



ePlex BCID-FP Control M320 v1.1

INTENDED USE:

The ePlex BCID-FP Control M320 v1.1 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 lusitanae*, *Candida parapsilosis*, *Candida tropicalis*, *Cryptococcus gattii*, *Cryptococcus neoformans*, *Fusarium*, and *Rhodotorula* on the ePlex® Blood Culture Identification Fungal Pathogen (BCID-FP) Panel performed on the ePlex System (GenMark Diagnostics, Inc.). The ePlex BCID-FP Control M320 v1.1 is composed of synthetic DNA specifically designed for and intended to be used solely with the ePlex BCID-FP Panel assay.

PRODUCT SUMMARY and PRINCIPLE:

ePlex BCID-FP Control M320 v1.1 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 M320 v1.1 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 M320 v1.1 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 M320 v1.1 when tested by the ePlex BCID-FP Panel on the ePlex System.

STORAGE and STABILITY:

ePlex BCID-FP Control M320 v1.1 should be stored refrigerated at 2-8°C. Unopened ePlex BCID-FP Control M320 v1.1 material is stable through the expiration date printed on the kit label when consistently stored refrigerated. ePlex BCID-FP Control M320 v1.1 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 M320 v1.1 is only for use with ePlex BCID-FP Panel on the 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 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 M320 v1.1 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 ePlex BCID-FP 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-FP 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.

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

EXPECTED VALUES:

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

The laboratory should follow Good Laboratory Practice (GLP) and establish its own performance characteristics for ePlex BCID-FP Control M320 v1.1 in demonstrating adequate system performance.

Table 1. Expected Results: ePlex BCID-FP Control M320 v1.1

Control Name	ePlex BCID-FP Positive A1	ePlex BCID-FP Positive B1	ePlex BCID-FP Negative
Fungal Pathogen	Result		
<i>Candida albicans</i>	Detected	Not Detected	Not Detected
<i>Candida auris</i>	Not Detected	Detected	Not Detected
<i>Candida dubliniensis</i>	Detected	Not Detected	Not Detected
<i>Candida famata</i>	Detected	Not Detected	Not Detected
<i>Candida glabrata</i>	Detected	Not Detected	Not Detected
<i>Candida guilliermondii</i>	Not Detected	Detected	Not Detected
<i>Candida kefyr</i>	Detected	Not Detected	Not Detected
<i>Candida krusei</i>	Not Detected	Detected	Not Detected
<i>Candida lusitanae</i>	Not Detected	Detected	Not Detected
<i>Candida parapsilosis</i>	Not Detected	Detected	Not Detected
<i>Candida tropicalis</i>	Not Detected	Detected	Not Detected
<i>Cryptococcus gattii</i>	Detected	Not Detected	Not Detected
<i>Cryptococcus neoformans</i>	Not Detected	Detected	Not Detected
<i>Fusarium</i>	Not Detected	Detected	Not Detected
<i>Rhodotorula</i>	Detected	Not Detected	Not Detected

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

ORDERING INFORMATION:

ePlex BCID-FP Control M320 v1.1

Part Number: M320v1.1

Kit Contains: 12 tubes x 50µL

4 each Positive A1, Positive B1 & Negative