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 x 10^{-9} unités Kunitz
DNase	< 1 x 10^{-6} unités Kunitz
ADN Humain	< 2 x 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 de15kGy (1.5 Mrads).
Stérilité : NAS 10^{-6}.

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STARLAB

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 throroughly 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 x 10 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

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

Certified by:

Dr. Lennart Walter
Product Manager

ISO 9001 & 13485 REGISTERED FIRM

STARLAB INTERNATIONAL GMBH
Neuer Höltigbaum 38
22143 Hamburg · Deutschland
www.starlabgroup.com

Tel. +49 (0) 40 / 675 99 39 0
Fax +49 (0) 40 / 675 99 39 20
E-Mail info@starlab.de

Geschäftsführer: Jörn Peplow
Amtsgericht:Hamburg HRB 122020
Ust.-Id.-Nr.: DE 214 891 717

Deutsche Bank, Hamburg
Konto-Nr. 0 205 260 00 · BLZ 200 700 00
BIC (Swift-Code): DEUTDEHH
IBAN: DE26 2007 0000 0020 5260 00

Certificat embouts pour pipettes TipOne®

Date d'émission : le 25 Février 2013

Les embouts pour pipette TipOne® sont fabriqués en Polypropylène vierge de la plus grande pureté et de la meilleure qualité et sans trace de métaux. Nos fournisseurs de Polypropylène n'utilisent et n'incorporent intentionnellement aucun agent de démoulage ni aucun agents antistatiques ou plastifiants (Phtalates). Au cours de la fabrication, aucune substance additionnelle tels que agents de démoulage ou agents antistatiques ne sont utilisés.

Dr. Lennart Walter
Product Manager

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Certificat d'Assurance

Date d'émission : 22 mai 2017

Produits sans substance d'origine animale

STARLAB confirme par la présente qu'aucune matière première d'origine animale n'est utilisée dans la fabrication des pointes TipOne® (seringues de distribution TipOne® Repeat inclues)

Certified by:

Dr. Lennart Walter
Senior Product Manager

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TYPICAL VALUES FOR TRACE METAL OF TIPONE® NATURAL POLYPROPYLENE PIPETTE TIPS

The values in the table indicate typical values of trace metal concentrations which are obtained after incubating TipOne® tips with concentrated nitric acid for 1 hour.
As the indicated values were determined in a one-time measurement, they cannot be guaranteed for every lot of TipOne® tips. Rather, they give the customer an idea to what extent elements can be eluted from TipOne® pipette tips.

	Trace Metal Release (ng/µl)								
Pipette Tip	Al	Cd	Cr	Cu	Hg	Mn	Ni	Pb	Zn
10 µl	0.006 ± 0.002	<0.00002	0.0003 ±0.0001	0.0003 ±0.0001	<0.001	<0.00005	0.0006 ±0.0001	<0.00005	0.001 ±0.001
10 µl XL	0.005	<0.00002	<0.00025	<0.00025	<0.001	<0.00005	<0.0005	<0.00005	<0.001
200 µl	0.002	<0.00002	<0.0001	<0.0001	<0.001	<0.00005	<0.0002	<0.00005	<0.001
300 µl	0.002	<0.00002	<0.0001	<0.0001	<0.001	<0.00005	<0.0017	<0.00005	<0.001
1000 µl	0.002 ± 0.001	<0.00002	<0.00005	<0.0001	<0.001	<0.00005	<0.0005	<0.00005	<0.001
1250 µl	0.002	<0.00002	<0.00005	<0.0001	<0.001	<0.00005	<0.0005	<0.00005	<0.001

Materials and Methods

The 0.1-10µl and 101-1000µl TipOne tips were filled with their nominal volume with concentrated nitric acid (65%) and incubated for 1 hour at room temperature (20°C). The dispensed nitric acid was analyzed by inductively coupled plasma – mass spectrometry (ICP-MS). The trace metal concentrations are expressed in ng/µl. The values are the average of three samples individually analyzed. The trace metal release of the remaining TipOne® tips was calculated from their surface/volume ratio. All values labeled "<" indicate concentrations below the detection limit of the ICP-MS method. No metal release was observed after 5-10 rinsings with concentrated nitric acid of after rinsing with 10% acetic acid or water. (All analyses were performed by GALAB Laboratories, Geesthacht, Germany accredited to DIN ISO/EC 17025).

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