

CERTIFICATE OF ASSURANCE



This certificate is your assurance that samples of
TipOne®, TipOne® Repeat, TubeOne® and PlateOne®
products are manufactured in a regularly controlled environment
certified free of RNase, DNase, human DNA and Pyrogens.

Limits of detection:

RNase	< 1 x 10 ⁻⁹ Kunitz Units
DNase	< 1 x 10 ⁻⁶ Kunitz Units
Human DNA	< 2 x 10 ⁻⁹ mg
Endotoxins	< 0.05 EU/ml

Sterile products have been sterilised by e-beam irradiation in accordance with
DIN EN ISO 11137-2:2007 with min. dose 15kGy (1.5 Mrads).

Sterility: SAL 10⁻⁶.

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Certificate of Assurance

STARLAB certifies that the following product is produced in a fully controlled environment that is designed to be free from detectable RNase, DNase, DNA, and Endotoxins.

Selected samples of product from this production line have been thoroughly tested by a pre-radiation bioburden-test for the absence of bacterial organisms and any detectable RNase, DNase, and DNA contamination. The samples are also tested by the Kinetic-turbidimetric LAL test for Endotoxins to be certified non-pyrogenic.

Product Number	S1605-XXXX, S1615-XXXX, S1620-XXXX	Lot Number
Product Description	TubeOne Steril	Date

RNase

testing method: Bioburden test / Pre-radiation bioburden test
limits: $< 1 \times 10^3$ Kunitz Units

DNase

testing method: Bioburden test / Pre-radiation bioburden test
limits: $< 1 \times 10^{-6}$ Kunitz Units

Human DNA

testing method: Bioburden test / Pre-radiation bioburden test
limits: $< 2 \times 10^{-9}$ mg

Endotoxin

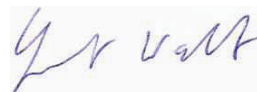
testing method: Kinetic-turbidimetric LAL-test (FDA Guidelines)
limits: < 0.05 EU/ml

e-beam irradiation min. dose 15kGy (1.5 Mrads)

Sterility SAL 10^{-6}

The concentration levels for RNase, DNase, DNA and Endotoxins are less than the above stated limits.

Certified by:



Dr. Lennart Walter
Product Manager