

eplex BCID-GP Control M323v1.1

INTENDED USE:

The eplex BCID-GP Control M323v1.1 is intended for use as an external positive and 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 cobas® eplex blood culture identification gram-positive (BCID-GP) panel performed on the cobas eplex system (Roche Diagnostics). The eplex BCID-GP Control M323v1.1 is composed of synthetic DNA specifically designed for and intended to be used solely with the cobas eplex BCID-GP panel assay. This product is not intended to replace manufacturer controls provided with the device.

PRODUCT SUMMARY and PRINCIPLE:

eplex BCID-GP Control M323v1.1 is composed of 4 controls, eplex BCID-GP Positive A, eplex BCID-GP Positive B1, eplex BCID-GP Positive C, and eplex BCID-GP Negative. The eplex BCID-GP Control M323v1.1 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-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 Control M323v1.1 is comprised of 12 tubes, 3 tubes of each positive control, A, B1, and C, and 3 tubes of negative control, 50µL each. The eplex BCID-GP 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-GP Control M323v1.1 when tested by the cobas eplex BCID-GP panel on the cobas eplex system.

STORAGE and STABILITY:

eplex BCID-GP Control M323v1.1 should be stored refrigerated at 2-8°C. Unopened eplex BCID-GP Control M323v1.1 material is stable through the expiration date printed on the kit label when continuously stored refrigerated. eplex BCID-GP Control M323v1.1 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 Control M323v1.1 is only for use with cobas eplex BCID-GP panel on the cobas 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 cobas 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.
- eplex BCID-GP Control M323v1.1 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.
- Quality control materials should be used in accordance with local, state, federal regulations and accreditation requirements.

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-GP 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-GP External Control Report. Refer to cobas eplex Operator Manual for more information on defining external controls on cobas eplex system.
5. Discard controls after use according to your local and federal regulations.

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

EXPECTED VALUES:

Table 1. lists the expected results when the controls are tested with cobas eplex BCID-GP panel on the cobas eplex system.

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for eplex BCID-GP Control M323v1.1 in demonstrating adequate system performance.

Table 1. Expected Results: eplex BCID-GP Control M323v1.1

Control Name	eplex BCID-GP Positive A	eplex BCID-GP Positive B1	eplex BCID-GP Positive C	eplex BCID-GP Negative
Part Number	M32437	M33737	M33837	M50237
Gram-Positive Pathogen	Result			
<i>Bacillus cereus</i> group	Detected	Not Detected	Not Detected	Not Detected
<i>Bacillus subtilis</i> group	Detected	Not Detected	Not Detected	Not Detected
<i>Corynebacterium</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Cutibacterium acnes</i> (<i>P. acnes</i>)	Not Detected	Detected	Not Detected	Not Detected
<i>Enterococcus</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Enterococcus faecalis</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Enterococcus faecium</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Lactobacillus</i>	Not Detected	Detected	Not Detected	Not Detected
<i>Listeria</i>	Not Detected	Detected	Detected	Not Detected
<i>Listeria monocytogenes</i>	Not Detected	Not Detected	Detected	Not Detected
<i>Micrococcus</i>	Not Detected	Not Detected	Detected	Not Detected
<i>Staphylococcus</i>	Not Detected	Detected	Detected	Not Detected
<i>Staphylococcus aureus</i>	Not Detected	Detected	Not Detected	Not Detected
<i>Staphylococcus epidermidis</i>	Not Detected	Not Detected	Detected	Not Detected
<i>Staphylococcus lugdunensis</i>	Not Detected	Not Detected	Detected	Not Detected
<i>Streptococcus</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Streptococcus agalactiae</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Streptococcus anginosus</i> group	Detected	Not Detected	Not Detected	Not Detected
<i>Streptococcus pneumoniae</i>	Detected	Not Detected	Not Detected	Not Detected
<i>Streptococcus pyogenes</i>	Detected	Not Detected	Not Detected	Not Detected
Pan Targets	Result			
Pan <i>Candida</i>	Not Detected	Detected	Not Detected	Not Detected
Pan Gram-Negative	Not Detected	Not Detected	Detected	Not Detected
Resistance Gene	Result			
<i>mecA</i>	N/A	Not Detected	Detected	N/A
<i>mecC</i>	N/A	Detected	Not Detected	N/A
<i>vanA</i>	Detected	N/A	N/A	N/A
<i>vanB</i>	Detected	N/A	N/A	N/A

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ORDERING INFORMATION:

eplex BCID-GP Control M323v1.1

Part Number: M323v1.1

Kit Contains 12 tubes x 50µL

3 each Positive A, Positive B1, Positive C & Negative