

CERTIFICAT D'ASSURANCE



Ce certificat est votre assurance que les produits
TipOne®, TipOne® Repeat, TubeOne® and PlateOne®
sont fabriqués dans un environnement régulièrement contrôlé
certifié sans RNase, DNase, ADN humain ni agents Pyrogènes.

Seuils de détection:

RNase	$< 1 \times 10^{-9}$ unités Kunitz
DNase	$< 1 \times 10^{-6}$ unités Kunitz
ADN Humain	$< 2 \times 10^{-9}$ mg
Endotoxines	< 0.05 EU/ml

Les produits stériles ont été stérilisés par rayonnement à faisceau d'électrons selon les
normes DIN EN ISO 11137-2:2007 avec une dose minimum de 15kGy (1.5 Mrads).

Stérilité : NAS 10^{-6} .

www.starlabgroup.com



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	S111X-XXXX, S112X-XXXX, S116X-XXXX, S118X-XXXX	Lot Number
Product Description	TipOne Tips 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

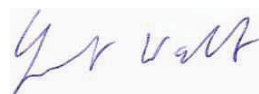
testing method: Kinetic-turbidimetric LAL-test (FDA Guidelines)
limits: < 0.05 EU/ml

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