MO BIO Laboratories, Inc.
www.mobio.com
2746 Loker Avenue West Carlsbad, CA 92010
800-606-6246 • Ph:760-929-9911 • Fax:760-929-0109 • info@mobio.com

RNase FREE CERTIFICATE OF ANALYSIS

10/3/2011

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

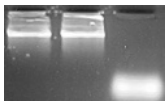
Lots tested:

Product:	Product code:	Lot #:
PRODUCTS FOR CRYOGENIE	**6411**	**11P1007502**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064600**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064601**

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.

a b c



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, 10/3/2011

Q.A. Nik von Atzigen, 10/3/2011

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DNase FREE CERTIFICATE OF ANALYSIS

10/3/2011

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

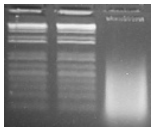
Lots tested:

Product:	Product code:	Lot #:
PRODUCTS FOR CRYOGENIE	**6411**	**11P1007502**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064600**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064601**

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.

a b c



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, 10/3/2011

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ENDOTOXIN-FREE CERTIFICATE OF ANALYSIS

10/3/2011

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	**6411**	**11P1007502**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064600**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064601**

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.

Certified by Laura Pittington, 10/3/2011

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PCR CERTIFIED (HUMAN)
CERTIFICATE OF ANALYSIS

10/3/2011

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

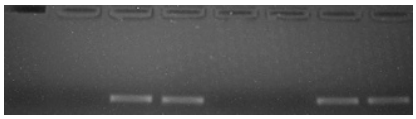
Lots tested:

Product:	Product code:	Lot #:
PRODUCTS FOR CRYOGENIE	**6411**	**11P1007502**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064600**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064601**

GEL PHOTOS:

Product Samples

a b c d e f g h



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.

[X] PCR certified
[X] Free of detectable Human DNA

[X] No PCR inhibition

Certified by Laura Pittington, 10/3/2011

Q.A. Nik von Atzigen, 10/3/2011

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ATP FREE CERTIFICATE OF ANALYSIS

10/3/2011
The following sample obtained from **Biosigma Srl** on **9/22/2011** is free of any detectable ATP contamination.

PRODUCT	PRODUCT CODE	LOT NUMBER	ATP-free
PRODUCTS FOR CRYOGENIE	**6411**	**11P1007502**	**X**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064600**	**X**
PRODUCTS FOR CRYOGENIE	**0520-0321**	**11P1064601**	**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: Laura Pittington, 10/3/2011 Q.A. Nik von Atzigen, 10/3/2011