

DNase FREE CERTIFICATE OF ANALYSIS

7/27/2011

This certifies that the following sample obtained from **Biosigma Srl** 7/21/2011 is free of any detectable DNase contamination.

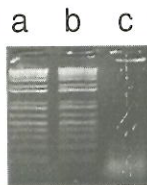
Lots tested:

Product:	Product code:	Lot #:
PRODUCTS FOR CRYOGENIE	CL1ARBIPS	11P1040600
PRODUCTS FOR CRYOGENIE	CL2ARIPS	11P1030000
PRODUCTS FOR CRYOGENIE	CL2ARBIPS	11P1040700

Product was tested for DNase activity by the following protocol:

Product was 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 sample. Therefore, the product can be considered DNase free.



Certified by Laura Pittington, 7/27/2011



Q.A. Nik von Atzigen, 7/27/2011

RNase FREE CERTIFICATE OF ANALYSIS

7/27/2011

This certifies that the following sample obtained from **Biosigma Srl** on 7/21/2011 is free of any detectable RNase contamination.

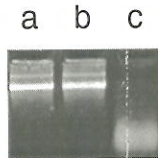
Lots tested:

Product:	Product code:	Lot #:
PRODUCTS FOR CRYOGENIE	CL1ARBIPS	11P1040600
PRODUCTS FOR CRYOGENIE	CL2ARIPS	11P1030000
PRODUCTS FOR CRYOGENIE	CL2ARBIPS	11P1040700

Product wastested for RNase activity by the following protocol:

Product was 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 sample. Therefore, the product can be considered RNase free.



Certified by Laura Pittington, 7/27/2011



Q.A. Nik von Atzigen, 7/27/2011

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

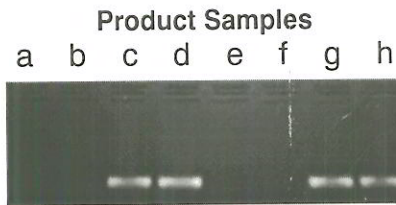
7/27/2011

This certifies that the following sample obtained from **Biosigma Srl** on 7/21/2011 is free of detectable human genomic DNA contamination, and will not inhibit PCR reactions.

Lots tested:

Product:	Product code:	Lot #:
PRODUCTS FOR CRYOGENIE	CL1ARBIPS	11P1040600
PRODUCTS FOR CRYOGENIE	CL2ARIPS	11P1030000
PRODUCTS FOR CRYOGENIE	CL2ARBIPS	11P1040700

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

Certified by Carl Tsang, 7/27/2011

Q.A. Nik von Atzigen, 7/27/2011

NON-PYROGENIC CERTIFICATE OF ANALYSIS

7/27/2011

This certifies that the following sample obtained from **Biosigma Srl** on **7/21/2011** is Non-Pyrogenic. Endotoxin levels are < 0.06 EU/ml.

Lots tested:

Product:	Product code:	Lot #'s:
PRODUCTS FOR CRYOGENIE	CL1ARBIPS	11P1040600
PRODUCTS FOR CRYOGENIE	CL2ARIPS	11P1030000
PRODUCTS FOR CRYOGENIE	CL2ARBIPS	11P1040700

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 FDA guidelines in pyrogen 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 FDA/USP guidelines set endotoxin limits for medical devices at 0.5 EU/ml, and 0.06 EU/ml for devices that contact cerebral spinal fluid. We test products according to the guidelines for medical devices that contact cerebral spinal fluid.



Certified by Laura Pittington, 7/27/2011



Q.A. Nik von Atzigen, 7/27/2011

ATP FREE CERTIFICATE OF ANALYSIS

7/27/2011

The following sample obtained from **Biosigma Srl** on 7/21/2011 is free of any detectable ATP contamination.


PRODUCT	PRODUCT CODE	LOT NUMBER	ATP-free
PRODUCTS FOR CRYOGENIE	CL1ARBIPS	11P1040600	X
PRODUCTS FOR CRYOGENIE	CL2ARIPS	11P1030000	X
PRODUCTS FOR CRYOGENIE	CL2ARBIPS	11P1040700	X

The product was tested for ATP activity using the following protocol:

The product was 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 product can be considered ATP free.



Certified by: Carl Tsang, 7/27/2011



Q.A. Nik von Atzigen, 7/27/2011