Certificate

CryoBank™ & Bank-It™

This certificate is your guarantee that representative samples of this product have been validated according to the following tests.

Non-toxic: Based on Elution Test of raw material according to USP.

USP VI: The material has successfully passed the USP biological reactivity class VI-50ºC test (7 days implant).

Leak-test: The product has been tested according to the Title 49 Code of Federal Regulations (CFR); Parts 100-199 (10/1/2002); 173.196 Infectious Substances Paragraph (a)(6-7), at an internal pressure producing a pressure differential of not less than 95 kPa (0,95 bar, 14psi), conditioning -40ºC to +55ºC and according to IATA International Air Transport Association; Dangerous Goods regulations, 44th Edition, 2003, packing instruction 602 and 650.

***Sterility:** Sterility is obtained through irradiation according to ISO 11137 (sterilization of health care products - requirements for validation and routine control - radiation sterilization) with SAL 10^{-6}. Closed systems are based on fluid path method.

DNase/RNase: The Product is certified free of DNase and RNase contamination.

***Non-pyrogenic:** Tested according to the principles of the LAL-test described in the FDA guidelines. Certified non-pyrogenic, as stated in the USP, as to the following points:

- For medical devices the requirement is that the documented endotoxin level must be less than 20 Endotoxin units/device (0.5 Endotoxin units/ml).
- For "water for pharmaceutical purpose" the requirement is that the documented endotoxin level must be less than 0.25 Endotoxin units/ml (10 Endotoxin units/device).

Red colour of this dot indicates exposure to irradiation.

For information on tests used please refer to **www.nuncbrand.com**

*Sterility and non-pyrogenic guarantee are only valid for CryoBank™

The Management System of Nunc A/S, Roskilde, Denmark, has been approved by Lloyd's Register Quality Assurance Limited to the Quality Management System Standard ISO 9001:2000, ISO 13485:2003 and Environmental Management System IS0 14001:1996

CE marked according to EU directive, 98/79/EC for IVD Medical devices.

LOT

Labo Baza
nowoczesne wyposażenie laboratorium
ul. Topolowa 5
62-002 Jelonek k/Poznania
tel.: 061 812 57 45
fax: 061 812 57 25
e-mail: biuro@labobaza.pl
www.labobaza.pl

Representative samples produced by Nunc A/S have passed the tests in our Quality Control Department with satisfactory result.

In case of complaint, please fill in the form below and return it to your supplier.

Name: _____

Company: _____

Address: _____

Nunc distributor: _____

Date: _____ Signature: _____

Cause for the complaint:

Defective product enclosed: ☐ Yes ☐ No

Nunc A/S · Kamstrupvej 90 · P.O. Box 280
DK-4000 Roskilde · Denmark
Tel +45 4631 2000 · Fax +45 4631 2175
E-mail: infociety@nunc.dk

www.nuncbrand.com

Nunc No. 74091/ver. 1.0 - YNI 08.2005