

# Certificate of Analysis

# GRIFOLS

8368 U.S. 70 BUS HWY  
West  
Clayton, NC 27520-0507

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<b>Packaged Final Container Batch Number</b>	B2AKA00413		
<b>Packaging Material Number</b>	729586		
<b>Material Description</b>	ALBUMIN (HUMAN) 25%, USP AB		
<b>Product Size</b>	50 mL	<b>Fill Number</b>	B2AKA00413
<b>Code</b>	AB	<b>Batch Disposition</b>	FULL RELEASE
<b>Date of Manufacture</b>	30-NOV-2016	<b>Dispositioned By</b>	Darlene Coor
<b>Date of Expiration</b>	29-NOV-2019	<b>Disposition Date</b>	31-JAN-17

Test Information	Component	Requirements	Results	Units
<u>APPEARANCE</u>	CLARITY	CLEAR, SLIGHTLY VISCOUS LIQUID - MUST COMPLY	COMPLIES	NONE
	COLOR	IT IS ALMOST COLORLESS, YELLOW, AMBER, OR GREEN- MUST COMPLY	COMPLIES	NONE
<u>CITRATE</u>	CITRATE	MAX 0.1 MMOL/L	< 0.1	MMOL/L
<u>HEAT STABILITY</u>	HEAT STABILITY	VISUALLY CLEAR - MUST COMPLY	COMPLIES	NONE
<u>VOLUMETRIC FILL CHECK</u>	LABELED FILL VOLUME	REPORT	50	MILLILITERS
	ACTUAL FILL VOLUME	REPORT	50.459	MILLILITERS
	VOLUMETRIC FILL CHECK	MEETS MINIMUM FILL VOLUME	MEETS MINIMUM FILL VOLUME	NONE
<u>PH, DILUTED</u>	PH	6.7 - 7.3	7.0	NONE
<u>SODIUM</u>	SODIUM	130-160 MEQ/L	146	MEQ/L
<u>POTASSIUM</u>	POTASSIUM	MAX 2 MEQ/L	< 1	MEQ/L
<u>PROTEIN</u>	SAMPLE PROTEIN	23.75 - 26.25% w/v	25.09	PERCENT
<u>MOLECULAR WEIGHT DISTRIBUTION</u>	DIMER	MAX 9%	1	PERCENT
	POLYMERS (>DIMER)	MAX 15%	6	PERCENT
	MONOMER	NLT 80%	93	PERCENT
	FRAGMENTS	MAX 6%	< 1	PERCENT
<u>SODIUM ACETYL TRYPTOPHAN</u>	SODIUM ACETYL TRYPTOPHAN	0.064 - 0.096 MMOL/G ALBUMIN	0.083	MMOL/G ALBUMIN
<u>SODIUM CAPRYLATE</u>	SODIUM CAPRYLATE	0.064 - 0.096 MMOL/G ALBUMIN	0.086	MMOL/G ALBUMIN
<u>PREKALLIKREIN ACTIVATOR</u>	PKA ACTIVITY	MAX 20 IU/ML	< 1	IU/ML
<u>ALUMINUM</u>	ALUMINUM	MAX 200 uG/L	< 17	uG/L

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Test Information	Component	Requirements	Results	Units
<u>HEME</u>	HEME ABSORBANCE (403NM)	MAX 0.15 ABSORBANCE	0.05	NONE
<u>STERILITY (USP)</u>	STERILITY	NO GROWTH - MUST COMPLY	COMPLIES	NONE
	DATE OF TEST	REPORT	07-DEC-2016	DD-MON-YYYY
<u>PYROGEN (USP)</u>	PYROGEN USP COMPLIANCE	MUST COMPLY	COMPLIES	NONE
	DATE OF TEST	REPORT	16-DEC-2016	DD-MON-YYYY
	NUMBER OF RABBITS	REPORT	3	NONE
	SUM TEMPERATURE RISE	REPORT	0.1	CELSIUS
<u>PURITY</u>	ALBUMIN	MIN 96%	99	PERCENT
	SUM ALPHA, BETA, GAMMA GLOBULIN	MAX 4%	1	PERCENT
<u>PRODUCT IDENTITY</u>	PRODUCT IDENTITY	MAIN COMPONENT CORRESPONDS TO THAT OF NORMAL HUMAN SERUM	COMPLIES	NONE
<u>PLASMA DONOR SCREENING</u>	HBSAG	NON-REACTIVE - MUST COMPLY	COMPLIES	NONE
	HIV-1/HIV-2 ANTIBODY	NEGATIVE - MUST COMPLY	COMPLIES	NONE
	ANTI-HCV	NEGATIVE - MUST COMPLY	COMPLIES	NONE
	HIV-1 BY NAT	NEGATIVE - MUST COMPLY	COMPLIES	NONE
	HCV BY NAT	NEGATIVE - MUST COMPLY	COMPLIES	NONE
	HBV BY NAT	NEGATIVE - MUST COMPLY	COMPLIES	NONE
	PARVO B-19 BY NAT	NON-ELEVATED - MUST COMPLY	COMPLIES	NONE
<u>PLASMA POOL SCREENING</u>	HBSAG	NON-REACTIVE - MUST COMPLY	COMPLIES	NONE
	HIV-1/HIV-2 ANTIBODY	NEGATIVE - MUST COMPLY	COMPLIES	NONE
	HIV-1 BY NAT	NEGATIVE - MUST COMPLY	COMPLIES	NONE
	HCV BY NAT	NEGATIVE - MUST COMPLY	COMPLIES	NONE
	HBV BY NAT	NEGATIVE - MUST COMPLY	COMPLIES	NONE
	PARVO B-19 BY NAT	NON-ELEVATED - MUST COMPLY	COMPLIES	NONE
	ANTI HCV	NEGATIVE - MUST COMPLY	COMPLIES	NONE

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Test Information	Component	Requirements	Results	Units
<u>POST PACKAGING IDENTITY</u>	IDENTITY	ALBUMIN PATTERN	ALBUMIN PATTERN	NONE
<u>MATERIAL REPROCESSED</u>	LOT CONTAINS REPROCESSED MATERIAL	REPORT YES/NO	NO	NONE
	TYPE OF REPROCESSING	REPORT TYPE	N/A	NONE

THE BATCH COMPLIES WITH SPECIFICATION

*Darlene R Coor 01 May 2017*