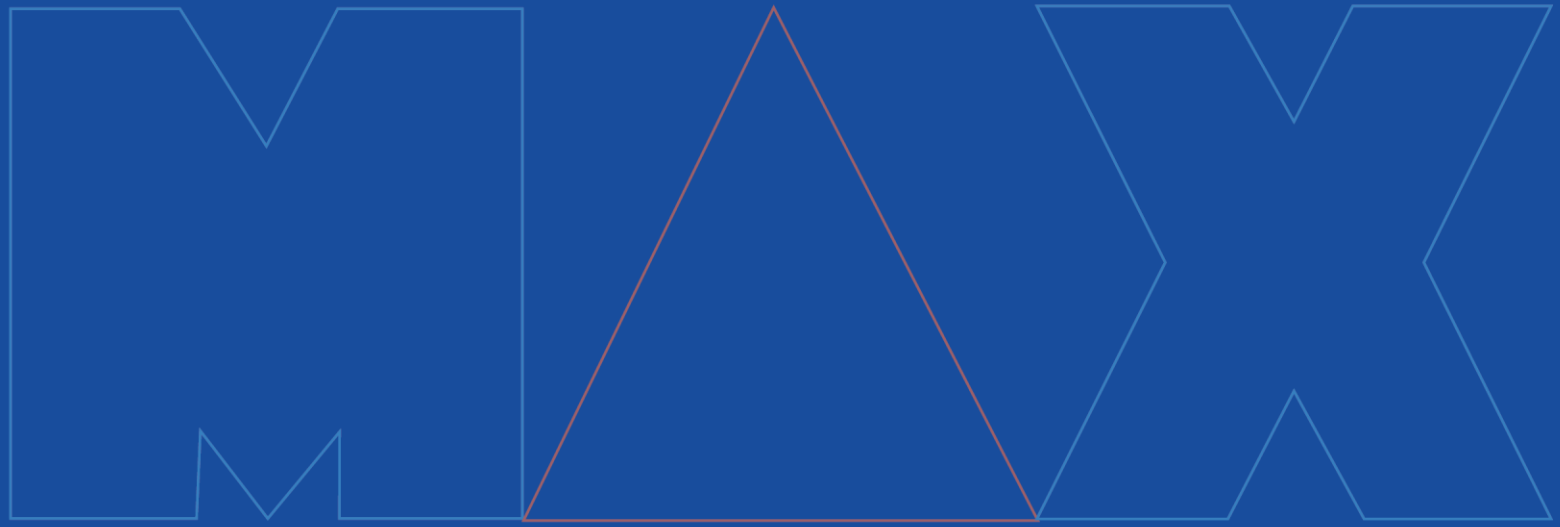
BD MAX™ Extended Enteric Bacterial Panel (xEBP)

BD



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WHY FOCUS ON ENTERIC TESTING?

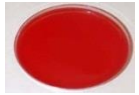
>1.7 BILLION CASES OF INFECTIOUS GASTRO-ENTERITIS PER YEAR WORLDWIDE[1]

2ND LEADING CAUSE OF DEATH IN CHILDREN < 5 YEARS OLD[1]

1 IN 6 AMERICANS GET SICK FROM FOOD-BORNE ILLNESSES PER YEAR[2]

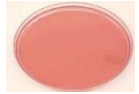
BD

Typical workflow with conventional methods



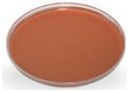
Campy agar
- 42° incubation
- Microaerophilic
- 48hr read
- 72hr hold
- QC requirements

TSA II blood Agar
- 35° incubation
- 24hr read
- 48hr hold



MacConkey agar
- 35° incubation
- 24hr read
- 48hr hold
- Non fermenters
- Suspicious colonies ID'd or subcultured

Broth culture
- 35° incubation
- 24hr read
- Subculture to additional plates
- 24-48hr incubation/screen



Salmonella/Shigella Agar
- 35° incubation
- Multiple types
- 24hr read
- 48hr hold
- High false positives H2S+

Yersinia (CIN) Agar
- 25° incubation
- 24hr read
- 48hr hold
- High false positives

E. Coli 0157 Agar
- 35° incubation
- 24hr read
- 48hr hold
- High false positives w/SMAC
- High cost with CHROMagar

Shigatoxin EIA
- Costly additional test
- Additional workflow
- 90 min test
- Direct fresh stool, broth or plate
- Culture most frequently used

25° incubator
- Used for Yesinia testing only

42° incubator
- Used almost solely for Campy testing

35° incubator
- Aerobic conditions
- Main incubator in lab

Campy EZ
- Used to generate environment for Campy
- QC requirements
- Campy stock culture reqd

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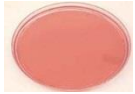

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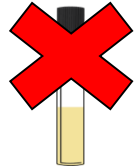

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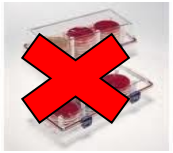

Campy EZ
- Used to generate environment for Campy
- QC requirements
- Campy stock culture reqd

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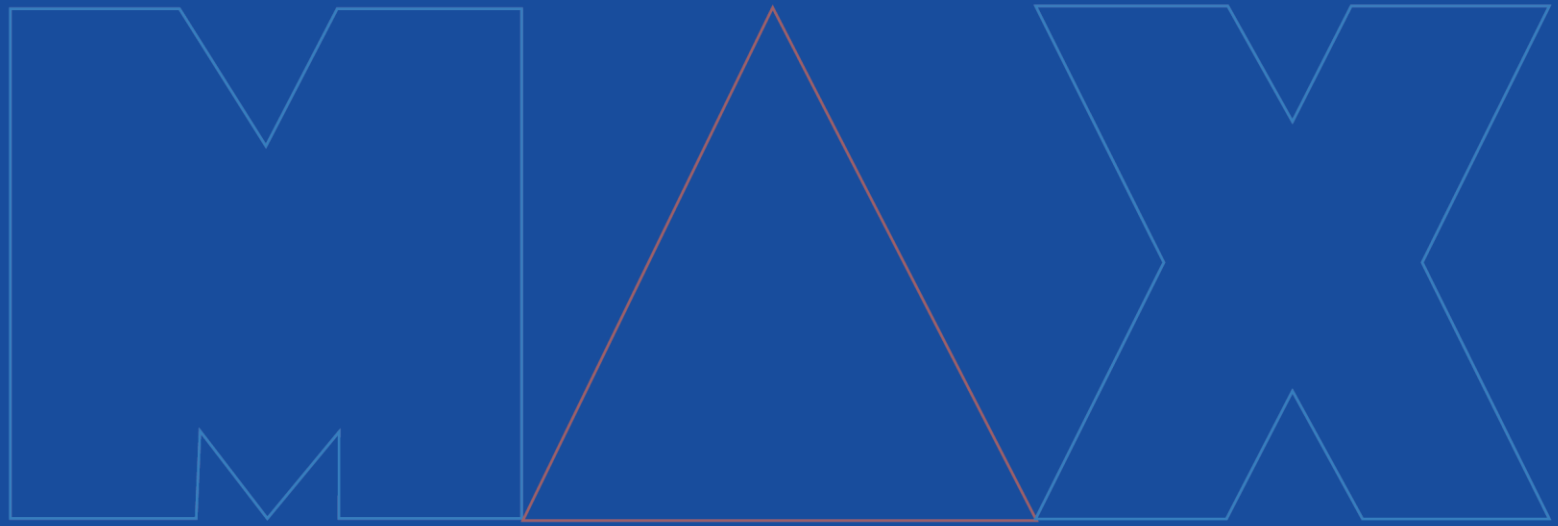
THE TRUE COST OF CULTURE[3]

64% of negative stool cultures required some testing beyond the primary media.

Due to low positivity rate, the cost of finding ONE positive = $427

5 technologists were monitored for time and supplies needed to work up 206 stool cultures
Cost = $2137.30, 5 positives were identified

Beal et al; ASM 2013



Product Overview

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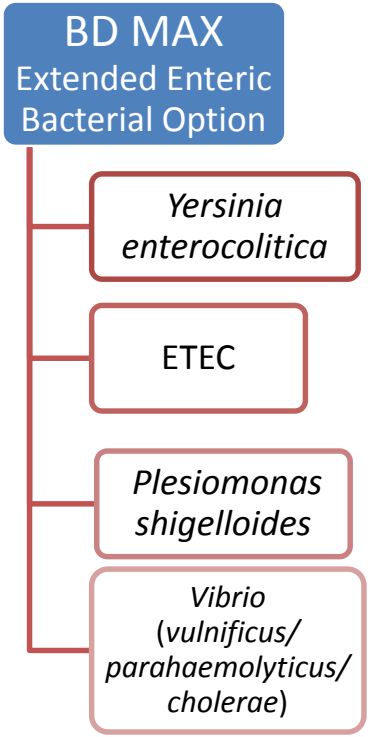
BD MAX™ EXTENDED ENTERIC BACTERIAL OPTION… FULL BACTERIAL COVERAGE WHEN NEEDED



Routine

- **Routine** use with the Enteric Bacterial Panel virtually eliminates need for culture or conventional tests to screen for bacterial pathogens

Versatile

- **Flexible** use based on patient status, history and clinical presentation

We give you a CHOICE!

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WHY TEST FOR THESE ORGANISMS?

- **ETEC**[4,5]
  - Leading cause of “travelers’ diarrhea”
  - High risk regions: Asia, Middle East, Africa, Mexico, Central and South America
  - Becoming recognized as an important source of foodborne illness in the U.S.
  - Frequently resistant to common antibiotics

- ***Vibrio spp.***[4]
  - CDC reports 80,000 illnesses per year in the U.S.
  - Associated with raw or undercooked seafood; seawater in wounds
  - Most infections occur May-October

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WHY TEST FOR THESE ORGANISMS?

Yersinia enterocolitica[7]

Ingestion of “chitterlings”, made from pig intestines: common in several countries and certain regions of the U.S.

- CDC reports 170,000 illnesses per year in the U.S.
- Occurs most often in young children

Plesiomonas shigelloides[8]

- Associated with environmental contamination of freshwater bodies
- Series of foodborne outbreaks attributed to *P. shigelloides* has occurred over the past 2 decades
- Often overlooked in stool samples

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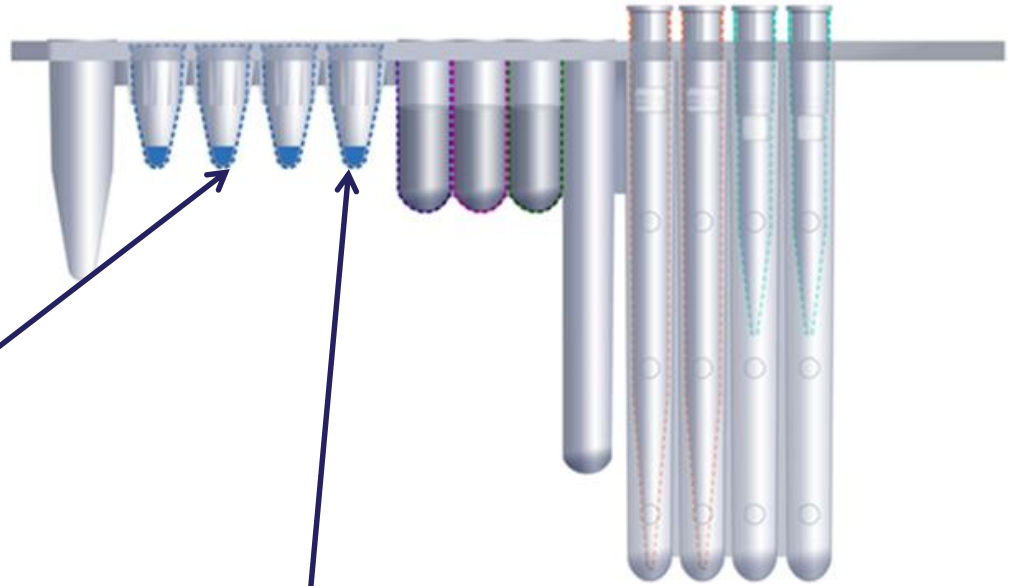
Why not Aeromonas?[9]

The genus *Aeromonas* is commonly found in aquatic environments, being isolated from rivers, lakes, ponds, seawater (estuaries), drinking water, groundwater, wastewater and sewage.

The exact incidence of *Aeromonas* infections on a global basis is unknown. *Aeromonas* is not a reportable condition in the U.S. or in most other countries around the world.

One of the troubling aspects of *Aeromonas* gastroenteritis has been the inability to document a clear-cut association between outbreaks of diarrheal disease that are unquestionably epidemiologically linked to it.

THE BD MAX EXTENDED ENTERIC BACTERIAL SOLUTION – CONFIGURATION



Enteric Bacterial Panel (existing)
- *Salmonella spp.*
- *Shigella spp.*
- *Campylobacter spp.*
- *Shiga-toxin producing E. coli*

Extended Enteric Bacterial Panel
- *Plesiomonas shigelloides*
- *Vibrio (V. vulnificus, V. parahaemolyticus, and V. cholera)*
- ETEC (Enterotoxigenic *E. coli)* - heat labile and stabile
- *Yersina enterocolitica*

THE BD MAX EXTENDED ENTERIC BACTERIAL SOLUTION – PROSPECTIVE PERFORMANCE

Specimen Type	*Vibrio*		*P. shigelloides*		*Y. enterocolitica*		*ETEC*	
	PPA	*NPA*	*PPA*	*NPA*	*PPA*	*NPA*	*PPA*	*NPA*
Unpreserved Prospective	No data	99.8%	No data	99.9%	No data	100%	100%	99.9%
Cary-Blair Prospective	100%	99.6%	No data	99.9%	No data	99.9%	100%	99.8%

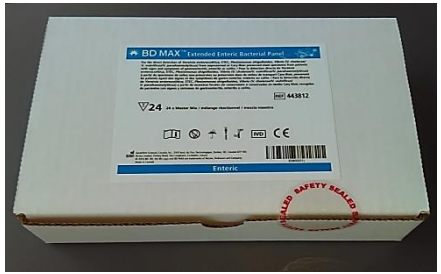
THE BD MAX EXTENDED ENTERIC BACTERIAL SOLUTION – RETROSPECTIVE PERFORMANCE

Specimen Type	*Vibrio*		*P. shigelloides*		*Y. enterocolitica*		*ETEC*	
	PPA	*NPA*	*PPA*	*NPA*	*PPA*	*NPA*	*PPA*	*NPA*
Unpreserved Retrospective	100%	97.8%	100%	97.9%	100%	100%	90%	96.3%
Cary-Blair Retrospective	100%	100%	100%	100%	No data	No data	100%	100%

THE BD MAX EXTENDED ENTERIC BACTERIAL SOLUTION – PACKAGING AND LABELLING

Kit Contents

- xEBP Package Insert
- 24 xEBP Master Mix snap-in tubes
  - 2 blue-top pouches of 12 each
  - xEBP MM snap-in tube blue foil, readable D8 code



*Assay Kit **DOES NOT** contain Sample Buffer Tubes, Strips, Extraction Reagents*

*xEBP Assay **CANNOT** run alone*

*xEBP **MUST** be run in combination with the **EBP assay***

THE BD MAX EXTENDED ENTERIC BACTERIAL SOLUTION – SPECIMEN TRANSPORT

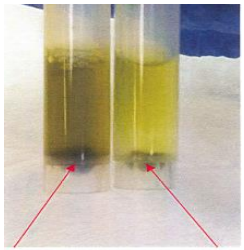
Specimens:

- Unpreserved liquid or soft stool samples
  - Transfer liquid or soft stool samples to a dry, clean container. Avoid contamination with water or urine.
- Preserved stool samples in Cary-Blair transport media
  - Transfer liquid or soft stool samples to a 15 mL transport device according to the manufacturer's instructions
- Store at 23-27ºC up to 24 hours or at 2-8ºC for up to 5 days

Enteric Bacterial and Extended Enteric Bacterial Sample Prep

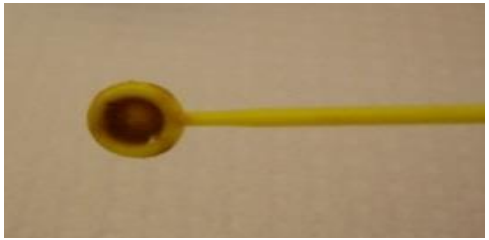
- Vortex unformed stool or Cary-Blair sample
- Insert a 10 µL disposable inoculation loop into stool sample
- Transfer properly loaded loop into the corresponding Sample Buffer Tube
- Roll the loop between fingers to release the specimen from loop
- Close the inoculated Sample Buffer Tube using a Septum Cap
- Vortex all prepared Sample Buffer Tubes for 1 minute
- Load Rack(s)

Incorrect Method



Incorrect Method
- Large mass of particulates
- SB is too dark

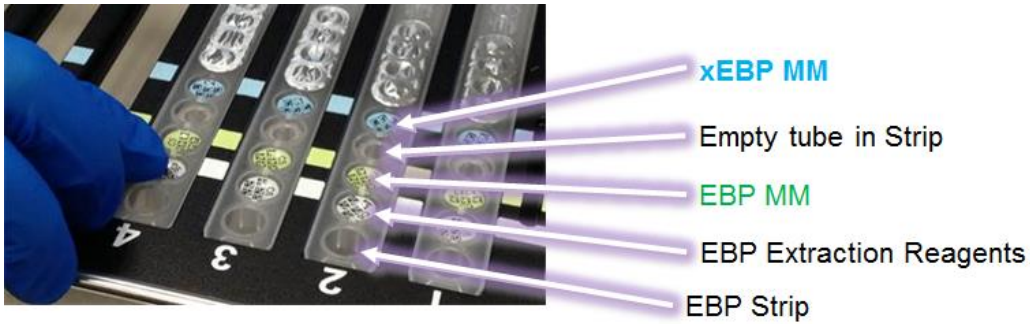
Correct Method
- Some settled particulates
- SB is “tea” stained in color



Correct method

THE BD MAX ENTERIC RUN SET UP

- Load rack, align Extraction, EBP MM and xEBP MM tubes according to designated colors
  - Rack with blue line is not a necessity…there will be no other place to put the xEBP MM except in the open spot (snap-4)once EBP reagents are loaded into the positions that are color coded
- Ensure cartridge has both top and bottom rows available



THE BD MAX ENTERIC HANDS ON/TOTAL TIME

• From loop collection device to end of PCR • HOT & TTR from R&D testing	**BD MAX™ xEBP (including EBP)**
Manual steps	• Inoculating loop of stool, transferring sample to SBT, vortexing • Run setup • All steps performed at room temperature
Hands-on-time (HOT)	• 22 minutes 28 seconds (24 samples)
Total-time (including extraction and PCR)	• 206 minutes 8 seconds (24 samples-2MM)

Reimbursement (U.S.)

as of 5/2017

	Number of Targets	Applicable Panel	Reimbursement
Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (e.g., Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes	6-10 (87506)	EBP/xEBP	$300 x 1

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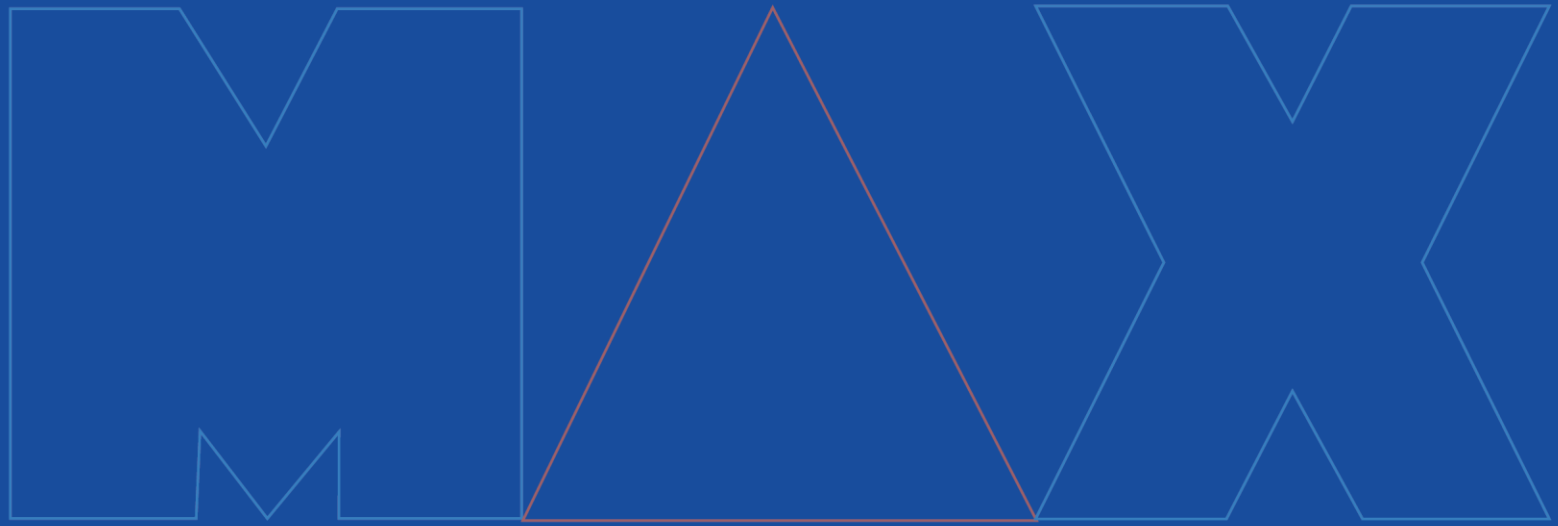
THE BD MAX ENTERIC RUN SET UP

- Results are reported for each target individually
  - UNR result may be obtained for one or more xEBP targets; the rest are reportable
- In the case of a complete (all targets) UNR, it is necessary to repeat the EBP/xEBP processing
  - Can be retested 1 time from Inoculated Sample Buffer Tubes

ASSAY RESULT REPORTED	INTERPRETATION OF RESULT
Plesio POS	*Plesiomonas shigelloides* DNA detected
Plesio NEG	*Plesiomonas shigelloides* DNA detected
Plesio UNR	Unresolved – inhibitory specimen or reagent failure; no target or Sample Processing Control amplification
Vibrio POS	*Vibrio* (*vulnificus, parahaemolyticus,* and/or *cholerae*) DNA detected
Vibrio NEG	No *Vibrio* (*vulnificus, parahaemolyticus,* and/or *cholerae*) DNA detected
Vibrio UNR	Unresolved – inhibitory specimen or reagent failure; no target or Sample Processing Control amplification
ETEC POS	Heat labile and/or heat stabile (LT/ST) ETEC (Enterotoxigenic *E. coli*) DNA detected
ETEC NEG	No heat labile and/or heat stabile (LT/ST) ETEC (Enterotoxigenic *E. coli*) DNA detected
ETEC UNR	Unresolved – inhibitory specimen or reagent failure; no target or Sample Processing Control amplification
Yersi POS	*Yersina enterocolitica* DNA detected
Yersi NEG	No *Yersina enterocolitica* DNA detected
Yersi UNR	Unresolved – inhibitory specimen or reagent failure; no target or Sample Processing Control amplification
Indeterminate (IND)	Indeterminate due to BD MAX™ System failure (with Warning or Error Codes)
Incomplete (INC)	Incomplete Run (with Warning or Error Codes)



Benefits of the Enteric Solution

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THE BD MAX™ SYSTEM PROVIDES A SIMPLE AND EFFICIENT WAY TO RUN MOLECULAR ASSAYS

GOAL

REACHING MORE PATIENTS WITH THE RIGHT TESTS AT THE RIGHT TIME

CHALLENGE

The lab needs one system with the ability to provide:

- A variety of testing options for infection control
- An expanding offering to keep up with emerging diagnostic requirements
- Tailored options based on specific patient needs

THE BD MAX SYSTEM FEATURES

- A broad and flexible syndromic test selection
- An innovative assay pipeline, with complete testing solutions in development
- A suite of Open System Reagents for User-Defined Protocols

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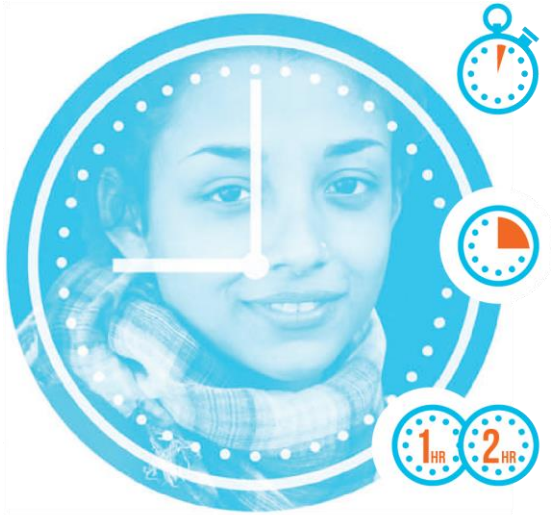
OPTIMIZE WORKFLOW TO IMPROVE PATIENT CARE



LESS THAN 1 MINUTE*
HANDS-ON TIME PER SPECIMEN[10]

15 MINUTES*
HANDS-ON TIME PER RUN[10]

OVER 2 HOURS*
WALK-AWAY TIME PER RUN[11]

TESTING FLEXIBILITY

- Runs 1–24 samples and different assays at the same time[10]
- Tests a wide range of sample types[11]

STAFF PRODUCTIVITY THROUGH AUTOMATION[11]

- Offers simple implementation and standardized workflow

OPPORTUNITY TO REDUCE TOTAL COST[13]

- Enables increased testing volume through streamlined workflow

*Based on processing 24 samples

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THE BD MAX ENTERIC SOLUTION

Efficiency: BD MAX Enteric panels provide more accurate[13] and faster[14] results (over conventional methods) for the diagnosis of infectious gastroenteritis

Versatility: Our focused syndromic approach offers clinicians the ability to order tests based on patient history and clinical presentation.

Performance: GI testing can be done on the same platform as higher-volume HAI testing, on a system that requires minimal expertise and hands-on time

BD

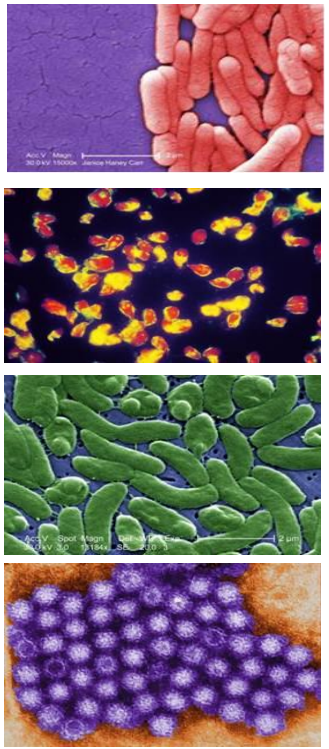
BD MAX Enteric Solutions…targeted, clinically relevant results in an automated, cost effective platform

Focused Panels designed for comprehensive pathogen detection allow for ***full flexibility*** based on clinical needs

BD MAX System provides full automation with broad IVD and OSR molecular menu options enhancing ***efficiency*** **and** ***accuracy*** for laboratories.

Cadence of panel launches addresses customer enteric testing needs based on IDSA guidelines

- **BD MAX Enteric Bacterial Panel and Extended Enteric Bacterial Panel**
- **BD MAX Enteric Parasite Panel**
- **BD MAX Enteric Viral Panel***



* Product under development. Not available for sale.

Microscopy images (top to bottom) courtesy of CDC Public Health Image Library (http://phil.cdc.gov/phil/details.asp)

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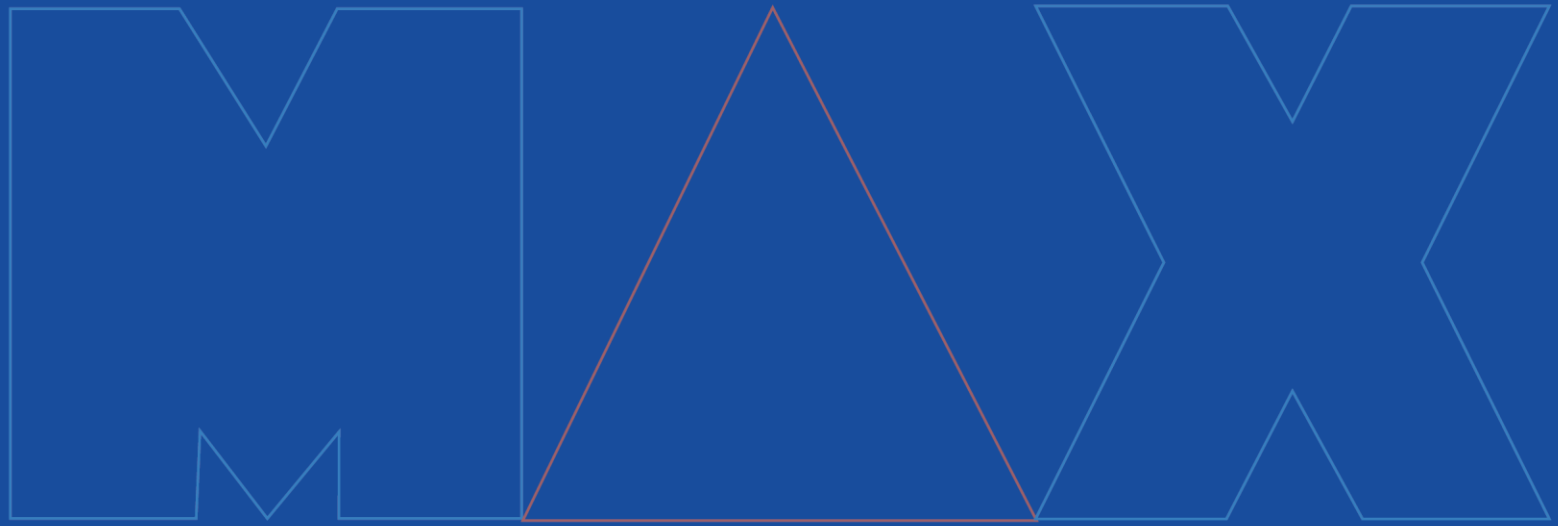

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