



ePlex BCID-GN Control M326

INTENDED USE:

The ePlex BCID-GN Control M326 is intended for use as an external positive and negative assayed 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 ePlex® Blood Culture Identification Gram-Negative (BCID-GN) Panel performed on the ePlex System (GenMark Diagnostics, Inc.). The ePlex BCID-GN Control M326 is composed of synthetic DNA specifically designed for and intended to be used solely with the ePlex BCID-GN Panel assay. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

ePlex BCID-GN Control M326 is composed of 4 controls, ePlex BCID-GN Positive A, ePlex BCID-GN Positive B, ePlex BCID-GN Positive C and ePlex BCID-GN Negative. The ePlex BCID-GN Control M326 positive controls contain surrogate control material composed of synthetic DNA corresponding to genome segments of pathogens and resistance genes listed in Table 1. 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 Control M326 is comprised of 12 tubes, 3 tubes of each positive control, A, B and C, and 3 tubes of negative control, 50µL each. The ePlex BCID-GN Positive controls contain synthetic DNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Table 1 lists the pathogens and resistance genes that are monitored by the ePlex BCID-GN Control M326 when tested by the ePlex BCID-GN Panel on the ePlex System.

STORAGE and STABILITY:

ePlex BCID-GN Control M326 should be stored refrigerated at 2-8°C. Unopened ePlex BCID-GN Control M326 material is stable through the expiration date printed on the kit label when continuously stored refrigerated. ePlex BCID-GN Control M326 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 Control M326 is only for use with ePlex BCID-GN Panel on the ePlex System. It does not contain the entire genome of the pathogens listed in Table 1.
- This product is not intended for use as a substitute for the internal controls provided in 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.
- Due to the sensitivity of the ePlex BCID-GN Panel test, it is important when handling the ePlex BCID-GN Control M326 to adhere to all precautions to prevent contamination.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.
- ePlex BCID-GN Control M326 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

INSTRUCTIONS FOR USE:

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

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-GN 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-GN External Control Report. Refer to ePlex Operator Manual for more information on defining external controls on ePlex System.
5. Discard controls after use according to your local and federal regulations.

EXPECTED VALUES:

Table 1 lists the expected results when the controls are tested with ePlex BCID-GN Panel on the ePlex System.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for ePlex BCID-GN Control M326 in demonstrating adequate system performance.

Table 1. Expected Results: ePlex BCID-GN Control M326

Control Name	ePlex BCID-GN Positive A	ePlex BCID-GN Positive B	ePlex BCID-GN Positive C	ePlex BCID-GN Negative
Part Number	M32717	M32817	M32917	M50317
Gram-Negative Pathogen				
Result				
<i>Acinetobacter baumannii</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Bacteroides fragilis</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Citrobacter</i>	Not Detected	Not Detected	Detected	Not Detected
<i>Cronobacter sakazakii</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Enterobacter</i> (non-cloacae complex)	Detected	Not Detected	Not Detected	Not Detected
<i>Enterobacter cloacae</i> complex	Detected	Not Detected	Not Detected	Not Detected
<i>Escherichia coli</i>	Not Detected	Detected	Not Detected	Not Detected
<i>Fusobacterium necrophorum</i>	Not Detected	Detected	Not Detected	Not Detected
<i>Fusobacterium nucleatum</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Haemophilus influenzae</i>	Not Detected	Not Detected	Detected	Not Detected
<i>Klebsiella oxytoca</i>	Not Detected	Not Detected	Detected	Not Detected
<i>Klebsiella pneumoniae</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Morganella morganii</i>	Not Detected	Not Detected	Detected	Not Detected
<i>Neisseria meningitidis</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Proteus</i>	Not Detected	Detected	Detected	Not Detected
<i>Proteus mirabilis</i>	Not Detected	Not Detected	Detected	Not Detected
<i>Pseudomonas aeruginosa</i>	Not Detected	Detected	Not Detected	Not Detected
<i>Salmonella</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Serratia</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Serratia marcescens</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Stenotrophomonas maltophilia</i>	Not Detected	Not Detected	Detected	Not Detected
Pan Targets				
Result				
Pan <i>Candida</i>	Not Detected	Detected	Not Detected	Not Detected
Pan Gram-Positive	Not Detected	Detected	Not Detected	Not Detected
Resistance Gene				
Result				
CTX-M	Not Detected	Detected	Not Detected	Not Detected
IMP	Not Detected	Not Detected	Detected	Not Detected
KPC	Not Detected	Not Detected	Detected	Not Detected
NDM	Not Detected	Not Detected	Detected	Not Detected
OXA	Detected	Not Detected	Not Detected	Not Detected
VIM	Detected	Not Detected	Not Detected	Not Detected

Notice: ePlex is a registered trademark of GenMark Diagnostics, Inc.

ORDERING INFORMATION:

ePlex BCID-GN Control M326
Part Number: M326
 Kit Contains 12 tubes x 50µL
 3 each Positive A, Positive B, Positive C & Negative