

Certificate of Analysis and Release

Product: FertiVit

Batchnumber :		FP18FVW06
Production date :	DD/MM/YYYY	9/05/2018
Expiry date :	DD/MM/YYYY	31/05/2019
Total batchsize:		148 Kits

FertiVit W1	Result	Specification
pH :	7,30	7.2 - 7.4
Sterility test :	PASSED	PASSED
Endotoxin :	< 0,1 EU/ml	< 0,25EU/mL
Osmolality:	1709	-
Concentration HSA:	16,447	13,9 - 20,9 g/liter
FertiVit W2		
pH :	7,29	7.2 - 7.4
Sterility test :	PASSED	PASSED
Endotoxin :	< 0,1 EU/ml	< 0,25EU/mL
Osmolality :	1258	-
Concentration HSA:	17,048	14,4 - 21,6 g/liter
FertiVit W3		
pH :	7,30	7.2 - 7.4
Sterility test :	PASSED	PASSED
Endotoxin:	< 0,1 EU/ml	< 0,25EU/mL
Osmolality :	848	805-850mOsm/kg
Concentration HSA:	17,373	14,9 - 22,3 g/liter
FertiVit W4		
pH :	7,36	7.2 - 7.4
Sterility test :	PASSED	PASSED
Endotoxin:	< 0,1 EU/ml	< 0,25EU/mL
Osmolality :	560	535-565mOsm/kg
Concentration HSA:	18,758	15,4 - 23,1 g/liter
FertiVit W5		
pH :	7,30	7.2 - 7.4
Sterility test :	PASSED	PASSED
Endotoxin:	<0,1 EU/ml	< 0,25EU/mL
Osmolality :	422	405-435mOsm/kg
Concentration HSA:	19,529	15,7 - 23,6 g/liter
FertiVit W6		
pH :	7,32	7.2 - 7.4
Sterility test :	PASSED	PASSED
Endotoxin:	<0,1 EU/ml	< 0,25EU/mL
Osmolality:	283	270-290mOsm/kg
Concentration HSA:	19,864	16,0 - 24,0 g/liter
MEA (1-cell to expanded blastocyst within 96 hours):	100%	≥ 80%

Product released by Lenie Bocklandt on 23/05/2018 (DD/MM/YYYY)



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Caution: All blood products should be treated as potentially infectious. Source material from which this product was derived was found negative when tested for antibodies to HIV, HBc, HCV, and non-reactive for HbsAg, HCV RNS and HIV-1 RNA and syphilis. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

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