

**Data Sheet**  
**Normal/ Processed Human Serum**  
**BCB-3 Grade 1**  
**(Lipid Stripped)**

### 1) IDENTIFICATIONS

Parameter	Method	Specification
Product Name	Not Applicable	BCB-3 Grade 1
ID. No	Visual inspection	HS201-010
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 at bottling	CASO Agar	< 10 <sup>2</sup> cfu/mL
Sterile Filtration	Membrane	0.2 µM sterile filtered
Freeze/thaw turbidity @ 546 nm	Spectrophotometry	<0,250
Preservative:	N/A	Anti-microbial Agent <0,01%

### 3) IMMUNOASSAY RESULTS

Test	Method	Specification
Cortisol	ECLIA - Roche	<7.0 µg/L
Progesterone	ECLIA - Roche	<0.30 µg/L
Testosterone, total	ECLIA - Roche	<0.15 µg/L
HCG	ECLIA - Roche	<1.5 IU/L
TSH	ECLIA - Roche	<0.20 mIU/L
FSH	ECLIA - Roche	<15 IU/L
DHEA	LC/MS/W. Xevo S	<0.10 µg/L
DHEAS	ECLIA - Roche	<0.10 mg/L
17-OH-Progesteron	LC/MS/W. Xevo S	<0.10 µg/L
fT3	ECLIA - Roche	<3.0 pmol/L

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fT4	ECLIA – Roche	<3.0 pmol/L
Estradiol	ECLIA – Roche	<15.00 ng/L

#### 4) 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	<2.0 mmol/L
Chloride	ISE/Direct	60-120 mmol/L
Glucose	GOD-PAP	<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	<0.75 mmol/L
Total Protein	Biuret	50-90 g/dL
Albumin	Bromocresol Green	35-55 g/L
Amylase	IFCC/+37°C	10-150 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	10-130 U/L
GGT	IFCC/SZASZ	15-50 U/L
Cholesterol	CHOD-PAP	<10 mg/dL
Triglycerides	GPO-PAP	<5.0 mg/dL
HDL	CHOD/Peroxidase	<5.0 mg/dL
LDL	Cholesterol Esterase/ Peroxidase	<5.0 mg/dL

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Test	Method	Specification
Iron	Ferrozine	75-250 µg/dL
CK-MB	Immunoinhibition	0-25 U/L

### 5) STABILITY

Shelf life of the product is 5 years <-20°C. Refer to the Certificate of Analysis for the recommended re-testing date. Avoid repeated freeze & thaw cycles.

### 6) 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.

### 7) STORAGE

For long term stability, BCB-3 Grade 1 must be stored frozen at  $\leq -20$  °C.

### 8) IMPORTANT NOTE

For Research and Manufacturing Only. Not for Injection.

### 9) WASTE MANAGEMENT

Observe local environmental regulations.

### 10) Country of Origin

Germany

### 11) FINAL STATEMENT

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

