AffiCHECK® Mycobacterium tuberculosis DNA **PCR Qualitative Positive Control**

AFG-CHK-0528

PRODUCT DESCRIPTION:

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

INTENDED USE:

AffiCHECK® Mycobacterium tuberculosis 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 Mycobacterium tuberculosis nucleic acid. It's essential in validating the performance of PCR assays in clinical, research, and diagnostic settings.

PRODUCT FEATURES:

Specificity: Tailored for Mycobacterium tuberculosis DNA detection.

Formulation: Lyophilized for enhanced stability. Convenience: Ready-to-use upon reconstitution.

Compatibility: Suitable for a wide range of PCR assays.

CHARACTERISTICS:

Cultivation & Extraction: Cultivated in Löwenstein-Jensen (LJ) medium and extracted using a reliable genomic DNA method.

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

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

PERFORMANCE CHARACTERISTICS:

Sensitivity: Optimized for high sensitivity in PCR detection.

Specificity: Exclusively detects Mycobacterium tuberculosis 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® Mycobacterium tuberculosis DNA.
- Centrifuge AffiCHECK® Mycobacterium tuberculosis 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-0528	AffiCHECK® Mycobacterium tuberculosis DNA PCR Qualitative Positive Control	1 vial + 500 μL Buffer	