



Certificate of Conformance

Item Description: CAP STRIP-8, DOMED 130 STRIPS

Catalog Number: TCS0801

Control Number: 122021

MFG Date: 2021-12-20

Expiration Date : Not applicable

This is a Certificate of Conformance for CAP STRIP-8, DOMED 130 STRIPS.

This above product was built, tested and meets all specifications per Bio-Rad Laboratories' specification TCS0801.

The molding process of the product is routinely process-sampled and has tested negative for DNase, Rnase, and human DNA (see Appendix for testing procedures).

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World Wide Manufacturing (WWM)

2024-11-04
Date

Appendix:

1) RNase Test: Test articles are extracted in RNase-free water. The extract is added to an RNA standard, and incubated alongside controls at 37°C for 1 hour. The RNA samples are then run on an agarose gel, photographed, and evaluated. For test articles to pass certification, the bands from the test samples must correspond to the negative control. The negative control must show no evidence of degradation (smearing). The positive control must show degradation for the test to be valid.
Test sensitivity: 10^{-9} Kunitz Units/ μ l

- ✓ Positive control shows degradation.
- ✓ Negative control shows no degradation.
- ✓ Test sample corresponds to the negative control.

2) DNase Test: Test articles are extracted in DNase-free water. The extract is added to a DNA standard, and incubated alongside controls at 37°C for 1 hour. The DNA samples are then run on an agarose gel, photographed, and evaluated. For test articles to pass certification, the bands from the test samples must correspond to the negative control. The negative control must show no evidence of degradation. The positive control must show degradation for the test to be valid.
Test sensitivity: 10^{-7} Kunitz Units/ μ l

- ✓ Positive control shows degradation.
- ✓ Negative control shows no degradation.
- ✓ Test sample corresponds to the negative control.

3) Human/Mouse DNA and PCR Inhibitor Test: Test articles incubated with a reaction mix containing primers specific for human and mouse DNA (in separate vessels). The samples are then subjected to thermal cycling alongside controls. The samples are then run on an agarose gel, photographed, and evaluated. For test articles to pass certification, the bands from the test samples must correspond to the negative control. The negative control must show no detectable product. The positive control must show bands of product.
Test sensitivity: 30pg genomic DNA

- ✓ Positive control shows bands of product.
- ✓ Negative control shows no detectable product.
- ✓ Test sample corresponds to the negative control.