AMPLIDIAG

A COMPREHENSIVE LINE OF PRODUCTS FOR HIGH-THROUGHPUT TESTING OF GASTROINTESTINAL PATHOGENS AND ANTIBIOTIC RESISTANCES

Creating a new standard for molecular testing

Mobidiag's new product line, Amplidiag®, encompasses innovative multiplex diagnostic tests for gastrointestinal infections, allowing wider access to rapid, reliable and comprehensive information compared to conventional methods.

Tests are done directly from the DNA extracts of a stool sample, using well-established qPCR technology. This ensures optimal performance, suitability for high-volume screening and cost-effectiveness in mid-sized to large laboratory settings.

Specialized software, Amplidiag Analyzer, eliminates the need for time-consuming manual interpretation of results by automating the necessary processes. Amplidiag Easy, an easy-to-use automation platform, ensures seamless transfer of information from sample to result.

AMPLIDIAG Bacterial GE

CE IVD

Simultaneously detects eight pathogens, streamlining laboratory processes and samples flows

Target panel

Campylobacter	EHEC
Salmonella	ETEC
Shigella / EIEC	EPEC
Yersinia	EAEC

Performance of Amplidiag Bacterial GE

In a multicentre study with a total of 1360 patient samples[1], Amplidiag Bacterial GE identified all culture-positive findings correctly, giving no false negative results compared to culture.

1) Kirveskari J et al. 2015: Evaluation of feasibility of new multiplex real-time PCR test in screening of bacterial diarrhoeal samples. ePoster #P0870, ECCMID 2015.

Performance

Target	Sensitivity %	Specificity %
Campylobacter	100 %	99,6 %
Salmonella	100 %	99,9 %
Shigella/EIEC	98,0 %	100 %
Yersinia	100 %	100 %
EHEC	100 %	100 %

Target	Sensitivity %	Specificity %
ETEC	93,1 %	99,9 %
EPEC	98,8 %	99,9 %
EAEC	100 %	99,8 %

Overall	**99,9 %**	**99,9 %**

AMPLIDIAG
CarbaR+VRE

CE IVD

Comprehensive, effective solution for identifying clinically relevant carbapenemases and VRE

Suitable for high-throughput screening of pure culture samples for all known variants of carbapenem-producing organisms (CPO) as well as vancomycin resistant Enterococci (VRE). Identifies the five clinically most relevant carbapenemase groups, *Acinetobacter baumannii* group selective carbapenemases and two vancomycin resistance markers.

Target	Sensitivity	Specificity
Acinetobacter OXA group	100 %	99,4 %
OXA-48 group	100 %	100 %
NDM group	100 %	100 %
VIM group	100 %	100 %
IMP group	100 %	100 %
KPC group	100 %	100 %
vanA	100 %	99,4 %
vanB	100 %	99,4 %

AMPLIDIAG
H. pylori+ClariR

CE IVD

Reliably identifies *Helicobacter pylori* and clarithromycin resistance directly from stool samples

Uses a novel, innovative integrated nested PCR method to detect *H. pylori* and its clarithromycin resistance within the same specific PCR product, having only a minimal cross-reactivity with closely related species. Enables effective primary therapy, potentially lowering therapy failures and decreasing the amount of gastroscopies, biopsies and gastric cancers.

Target panel

Target	Identified gene / mutation
Helicobacter pylori	23S rRNA gene
Clarithromycin resistance	SNPs at sites 2142 and 2143 of 23S rRNA gene

Performance

Target	Sensitivity	Specificity
Helicobacter pylori	91,4 %	99,6 %
Clarithromycin resistance gene mutations	100 %	100 %

AMPLIDIAG Stool Parasites

CE IVD

Enhances screening processes by identifying multiple enteric parasites in a single reaction

Identifies the three most frequent enteric parasites from a single stool sample in a single reaction. Allows effective detection of *Cryptosporidium* spp., *Giardia lamblia*, *Entamoeba histolytica* and *Dientamoeba fragilis*. Microscopy can be targeted to samples that need further investigation, allowing a more effective and accurate screening process.

Target panel

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

AMPLIDIAG Viral GE

Detects the five most important viral enteric pathogens from a single sample

This comprehensive test allows rapid screening of relevant viral pathogens at once, without parallel or subsequent testing.

Target panel

Norovirus GI and GII	Astrovirus
Rotavirus A	Adenovirus 40 and 41
Sapovirus	

AMPLIDIAG *C. difficile*+027

CE IVD

Catches pathogenic *C. difficile* and its hypervirulent 027 ribotype immediately at screening

A qualitative qPCR-based screening test for rapidly and cost-efficiently identifying pathogenic *C. difficile* and its hypervirulent 027 ribotype directly from stool samples. Detects the *tcdB* (toxin B) gene and discriminates between 027 and non-027 strain in a single reaction.

Performance

Target	Sensitivity	Specificity
Toxin B gene	97,8 %	100 %
Ribotype 027	94,4 %	100 %

AMPLIDIAG Easy

Faster results with automated processing of all Amplidiag products

All Amplidiag products are designed for high-volume screening purposes. Automating the workflow can minimize the amount of hands-on time for processing samples, while enhancing the analysis process. With Amplidiag Easy, the nucleic acid extraction and PCR plate setup for all Amplidiag products can be automated.

This automatic process is much faster than with other nucleic acid extraction or pipetting robot solutions. Through its design, rapidity and ease-of-use, Amplidiag Easy allows the processing of several batches in a day, generating results faster than any other high-volume nucleic acid screening solution currently available.

AMPLIDIAG Easy

Runs all Amplidiag tests, allowing one platform to be used for nearly all stool testing purposes

Automated processing of stool samples from primary tubes (liquid transport media)

Allows batch processing of up to 48 samples in one hour

Well-suited for processing high amounts of stool samples

Reliably and consistently executes full workflow from sample to a finished pipetted PCR plate for qPCR analysis

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