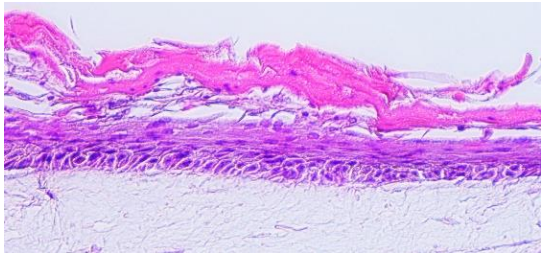


**Technical DATA, SAFETY SHEET AND CERTIFICATE OF ANALYSIS OF
RECONSTRUCTED FULL-THICKNESS EPIDERMAL MODEL ON COLLAGEN
SCAFFOLD**

| | | | |
|--|---|---|---|
| Description | LabSkin EPI-Barrier 4.5 cm ² epidermis reconstructed by Air-Liquid interface co-culture of normal human fibroblasts and keratinocytes for 12 days in chemically defined and serum-free medium on collagen lattice | | |
| 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 Human fibroblast (Caucasian): 8 passage | | |
| Batch number | 15-EPI FT-05 | | |
| Histology analysis |  | | |
| QC | Test | Acceptable range | Results |
| | Mono-layer culture of keratinocytes and fibroblast at parallel for 10 days | Cell growth ability and colony formation analysis | <i>Confirmed</i> |
| | Histology and morphology analysis at day 12 (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: 7-8 layers of cells were observed</i> |
| | Cell viability (MTS assay n=3) | O.D.> 0.8 | <i>Confirmed O.D.= 1.12 ± 0.082</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 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 full-thickness skin 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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