanB3	100%	100%	100%	100%
Total		98%	99%	98%	99%

 $N \!\! = \!\! > \!\! 2000 \text{ patient samples (stool and rectal swabs), } N \!\! = \!\! 200 \text{ (pure culture samples)} \quad \text{*See detailed variant information from the user manual}$ 





Product no AD-CPM-100 96 tests

## Detects clinically most relevant carbapenemases and colistin resistance in one single test

Sample type: DNA extracted from stool samples, rectal swabs or pure culture

Time to result: <2 hours

		Combined stool & rectal swabs		Culture	
Target	Variant	Sensitivity	Specificity	Sensitivity	Specificity
KPC	KPC-1 through KPC-24	100%	99,8%	100%	99,5%
NDM	NDM-1 through NDM-16	95,5%	99,7%	91,7%	100%
VIM	VIM-1 through VIM-21; VIM-23 through VIM-46	100%	98,5%	100 %	100 %
IMP	IMP-1 through IMP-35; IMP-37; IMP-38; IMP-40 through IMP-45; IMP-47; IMP-48; IMP-51; IMP-53	100%	99,2%	100%	99,5%
OXA-48, OXA-181	OXA-48; OXA-162; OXA-181; OXA-204; OXA-232; OXA-244; OXA-245; OXA-405	100%	99,5%	100%	99,4%
Acinetobacter OXA	ISAbal-OXA-51*, OXA-23*, OXA-24/40*, OXA-58*	91,1%	97,4%	95,7%	97,3%
MCR	MCR-1, MCR-2	97,5%	98,9%	93,3%	100%
GES	GES-2, GES-4 through GES-6, GES-13 through GES-16, GES 18, GES-20, GES-21, GES-24	94,7%	100%	91,7%	97,9%
Total		97,3%	99,1%	96,5%	99,2%

# ∩MPLIDI∩G Easy

# Faster results with automated processing of all Amplidiag® products

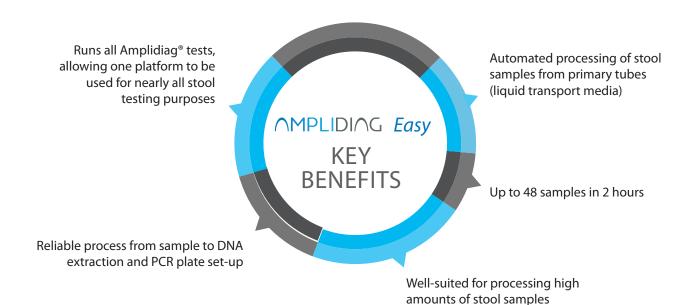
Amplidiag® Easy system is well-suited for mid to high volume screening purposes. Automating the workflow minimizes the amount of hands-on time for processing samples, while enhancing the analysis process. With Amplidiag® Easy, the **nucleic acid extraction and PCR plate set-up** for all Amplidiag® tests is automated.

Through its design, rapidity and ease-of-use, Amplidiag® Easy allows the processing of several batches in a day, generating results faster and more reliably.

# **Amplidiag® Easy system workflow**

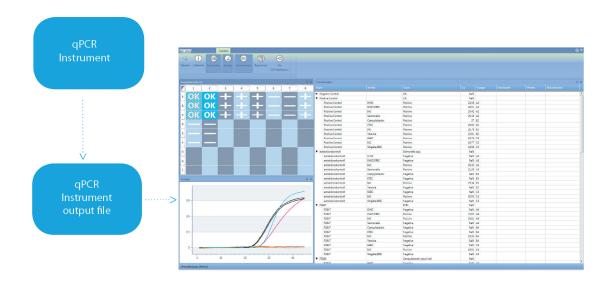


\* Amplidiag® Easy is compatible with Bio-Rad CFX PCR instrument (ask us for more information)



# Amplidiag® Analyzer Software

Each Amplidiag® test is delivered with the Amplidiag® Analyzer, a dedicated software eliminating the need for time-consuming manual interpretation of results by automating the necessary processes.



# **KEY BENEFITS**

Automated result analysis - saves ~2 hrs manual work/run

Clearly reports findings for samples, analyzes and interprets all controls

No need for manual interpretation, reduced risk of manual errors

Stores all analyses - traceability of results

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