

Data Sheet
Normal/ Processed Human Serum
BCB-1
(Non-Lipid Stripped)

1) IDENTIFICATIONS

Parameter	Method	Specification
Product Name	Not applicable	BCB-1
ID. No	Visual inspection	HS201-007
Lot No	Visual inspection	Refer to CoA
Expiry Date	Visual inspection	Refer to CoA
Manufacturing Date	Visual inspection	Refer to CoA
Form	Visual inspection	Frozen
Volume	Visual inspection	1.0 L, 2.5 L, 5.0 L, 10.0 L
Container	Visual inspection	HDPE Bottle

2) CHEM./BIOL. CHARACTERISTICS

Test	Method	Specification
pH	pH-Meter	7.0 – 7.4
Bioburden	CASO Agar	< 10 ² cfu/mL
Sterile Filtration	Membrane	0.2 µM sterile filtered
Freeze/thaw turbidity @ 546 nm	Spectrophotometry	<0.500
Preservative:	-	Anti-microbial agent <0.01%

3) ANALYTES BIOCHEMISTRY PROFILE

The following parameters are given as further detail for user.

Test	Method	Specification
Sodium	ISE/Direct	75-150 mmol/L
Potassium	ISE/Direct	<1.0 mmol/L
Chloride	ISE/Direct	60-120 mmol/L
Glucose	GOD-PAP	15-25 mg/dL
BUN	Urease-GLDH	5-25 mg/dL
Creatinine	Jaffe	0,00 mg/dL
Calcium	o-CPC	<2.00 mmol/L
Magnesium	Xylidyl Blue	0,10-0,20 mmol/L
Total Protein	Biuret	50-90 g/L

Data Sheet
Normal/ Processed Human Serum
BCB-1
(Non-Lipid Stripped)

Test	Method	Specification
Albumin	Bromocresol Green	35-55 g/L
Amylase	IFCC/+37°C	50-150 U/L
IgA	Turbidimetric	150-300 mg/dL
IgM	Turbidimetric	75-200 mg/dL
IgG	Turbidimetric	800-1500 mg/dL
Uric Acid	Uricase-PAP	0,0 mg/dL
GOT (ASAT)	IFCC/+37°C	15-45 U/L
GPT (ALAT)	IFCC/+37°C	10-50 U/L
Alkaline Phosphatase	IFCC/+37°C	40-130 U/L
GGT	IFCC/SZASZ	15-50 U/L
Cholesterol	CHOD-PAP	100-240 mg/dL
Triglycerides	GPO-PAP	50-150 mg/dL
HDL	CHOD/Peroxidase	25-75 mg/dL
LDL	Cholesterol Esterase/ Peroxidase	75-180 mg/dL
Iron	Ferrozine	75-250 µg/dL
CK-MB	Immunoinhibition	5-25 U/L

4) STABILITY

Shelf life of the product is 2 years <-20°C. Refer to the Certificate of Analysis for the recommended re-testing date. Avoid repeated freeze & thaw cycles.

5) BIOHAZARD / HEALTH AND SAFETY INFORMATION

The used H. Plasma units of European origin have been tested by CE-marked test kits and found to be non-reactive for HBsAg, anti-HIV 1+2, anti-HCV, and Syphilis. In addition, HAV, HBV, HCV, HIV-1, and Parvo B19 have been tested by PCR. The above referenced lot was only formed with these donors.

However, all human material should be considered potentially infectious. Since no testing method can rule out the potential risk of infection with absolute certainty, the material should be handled with the same level of care as a patient specimen.

6) STORAGE

For long term stability, BCB-1 must be stored frozen at ≤ -20 °C.

Data Sheet
Normal/ Processed Human Serum
BCB-1
(Non-Lipid Stripped)

7) IMPORTANT NOTE

For Research and Manufacturing Only. Not for Injection.

8) WASTE MANAGEMENT

Observe local environmental regulations.

9) Country of Origin

Germany

10) FINAL STATEMENT

This batch has been manufactured, tested, released, and packed in accordance with JTC Diagnostics' Quality System.

