fdl V3\_0611 PEA020066-OC05

# **CERTIFICATE OF ANALYSIS**

# HUMAN SKIN TISSUE AND DERIVATED PRODUCTS

Catalog number: PEA020

Batch number: PEA020066-OC05

#### FOR IN VITRO AND RESEARCH USES ONLY

For your safety /// Biohazard information /// These biologicals have to be considered as potentially dangerous, take maximum care in order to protect yourself, your colleagues and your environment.

According to French laws, this product is considered as "product and element of body taken during a surgical procedure", and used for scientific research, French law L.1245 CSP.

#### 1 BIOLOGICAL MATERIAL

INFORMATION	Comments				
• Sex		• female 🖂 male			
<ul> <li>Origin</li> </ul>		• Caucasian 🛛 Africa	an 🗌 Other 🗌		
<ul> <li>Anatomical site</li> </ul>		• abdomen  breast	☐ face ☐ other ☐		
• Age		• 70 years old			
• BMI		• 23			
SAFETY DATA					
Virological status		Specification	Result		
Hepatitis B (HBs antiger)	n, anti HBc antibody)		Positive Negative In progress		
• Hepatitis C (anti HCV antibody)		Negative	Positive Negative In progress		
• HIV-1 and HIV-2 (anti HIV-1 and -2 antibodies)		<u> </u>	Positive ☐ Negative ☒ In progress ☐		
Virological status for HIV1-2	2, HCV, HBV is carri	ed out on the patient by serolog	gical screening using appr	oved diagnostic kits.	
Biosafety level		All human sourced products should be handled at the Biological Safety Level. 2 (BSL 2) to minimize exposure of potentially infectious products			
DESCRIPTION					
Skin decontamination before surgery				Comments	
Betadine		Hibitane			
Betadine alcohol		Hibiscrub			
Betadine scrub		Chlorhexidine			
Chlorhexidine alcohol		Other			



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	V3	COA PEA / EXP / TRA / STR	Created on July, 2010	Revised on June 10, 2011	To Revise on June, 2012
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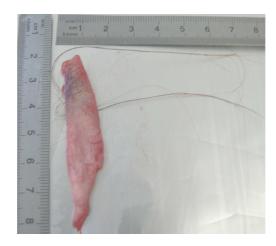
CERTIFICATE OF ANALTSIS								
Shipping conditions between the sampli			ng site and Biopredic				Comments	
Time								
Transit time less than 6 h				$\boxtimes$			Real time: 03h00	
• Transit t	ime less tl	nan 12 h						
Temperature	,							
• Room te	mperature	2						
• Between	+4°C and	d+15°C			$\boxtimes$			
At less the second control of the secon	han -20°C	l						
2 PRC	DUCT							
<b>Production</b>	informat	tion						
Surgery date			January 19, 2012 at 05 h 00 PM					
Production date			January 20, 2012 at 10 h 30 AM					
Production performed on			fresh skin  frozen skin					
Full thickness skin with adipose tissue			$\boxtimes$					
• Full thickness skin without adipose tissue			е					
• Dermato	med skin							
Stratum corneum								
Fresh		Frozen	$\boxtimes$	Other		/		
Surface		5 cm <sup>2</sup>			1		<b>,</b>	
3 CONTROL								
Macroscopic examination of the full-thickness skin								
Presence of stretch marks		Yes		No	$\boxtimes$	With hair		
• Presence of scars		Yes		No	$\boxtimes$			
• Presence of marks (surgical marker)		Yes		No				
• Presence of pubic hair		Yes		No	$\boxtimes$			
					•	1		



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## Skin picture



## 4 STORAGE AND DELIVERY

Storage				
<ul> <li>At room temperature</li> <li>At 4°C</li> <li>At - 20°C</li> <li>At - 80°C</li> </ul>				
Delivery				
<ul> <li>At room temperature</li> <li>At 4°C</li> <li>At lower than – 20°C</li> </ul>				

# **VISA FOR BATCH RELEASE**

Name	Signature	Date		
Nathalie ROUGIER, PhD	Carfrey	February 17, 2012		

