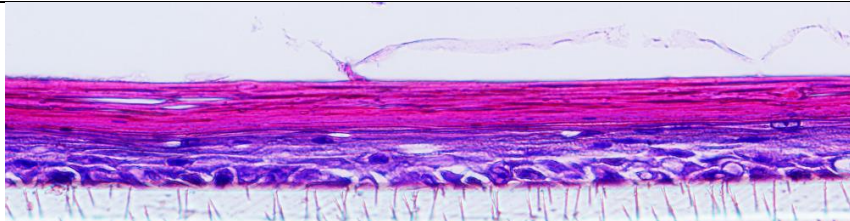




Technical DATA, SAFETY SHEET AND CERTIFICATE OF ANALYSIS OF RECONSTRUCTED EPIDERMAL MODEL ON TISSUE CULTURE INSERTS

Description	LabSkin EPI 4.5 cm ² epidermis reconstructed by Air-Liquid interface culture of normal human keratinocytes for 14 days in chemically defined and serum –free medium on PET membrane filters		
Application	For scientific use only-Product of human origin		
Storage	The following product is reconstructed and cultured in aseptic condition in saturated humidity at 37 °C, 5% CO ₂		
Cell line	Human keratinocytes (Caucasian): 6 passage		
Batch number	15-EPI-02		
Histology analysis			
QC	Test	Acceptable range	Results
	Mono-layer culture of keratinocytes at parallel for 10 days	Cell growth ability and colony formation analysis	<i>Confirmed</i>
	Histology and morphology analysis at day 14 (H&E staining)	Formation of stratum corneum with defined thickness, presences of basal layer, spinous, granular layer at upper most layers. Lack of morphological abnormalities. Lack of structure inconsistency at different levels of tissue model	<i>Confirmed: 5 layers of cells were observed</i>
	Cell viability (MTS assay n=3)	O.D.> 0.7	<i>Confirmed</i> <i>O.D.= 0.812 ± 0.065</i>
	ET ₅₀ (50% loss of cell viability upon exposure to Triton X-100 compared to control) for barrier function Formation of resistance barrier on superficial layers with acceptance resistance toward surfactants. Indication of differentiation consistency in whole tissue (MTS assay n=3)	4hr>ET ₅₀ > 8hr	<i>Confirmed</i> <i>4hr>ET₅₀> 8hr</i>
Biological Safety	<ul style="list-style-type: none"> ○ Absences of HIV-1 and HIV-2, checked with cell donor supplier ○ Absence of hepatitis C, checked with cell donor supplier ○ Absence of hepatitis B, checked with cell donor supplier 		
Expiry date	Day 21 of airlifted culture/ 6 days after delivery		
“The use of this product strictly limited for in vitro testing provided such testing does not include extraction of the cells constitutive of the epidermal model for culture, maintenance and expansion. The use of this product for therapeutic, diagnostic and application in any human subject is strictly prohibited”			

Data validation**QC Manager:****Mehdi Movahednia**<http://www.labskinpro.com>

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