



eplex BCID-GN Negative

INTENDED USE:

The eplex BCID-GN 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 gram-negative pathogens: *Acinetobacter baumannii*, *Bacteroides fragilis*, *Citrobacter*, *Cronobacter sakazakii*, *Enterobacter* (non-cloacae complex), *Enterobacter cloacae* complex, *Escherichia coli*, *Fusobacterium necrophorum*, *Fusobacterium nucleatum*, *Haemophilus influenzae*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Morganella morganii*, *Neisseria meningitidis*, *Proteus*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Salmonella*, *Serratia*, *Serratia marcescens*, *Stenotrophomonas maltophilia*; Pan targets: Pan *Candida*, Pan Gram-Positive; and resistance genes: CTX-M, IMP, KPC, NDM, OXA and VIM on the cobas® eplex blood culture identification gram-negative (BCID-GN) panel performed on the cobas eplex system (Roche Diagnostics).

PRODUCT SUMMARY and PRINCIPLE:

eplex BCID-GN 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-GN 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-GN Negative when tested by the cobas eplex BCID-GN panel on the cobas eplex system.

STORAGE and STABILITY:

eplex BCID-GN Negative should be stored refrigerated at 2-8°C. Unopened eplex BCID-GN Negative material is stable through the expiration date printed on the kit label when consistently stored refrigerated. eplex BCID-GN 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-GN Negative is only for use with cobas eplex BCID-GN panel on the cobas eplex system.
- This product is not intended for use as a substitute for the internal controls provided in cobas eplex BCID-GN 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-GN Negative cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

ORDERING INFORMATION:

eplex BCID-GN Negative

Part Number: M50337-6

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 cobas eplex BCID-GN panel test on the cobas eplex system as you would a patient sample.
Note: Sample can be pre-defined as External Control to generate a BCID-GN External Control Report. Refer to cobas eplex Operator Manual for more information on defining external controls on cobas eplex system.
5. Discard control after use according to your local and federal regulations.

For complete cobas eplex BCID-GN panel instructions, refer to the cobas eplex BCID-GN panel package insert provided by Roche Diagnostics.

EXPECTED VALUES:

Table 1. lists the expected results when the control is tested with cobas eplex BCID-GN panel on the cobas eplex system.

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

Table 1. Expected Results: eplex BCID-GN Negative

Control Name	eplex BCID-GN Negative
Part Number	M50337
Gram-Negative Pathogen	Result
<i>Acinetobacter baumannii</i>	Not Detected
<i>Bacteroides fragilis</i>	Not Detected
<i>Citrobacter</i>	Not Detected
<i>Cronobacter sakazakii</i>	Not Detected
<i>Enterobacter</i> (non-cloacae complex)	Not Detected
<i>Enterobacter cloacae</i> complex	Not Detected
<i>Escherichia coli</i>	Not Detected
<i>Fusobacterium necrophorum</i>	Not Detected
<i>Fusobacterium nucleatum</i>	Not Detected
<i>Haemophilus influenzae</i>	Not Detected
<i>Klebsiella oxytoca</i>	Not Detected
<i>Klebsiella pneumoniae</i> group	Not Detected
<i>Morganella morganii</i>	Not Detected
<i>Neisseria meningitidis</i>	Not Detected
<i>Proteus</i>	Not Detected
<i>Proteus mirabilis</i>	Not Detected
<i>Pseudomonas aeruginosa</i>	Not Detected
<i>Salmonella</i>	Not Detected
<i>Serratia</i>	Not Detected
<i>Serratia marcescens</i>	Not Detected
<i>Stenotrophomonas maltophilia</i>	Not Detected
Pan Targets	Result
Pan <i>Candida</i>	Not Detected
Pan Gram-Positive	Not Detected
Resistance Gene	Result
CTX-M	N/A
IMP	N/A
KPC	N/A
NDM	N/A
OXA	N/A
VIM	N/A

Notice: COBAS and EPLEX are trademarks of Roche