Research Use Only

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eplex BCID-FP Control M320v1.1

INTENDED USE:

The eplex BCID-FP Control M320v1.1 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 *Candida albicans*, *Candida auris*, *Candida dubliniensis*, *Candida famata*, *Candida glabrata*, *Candida guilliermondii*, *Candida kefyr*, *Candida krusei*, *Candida lusitaniae*, *Candida parapsilosis*, *Candida tropicalis*, *Cryptococcus gattii*, *Cryptococcus neoformans*, *Fusarium*, and *Rhodotorula* on the cobas® eplex blood culture identification fungal pathogen (BCID-FP) panel performed on the cobas eplex system (Roche Diagnostics). The eplex BCID-FP Control M320v1.1 is composed of synthetic DNA specifically designed for and intended to be used solely with the cobas eplex BCID-FP panel assay.

PRODUCT SUMMARY and PRINCIPLE:

eplex BCID-FP Control M320v1.1 is composed of 3 controls, eplex BCID-FP Positive A1, eplex BCID-FP Positive B1, and eplex BCID-FP Negative. The eplex BCID-FP Control M320v1.1 positive controls contain surrogate control material composed of synthetic DNA corresponding to genome segments of pathogens listed in Table 1. eplex BCID-FP 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-FP Control M320v1.1 is comprised of 12 tubes, 4 tubes of each positive control, A1 and B1, and 4 tubes of negative control, 50µL each. The eplex BCID-FP Positive controls contain synthetic DNA suspended in a non-infectious solution of buffers, preservatives and stabilizers. Table 1 lists the fungal pathogens that are monitored by the eplex BCID-FP Control M320v1.1 when tested by the cobas eplex BCID-FP panel on the cobas eplex system.

STORAGE and STABILITY:

eplex BCID-FP Control M320v1.1 should be stored refrigerated at 2-8°C. Unopened eplex BCID-FP Control M320v1.1 material is stable through the expiration date printed on the kit label when consistently stored refrigerated. eplex BCID-FP Control M320v1.1 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-FP Control M320v1.1 is only for use with cobas eplex BCID-FP panel on the cobas eplex system. It does not contain the entire genome of the fungal pathogens listed in Table 1.
- This product is not intended for use as a substitute for the internal controls provided in the cobas eplex BCID-FP 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-FP Control M320v1.1 cannot be cloned, sold, or transferred without the explicit written consent of MMQCI.

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

EXPECTED VALUES:

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

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for eplex BCID-FP Control M320v1.1 in demonstrating adequate system performance.

Table 1. Expected Results: eplex BCID-FP Control M320v1.1

Control Name	eplex BCID-FP Positive A1	eplex BCID-FP Positive B1	eplex BCID-FP Negative
Fungal Pathogen	**Result**		
Candida albicans	**Detected**	Not Detected	Not Detected
Candida auris	Not Detected	**Detected**	Not Detected
Candida dubliniensis	**Detected**	Not Detected	Not Detected
Candida famata	**Detected**	Not Detected	Not Detected
Candida glabrata	**Detected**	Not Detected	Not Detected
Candida guilliermondii	Not Detected	**Detected**	Not Detected
Candida kefyr	**Detected**	Not Detected	Not Detected
Candida krusei	Not Detected	**Detected**	Not Detected
Candida lusitaniae	Not Detected	**Detected**	Not Detected
Candida parapsilosis	Not Detected	**Detected**	Not Detected
Candida tropicalis	Not Detected	**Detected**	Not Detected
Cryptococcus gattii	**Detected**	Not Detected	Not Detected
Cryptococcus neoformans	Not Detected	**Detected**	Not Detected
Fusarium	Not Detected	**Detected**	Not Detected
Rhodotorula	**Detected**	Not Detected	Not Detected

ORDERING INFORMATION:

eplex BCID-FP Control M320v1.1
Part Number: **M320v1.1**
Kit Contains: 12 tubes x 50µL
4 each Positive A1, Positive B1 & Negative