

Certificate of Analysis and Release

Product: Sil-Select Plus - Lower Layer

Batchnumber :		FP18SIP25L
Production date :	DD/MM/YYYY	29/05/2018
Expiry date :	DD/MM/YYYY	30/11/2019
Total volume :		16105 ml

Sil-select Plus: Lower layer	<i>Result</i>	<i>Specification</i>
pH :	7,49	7.20 - 7.60
Osmolality :	305	290-330mOsm/kg
Bacterial screen :	NEGATIVE	NEGATIVE
Fungal screen :	NEGATIVE	NEGATIVE
Endotoxin :	< 0,1 EU/MI	< 0,5EU/mL
Density (g/ml):	1,1077	1.1050 - 1.1150 g/mL
Viscosity in cP (25°C):	1,54	< 1.65 cP
Sperm survival test (4 hours exposure)	96%	≥ 80%
Sperm survival test (24 hours exposure)	92%	≥ 75%
Concentration HSA	0,245*	0.3– 0.5 g/l

Product released by Lenie Bocklandt on 15/06/2018 (DD/MM/YYYY)



Bocklandt lenie

* The slightly lower concentration of human serum albumin has been accepted based on the output of the performed risk analysis. Therefore, this batch is released under concession. More information on this matter is available upon request.