

**RNase FREE CERTIFICATE OF ANALYSIS**

**12/21/2011**

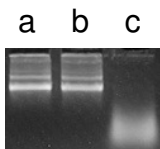
This certifies that the following samples obtained from **Biosigma Srl** on 12/9/2011 are free of any detectable RNase contamination.

**Lots tested:**

Product:	Product code:	Lot #:
<b>PRODUCTS FOR CRYOGENIE</b>	<b>0520-0321</b>	<b>11P1083500</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL1ARBEPS</b>	<b>11P1086300</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL3ARBEPS</b>	<b>11P1077300</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL5ARIPS</b>	<b>11P1076701</b>

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.

*Laura Gloss*

Certified by Laura Gloss, 12/21/2011

*Carl Tsang*

Q.A. Carl Tsang, 12/21/2011

**DNase FREE CERTIFICATE OF ANALYSIS**

**12/21/2011**

This certifies that the following samples obtained from **Biosigma Srl** 12/9/2011 are free of any detectable DNase contamination.

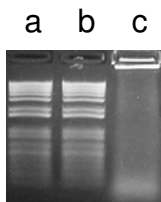
**Lots tested:**

Product:	Product code:	Lot #:
<b>PRODUCTS FOR CRYOGENIE</b>	<b>0520-0321</b>	<b>11P1083500</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL1ARBEPS</b>	<b>11P1086300</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL3ARBEPS</b>	<b>11P1077300</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL5ARIPS</b>	<b>11P1076701</b>

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.

*Laura Gloss*

Certified by Laura Gloss, 12/21/2011

*Carl Tsang*

Q.A. Carl Tsang, 12/21/2011

### ENDOTOXIN-FREE CERTIFICATE OF ANALYSIS

12/21/2011

This certifies that the following samples obtained from **Biosigma Srl** on 12/9/2011 are Endotoxin-Free. Endotoxin levels are < 0.06 EU/ml.

**Lots tested:**

Product:	Product code:	Lot #'s:
<b>PRODUCTS FOR CRYOGENIE</b>	<b>0520-0321</b>	<b>11P1083500</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL1ARBEPS</b>	<b>11P1086300</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL3ARBEPS</b>	<b>11P1077300</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL5ARIPS</b>	<b>11P1076701</b>

Products were tested for Endotoxins by the Limulus Amebocyte Lysate (LAL) Gel Clot Assay.

**Procedure:**

A representative sampling of the products were 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 Gloss, 12/21/2011



Q.A. Carl Tsang, 12/21/2011

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

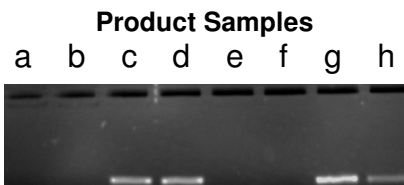
12/21/2011

This certifies that the following samples obtained from **Biosigma Srl** on 12/9/2011 are free of detectable human genomic DNA contamination, and will not inhibit PCR reactions.

**Lots tested:**

Product:	Product code:	Lot #:
<b>PRODUCTS FOR CRYOGENIE</b>	<b>0520-0321</b>	<b>11P1083500</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL1ARBEPS</b>	<b>11P1086300</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL3ARBEPS</b>	<b>11P1077300</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL5ARIPS</b>	<b>11P1076701</b>

**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 Gloss*

Certified by Laura Gloss, 12/21/2011

*Carl Tsang*

Q.A. Carl Tsang, 12/21/2011

### ATP FREE CERTIFICATE OF ANALYSIS

**12/21/2011**

The following samples obtained from **Biosigma Srl** on **12/9/2011** are free of any detectable ATP contamination.

PRODUCT	PRODUCT CODE	LOT NUMBER	ATP-free
<b>PRODUCTS FOR CRYOGENIE</b>	<b>0520-0321</b>	<b>11P1083500</b>	<b>X</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL1ARBEPS</b>	<b>11P1086300</b>	<b>X</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL3ARBEPS</b>	<b>11P1077300</b>	<b>X</b>
<b>PRODUCTS FOR CRYOGENIE</b>	<b>CL5ARIPS</b>	<b>11P1076701</b>	<b>X</b>

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.



Certified by: Laura Gloss, 12/21/2011



Q.A. Carl Tsang, 12/21/2011