AMPLIDIAG®

Wider access to rapid, reliable and comprehensive information for gastrointestinal infection diagnostics

Summary of lunch seminar
April 11th, 2016
ECCMID, Amsterdam, The Netherlands

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Mobidiag in brief

Mobidiag develops and manufactures the Amplidiag® product line

Company Focus	Molecular IVD solutions for infectious diseases
Background	Strong combination of capabilities created in three-way merger 2013, established in 2001 (Mobidiag, Amplidiag and Genewave)
Core Technologies	Stool-based assay technologies Pathogen and ABR detection technologies Integrated diagnostic platform technologies Reagent development and manufacturing
Locations	Headquartered in Espoo, Finland Subsidiaries in Paris, France and Stockholm, Sweden
Team	Employs about 40 experts of various fields Cross company teams with world-class development partners
IVD Product Lines	Amplidiag® Prove-it™ Novodiag® (under development)
Quality	ISO 9001 certified ISO 13485 certified

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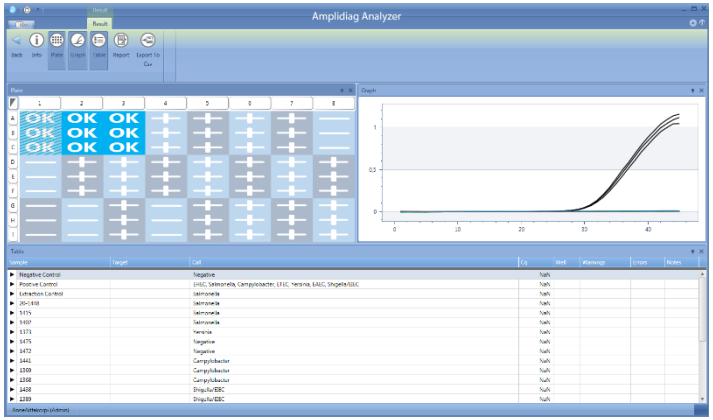
Amplidiag® product line

- Manufacturing of all key components in-house
- Tests pre-developed in a large clinical laboratory
- Includes Amplidiag® Analyzer software automates result analysis



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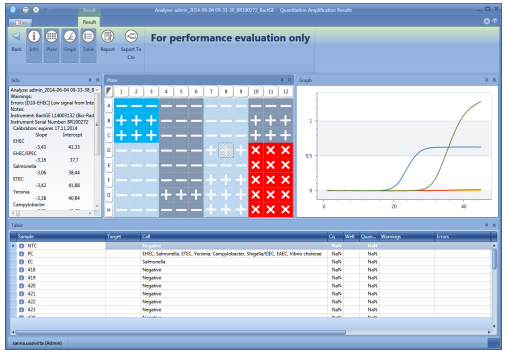
All Amplidiag® products share the same workflow

DNA extraction & qPCR plate setup → Real-Time PCR amplification → Automatic analysis and reporting



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Test panels

Amplidiag® Bacterial GE
Campylobacter coli/jejuni
Shigella/EIEC
Salmonella
Yersinia enterocolitica/ pseudotuberculosis/pestis
EHEC
ETEC
EPEC
EAEC

Amplidiag® *C. difficile+027*
tcdB (toxin B gene marker)
027 positive marker
027 negative marker

Amplidiag® *H. pylori*+ClariR
Helicobacter pylori
Clarithromycin resistance marker

Amplidiag® CarbaR+VRE
KPC
NDM
VIM
OXA-48/-181
ISAbaI-OXA-51, OXA-23, OXA-40, OXA-58
IMP
vanA
vanB

Amplidiag® Viral GE
Norovirus GI/GII
Adenovirus 40/41
Rotavirus
Astrovirus
Sapovirus

Amplidiag® Stool Parasites
Giardia lamblia
Cryptosporidium spp.
Entamoeba histolytica
Dientamoeba fragilis

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Lunch seminar agenda

- Amplidiag® Stool Parasites – From evaluation to easy routine
  - Sakari Jokiranta, Medical Director, United Medix Laboratories, Finland
- Amplidiag® Bacterial GE evaluation and user experiences
  - Juha Kirveskari, R&D Director, Mobidiag, Finland
  - Helena Enroth, Molecular Biologist R&D, Unilabs, Sweden
- Amplidiag® H.pylori+ClariR – A rapid and easy detection
  - Lucie Bruhl-Benejat, Engineer, CNRCH Bordeaux, France

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Sakari Jokiranta

Medical Director, United Medix Laboratories, Finland

AMPLIDIAG® STOOL PARASITES - FROM EVALUATION TO EASY ROUTINE

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Amplidiag® Stool Parasites

- Optimize stool parasite screening by qPCR
- Target microscopy only to samples needing further investigation
- Directly from DNA extract of stool sample
- Multiplex qualitative qPCR kit
- Workflow automation possibility
- Result analysis and reporting: automated with supplied Amplidiag® Analyzer software

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Amplidiag® Stool Parasites

- Intended as the primary screening of four enteric parasites in a single test
  - *Giardia lamblia*
  - *Cryptosporidium spp.*
  - *Entamoeba histolytica*
  - *Dientamoeba fragilis*
- Test directly from stool sample
- Reduces substantially the burden of microscopy, time to process samples and human errors

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Amplidiag® Stool Parasites testing

- Results
  - All tested assays* performed well with *Cryptosporidium* spp.
  - Amplidiag® Stool Parasites is more sensitive than other tested assays for *Dientamoeba* fragilis
  - Amplidiag® Stool Parasites is more sensitive than other tested assays for *Giardia lamblia*
- Conclusion
  - When looking at detection of all targets, Amplidiag® Stool Parasites performed best

* Test comparison between Amplidiag® Stool Parasites and 2 other commercially available assays

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Helena Enroth
Molecular Biologist R&D, Unilabs, Sweden

Juha Kirveskari
R&D Director, Mobidiag, Finland

AMPLIDIAG® BACTERIAL GE EVALUATION AND USER EXPERIENCES

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Amplidiag® Bacterial GE

- Use as primary screening method for stool samples (for bacterial identification)
- Covers wide range of pathogens, including some not identified by current methods, in a single test
  - *Campylobacter coli/jejuni*
  - *Shigella*/EIEC
  - *Salmonella*
  - *Yersinia enterocolitica/ pseudotuberculosis/pestis*
  - EHEC
  - ETEC
  - EPEC
  - EAEC
- Directly from stool sample without culturing
- Multiplex qualitative qPCR kit
- Workflow automation possibility
- Result analysis and reporting: automated with supplied Amplidiag® Analyzer software

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Amplidiag® Bacterial GE testing

- Results
  - Performance figures were in line with prior set performance criteria: minimum sensitivity of 90%, and 95% specificity achieved for all targets
  - No culture positive were missed
  - Very good agreement with molecular methods
  - Selected evaluation feedback
- Conclusions
  - Good medical performance
    - Easy to use
    - No cross-contaminations
    - Non-product related process parts were considered laborious

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Sakari Jokiranta
Medical Director, United Medix Laboratories, Finland

Lucie Bruhl-Benejat
Engineer, CNRCH Bordeaux, France

AMPLIDIAG® H.PYLORI+CLARIR – A RAPID AND EASY DETECTION

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Amplidiag® H.pylori+ClariR

- Screen *Helicobacter pylori* and clarithromycin resistance (ClariR) simultaneously
- Test directly from DNA extract of stool sample
- Multiplex qualitative qPCR kit
- Workflow automation possibility
- Result analysis and reporting: automated with supplied Amplidiag® Analyzer software

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Amplidiag® H.pylori+ClariR

- Currently reliable identification relies on invasive methods (endoscopy + biopsy)
- Key innovation: Integrated nested PCR test directly from stool including both detection of *H. pylori* and its clarithromycin resistance
- Key benefit: potential to lower therapy failures, decrease the amount of gastroscopies and biopsies, and gastric cancer
- Minimal cross-reactivity with closely related species
- The method is non-invasive and suited for volume testing – first direct-stool NAT on the market
- Performance of *H.pylori*+ClariR was evaluated with 299 patient samples

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Amplidiag® H.pylori+ClariR testing

- Current diagnostics can be improved by replacing the antigen detection and breath tests with the unique Amplidiag® H.pylori+ClariR test
- Cost-benefit analysis in real life needs to be performed but likely to favour ClariR testing
- Amplidiag® H.pylori+ClariR showed good performance and was easy to use for both stool samples and biopsies

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Summary

- Amplidiag® tests provide in many cases more clinically relevant information than conventional or other molecular methods
- Amplidiag® Stool Parasites globally performed better than other available assays
- Amplidiag® Bacterial GE showed good medical performance
  - Easy to use
  - No cross-contaminations
  - Non-product related process parts were considered labourous
- Amplidiag® H.pylori+ClariR could improve current diagnostics by replacing the antigen detection and breath tests (including a higher performance with biopsies)

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