

BD MAX™ Enteric Bacterial Panel and Extended Enteric Bacterial Panel - Simplified Protocol



- For more detailed information see Instructions for Use: bd.com/e-labeling
- To access sample preparation video, please scan the QR code.

1. Reagent, Storage and Stability

Ref.	Name	Storage	Stability	Quantity
442963	BD MAX™ Enteric Bacterial Panel	2–25°C	Unopened reagents: up to expiration date. Opened reagent pouches: up to 31 days and re-sealing of the pouch.	24 tests: Sample Buffer Tubes, Septum caps, Strips, Extraction tubes and Master Mix tubes
443812	BD MAX™ Extended Enteric Bacterial Panel	2–25°C	Unopened reagents: up to expiration date. Opened reagent pouches: up to 31 days and re-sealing of the pouch.	24 tests: Master Mix tubes (only)
220258*	BD FecalSwab™	5–25 °C	Until expiration date.	Tube (filled with 2 mL of modified Cary-Blair medium), Specimen collection swab
437519	BD MAX™ PCR Cartridges	2–25°C	Until expiration date.	24 cartridges

*BD FecalSwab™ (220258) and Copan FecalSwab™ (4C024S) are validated to be used with BD MAX™ Enteric assays.

2. Specimen Stability

- Collected liquid or soft stool specimens, either unpreserved, preserved in Cary-Blair transport media or in FecalSwab™, should be kept between 2 °C and 25 °C during transport.
- Specimens can be stored for up to 120 hours (5 days) at 2–8 °C or for up to 24 hours at 2–25 °C before testing.

3. Sample Preparation

- Label a barcoded BD MAX™ Enteric Bacterial Sample Buffer Tube (clear cap) with the appropriate specimen identification. Do not obscure, write or label over the 2D-barcode.
- Vortex stool specimen at high speed for 15 seconds.
- Remove the clear cap from the Sample Buffer Tube and inoculate as follows:
 - Unpreserved or Cary-Blair preserved stool specimen:**
 - Insert a 10 µL disposable inoculation loop until the entire loop portion is submerged in the specimen. Do not insert beyond the loop as any additional stool on the shaft can overload the PCR reaction.
 - Insert the loaded loop into the Sample Buffer Tube and express the specimen using a swirling motion. Remove and discard the loop.
NOTE: It is not necessary to remove the entire specimen from the loop. The Sample Buffer Tube solution should be “tea-stained” in color.
 - FecalSwab™ stool specimen:**
 - Using a fixed volume pipette and long tips transfer **50 µL** volume into the Sample Buffer Tube.
NOTE: Use of long pipette tips is recommended to avoid sample contamination
- Recap the inoculated Sample Buffer Tube using a Septum Cap.
- Vortex all prepared Sample Buffer Tubes at maximum speed for one (1) minute.
- Proceed to the BD MAX™ Rack and BD MAX™ System Run section below.



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The BD MAX™ System, the BD MAX™ Enteric Bacterial Panel and Extended Enteric Bacterial Panel Assay are in vitro diagnostic medical devices, bearing a CE mark.

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4. BD MAX™ Rack and BD MAX™ System Run

- a. For each sample to be tested, place one Unitized Reagent Strip into the BD MAX™ Rack.
- b. Snap one Extraction Tube (white foil) into each Strip in Position 1.
- c. Snap one Master Mix Tube (green foil) into each Strip in Position 2.
- d. Strip Position 4:
 - i. Enteric Bacterial Panel: Leave unfilled.
 - ii. Extended Enteric Bacterial Panel: Snap in one Master Mix Tube (blue foil).
- e. Create the Worklist making sure to select the correct Test:
 - i. **< BD MAX ENT BAC 52 > OR**
 - ii. **< BD MAX EX ENT BAC 26 >**
- f. Place the prepared Sample Buffer Tube in the BD MAX™ Rack corresponding to the appropriate assembled Strip.
- g. Place the assembled BD MAX™ Rack(s) and required number of BD MAX™ PCR cartridge(s) into the instrument.
- h. Close BD MAX™ door and Start run.



5. Results and Repeats

- a. The BD MAX™ System software automatically interprets test results and reports results for each target individually.
 - i. A test result may be called NEG (negative), POS (positive) or UNR (unresolved) based on the amplification status of the target and of the Sample Processing Control.
 - ii. In the case of an IND, INC and complete UNR, where all targets have a UNR result, it is recommended to repeat the test.
 - iii. In the case of a partial UNR, when one or more targets have a POS result and all other targets have a UNR result, it is recommended to repeat the test.
- b. Prepared Sample Buffer Tubes can be stored at 2–8 °C for up to 120 hours (5 days) or at 25 ± 2 °C for a maximum of 48 hours. Sufficient volume is available for one repeat test.

	BD MAX ENT BAC 52 (green foil)	BD MAX EX ENT BAC 26 (blue foil)
Channel 475/520 LIS code	<i>Campylobacter jejuni</i> and <i>coli</i> Campy	<i>Yersinia enterocolitica</i> Yersi
Channel 530/565 LIS code	<i>Salmonella</i> sp. Salm	Enterotoxigenic <i>E. coli</i> ETEC
Channel 585/630 LIS code	<i>Shigella</i> sp. and EIEC Shig	<i>Vibrio</i> sp. Vibrio
Channel 630/665 LIS code	Shiga toxins; STEC and <i>S. dysenteriae</i> STX	<i>Plesiomonas shigelloides</i> Plesio
Channel 680/715	Sample Processing Control	Sample Processing Control

Time in minutes		Number of samples						
Assay	PCR time	24	20	16	12	8	4	
Enteric Bacterial	81	prep time	82	76	70	61	53	45
		time to results	163	157	151	141	133	125
Extended Enteric Bacterial	82	prep time	98	89	81	69	58	47
		time to results	180	172	163	150	139	128