AffiCHECK® Clostridium difficile DNA PCR Qualitative Positive Control

AFG-CHK-0466

PRODUCT DESCRIPTION:

AffiCHECK® Clostridium difficile DNA - PCR Qualitative Control is a high-quality, reliable standard containing known quantities of Clostridium difficile DNA. It's designed using modified and non-infectious bacteria to ensure stability, thereby contributing to accurate and reliable results in PCR applications.

INTENDED USE:

AffiCHECK® *Clostridium difficile* **DNA - PCR Qualitative Control** serves as a comprehensive process control for the evaluation of the performance of nucleic acid tests for determination of the presence of *Clostridium difficile* nucleic acid. It's essential in validating the performance of PCR assays in clinical, research, and diagnostic settings.

PRODUCT FEATURES:

Specificity: Tailored for Clostridium difficile DNA detection.

<u>Formulation:</u> Lyophilized for enhanced stability. Convenience: Ready-to-use upon reconstitution.

Compatibility: Suitable for a wide range of PCR assays.

CHARACTERISTICS:

<u>Cultivation & Extraction:</u> Cultivated in cycloserine-cefoxitin fructose agar (CCFA) and extracted using a reliable genomic DNA method.

Quality Control: Subjected to rigorous testing to ensure batch consistency and reliability.

<u>Packaging</u>: Provided in a protective, heat-sealed foil pouch with silica gel.

PERFORMANCE CHARACTERISTICS:

<u>Sensitivity:</u> Optimized for high sensitivity in PCR detection. <u>Specificity:</u> Exclusively detects *Clostridium difficile* DNA.

Reproducibility: Consistent results across different test runs and batches.

PACK CONTENT:		
Components	Pack Size	Note
DNA Control Lyophilized (1x10 ⁴ to 2x10 ⁴ Copies/μL)	1 Vial	Quantified by Real-Time PCR.
Buffer	500 μL	Water, DNase, RNase Free.

PRECAUTIONS:

- For research use or diagnostic control purposes only.
- Follow standard laboratory practices and use PPE.
- Use <u>Sterile Filter Tips</u> to prevent contamination.
- Handle infectious specimens with precautions.
- Disinfect work surfaces.
- Maintain separate working areas for testing.
- Dispose of unused reagents and waste as per regulations.
- May contain genetic material, handle with care.
- No method ensures total absence of infectious agents.
- Follow local waste disposal rules.
- Dilute below 10³ copies/µL immediately before use.
- Avoid freezing for low-copy dilutions to prevent DNA degradation.

INSTRUCTIONS FOR USE:

- Open the foil pouch of AffiCHECK® Clostridium difficile DNA.
- Centrifuge AffiCHECK® Clostridium difficile DNA Lyophilized Powder at 1000 g for 1 minute.
- Add 100 µL of the Buffer and thoroughly mix until fully reconstituted.
- The concentration will be $1x10^4$ to $2x10^4$ Copies/ μ L once reconstituted.
- Vortex for 1 min for complete dissolution and homogenization.

RECOMMENDED STORAGE:

- Before Reconstitution: Store at 2-8°C.
- After Reconstitution: Store at -20°C.
- Shipping: No special instructions
- Shelf Life: 12 months from production date.

ORDERING INFORMATION: Catalog Number Description Size AFG-CHK-0466 AffiCHECK® Clostridium difficile DNA PCR Qualitative Positive Control