



ePlex BCID-GP Negative

INTENDED USE:

The ePlex BCID-GP Negative is intended for use as an external negative quality control to monitor the performance of *in vitro* laboratory nucleic acid testing procedures for the qualitative detection of the gram-positive pathogens: *Bacillus cereus* group, *Bacillus subtilis* group, *Corynebacterium*, *Cutibacterium acnes* (*P.acnes*), *Enterococcus*, *Enterococcus faecalis*, *Enterococcus faecium*, *Lactobacillus*, *Listeria*, *Listeria monocytogenes*, *Micrococcus*, *Staphylococcus*, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Streptococcus*, *Streptococcus agalactiae*, *Streptococcus anginosus* group, *Streptococcus pneumoniae*, *Streptococcus pyogenes*; Pan targets: Pan *Candida* and Pan Gram-Negative; and resistance genes: *mecA*, *mecC*, *vanA* and *vanB* on the ePlex® Blood Culture Identification Gram-Positive (BCID-GP) Panel performed on the ePlex System (GenMark Diagnostics, Inc.).

PRODUCT SUMMARY and PRINCIPLE:

ePlex BCID-GP Negative contains no DNA.

Routine use of quality controls that are consistent lot to lot assists the laboratory in identifying shifts, trends, and increased frequency of random errors caused by variations in the test system, such as failing reagents. Early investigation can prevent failed assay runs.

COMPOSITION:

ePlex BCID-GP Negative is comprised of 6 tubes of negative control, 50µL each. Table 1 lists the pathogens and resistance genes that are monitored by the ePlex BCID-GP Negative when tested by the ePlex BCID-GP Panel on the ePlex System.

STORAGE and STABILITY:

ePlex BCID-GP Negative should be stored refrigerated at 2-8°C. Unopened ePlex BCID-GP Negative material is stable through the expiration date printed on the kit label when consistently stored refrigerated. ePlex BCID-GP Negative components are for single use. Discard after use according to your local and federal regulations.

PRECAUTIONS and WARNINGS:

- Use the control as provided. Do not dilute or transfer to another tube.
- This product is intended for *in vitro* analytical testing and is provided for Research Use Only, not for use in diagnostic procedures.
- ePlex BCID-GP Negative is only for use with ePlex BCID-GP Panel on the ePlex System.
- This product is not intended for use as a substitute for the internal controls provided in ePlex BCID-GP Panel.
- This product does not contain any biological material of human or animal origin. Universal Precautions are NOT required when handling this product.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- ePlex BCID-GP Negative cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

ORDERING INFORMATION:

ePlex BCID-GP Negative

Part Number: M50237-6

Kit Contains 6 tubes of Negative x 50µL

INSTRUCTIONS FOR USE:

1. Allow the control to be tested to come completely to room temperature (18° – 25°C).
2. Immediately before use thoroughly mix the control by flicking the tube several times, followed by vortexing for 5-10 seconds. Shake the tube down or tap it on bench to remove any droplets remaining in the cap.
3. Use a calibrated pipette to aspirate 50µL of control and transfer into the cartridge sample port chamber.
4. Continue to process and analyze the control with the ePlex BCID-GP Panel test on the ePlex System as you would a patient sample.
Note: Sample can be pre-defined as External Control to generate a BCID-GP External Control Report. Refer to ePlex Operator Manual for more information on defining external controls on ePlex System.
5. Discard control after use according to your local and federal regulations.

For complete ePlex BCID-GP Panel instructions, refer to the ePlex BCID-GP Panel package insert provided by GenMark Diagnostics, Inc.

EXPECTED VALUES:

Table 1. lists the expected results when the control is tested with ePlex BCID-GP Panel on the ePlex System.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for ePlex BCID-GP Negative in demonstrating adequate system performance.

Table 1. Expected Results: ePlex BCID-GP Negative

Control Name	ePlex BCID-GP Negative
Part Number	M50237
Gram-Positive Pathogen	Result
<i>Bacillus cereus</i> group	Not Detected
<i>Bacillus subtilis</i> group	Not Detected
<i>Corynebacterium</i>	Not Detected
<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	Not Detected
<i>Enterococcus</i>	Not Detected
<i>Enterococcus faecalis</i>	Not Detected
<i>Enterococcus faecium</i>	Not Detected
<i>Lactobacillus</i>	Not Detected
<i>Listeria</i>	Not Detected
<i>Listeria monocytogenes</i>	Not Detected
<i>Micrococcus</i>	Not Detected
<i>Staphylococcus</i>	Not Detected
<i>Staphylococcus aureus</i>	Not Detected
<i>Staphylococcus epidermidis</i>	Not Detected
<i>Staphylococcus lugdunensis</i>	Not Detected
<i>Streptococcus</i>	Not Detected
<i>Streptococcus agalactiae</i>	Not Detected
<i>Streptococcus anginosus</i> group	Not Detected
<i>Streptococcus pneumoniae</i>	Not Detected
<i>Streptococcus pyogenes</i>	Not Detected
Pan Targets	Result
Pan <i>Candida</i>	Not Detected
Pan Gram-Negative	Not Detected
Resistance Gene	Result
<i>mecA</i>	N/A
<i>mecC</i>	N/A
<i>vanA</i>	N/A
<i>vanB</i>	N/A

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