

DNase FREE CERTIFICATE OF ANALYSIS

10/4/2011

This certifies that the following samples obtained from **Biosigma Srl** 9/22/2011 are free of any detectable DNase contamination.

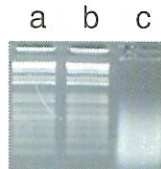
Lots tested:

Product:	Product code:	Lot #:
PRODUCTS FOR CRYOGENIE	CL1ARBEPS	11P1060300
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049002
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049003
PRODUCTS FOR CRYOGENIE	CL3ARBEPS	11P1060400

Products were tested for DNase activity by the following protocol:

Products were extracted in DNase free water. The extract was then added to a DNA standard. The DNA standard was incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. DNA samples were then run on an agarose gel, photographed, and evaluated for degradation.

FIGURE 1.



Lane (a) **Product Samples** b) unexposed DNA standard as a negative control, (c) DNA standard exposed to DNase as a positive control.

Conclusions:

No visible degradation is present in the product samples. Therefore, the products can be considered DNase free.



Certified by Laura Pittington, 10/4/2011



Q.A. Nik von Atzigen, 10/4/2011

RNase FREE CERTIFICATE OF ANALYSIS

10/4/2011

This certifies that the following samples obtained from **Biosigma Srl** on 9/22/2011 are free of any detectable RNase contamination.

Lots tested:

Product:	Product code:	Lot #:
PRODUCTS FOR CRYOGENIE	CL1ARBEPS	11P1060300
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049002
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049003
PRODUCTS FOR CRYOGENIE	CL3ARBEPS	11P1060400

Products were tested for RNase activity by the following protocol:

Products were extracted in RNase free water. The extract was then added to an RNA standard. The RNA standard was incubated at 37° C for 1 hour then heated to 65° C for 5 minutes. RNA samples were then run on an agarose gel, photographed, and evaluated for degradation.

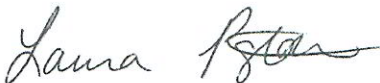
FIGURE 1.



Lane (a) **Product Samples**, (b) unexposed RNA standard as a negative control, (c) RNA standard exposed to RNase as a positive control.

Conclusions:

No visible degradation is present in the product samples. Therefore, the products can be considered RNase free.



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**PCR CERTIFIED (HUMAN)
CERTIFICATE OF ANALYSIS**

10/4/2011

This certifies that the following samples obtained from **Biosigma Srl** on 9/22/2011 are free of detectable human genomic DNA contamination, and will not inhibit PCR reactions.

Lots tested:

Product:	Product code:	Lot #:
PRODUCTS FOR CRYOGENIE	CL1ARBEPS	11P1060300
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049002
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049003
PRODUCTS FOR CRYOGENIE	CL3ARBEPS	11P1060400

GEL PHOTOS:



Lane (a) negative control, lane (b) negative control, lane (c) positive control 1 pg Human DNA, lane (d) positive control 1 pg human DNA, lane (e) DNA contamination test of the products listed above, lane (f) DNA contamination test of the products listed above, lane (g) product PCR inhibition test, lane (h) product PCR inhibition test.

PCR certified
 Free of detectable Human DNA

No PCR inhibition

Laura Pittington

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ATP FREE CERTIFICATE OF ANALYSIS

10/4/2011

The following samples obtained from **Biosigma Srl** on **9/22/2011** are free of any detectable ATP contamination.

PRODUCT	PRODUCT CODE	LOT NUMBER	ATP-free
PRODUCTS FOR CRYOGENIE	CL1ARBEPS	11P1060300	X
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049002	X
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049003	X
PRODUCTS FOR CRYOGENIE	CL3ARBEPS	11P1060400	X

The products were tested for ATP activity using the following protocol:

The products were extracted in Swab Buffer/Negative Control. ATP assay reagents were added to the extract, then the extract was placed in a luminometer and an RLU reading was obtained.

Conclusions:

The product RLU reading was found to be below the baseline cut-off value. Therefore, the products can be considered ATP free.



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ENDOTOXIN-FREE CERTIFICATE OF ANALYSIS

10/4/2011

This certifies that the following sample obtained from **Biosigma Srl** on 9/22/2011 is Endotoxin-Free. Endotoxin levels are < 0.06 EU/ml.

Lots tested:

Product:	Product code:	Lot #'s:
PRODUCTS FOR CRYOGENIE	CL1ARBEPS	11P1060300
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049002
PRODUCTS FOR CRYOGENIE	CL2ARBEPS	11P1049003
PRODUCTS FOR CRYOGENIE	CL3ARBEPS	11P1060400

Product was tested for Endotoxins by the Limulus Amebocyte Lysate (LAL) Gel Clot Assay.

Procedure:

A representative sampling of the product was extracted according to current USP and AAMI guidelines in endotoxin-free water and the extract solution was then assayed along with positive and negative controls. The sensitivity of the LAL Gel Clot Assay was 0.06 EU/ml.

Results:

Endotoxin levels < 0.06 EU/ml.

Comments:

Current USP guidelines set endotoxin limits for medical devices at 0.5 EU/ml (20 EU per device), and 0.06 EU/ml (2.15 EU per device) for devices that contact cerebral spinal fluid. We test products according to the USP guidelines for medical devices that contact cerebral spinal fluid.



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