Biotrol

IVD CE

(ABNORMAL – CONTROL SERUM)

PRODUCT CODE
CC002

Product Description
The control serum is prepared from human serum with human and nonhuman enzymes and nonprotein constituents added. Bacteriostatic agents have been added.

Caution
Human serum was used in the manufacture of this product.
Each donor unit was tested with licensed reagents and found negative for HBsAg and nonreactive for the HIV antibody.
Because of no test method can offer complete assurance that products derived from human blood will not transmit infection agents, it is recommended that this product be handled with the same precautions used for patient specimens.
The disposal of the residues has to be made according to local regulations

Additional Equipment
Volumetric pipettes.

Preparation
Add exactly 5 ml, of deionized water to each vial.
Allow to sit 5 to 10 minutes.
Swirl the contents until homogeneous.
This control serum should be handled as if a sample from human origin.
Analytical values should fall in between the assay range

Storage and Stability
Before Reconstitution, the product remains stable, when Store at 2 - 8 ° C., until the expiration date stated on the label.
Once rehydrated, the constituents are stable for 7 days, when stored at 2 - 8 ° C, 8 hours at 25 ° C and 1 month at -20°C.
Except for Acid phosphatase, only stable for 48 h, at 2 - 8 ° C and 1 month at -20°C, For Alkaline phosphatase, rehydrate the serum and let Stand for one hour at room temperature.
Bilirubin is stable for 4 days at 2-8°C. It is recommended not to store at room temperature or freeze. Since Bilirubin is a light-Sensitive metabolite it is advisable, for the sake of better storage Conditions, to keep the Control in the dark

Assigned Values
The assigned concentrations for each parameter are lot specific.
The value and expected range for each constituent are derived from interlaboratory data and they are given for orientation only; each laboratory should establish its own acceptation range. The mean of several determinations may not duplicate the value printed on the insert but should fall within the expected range, To determine the accuracy and precision of a certain analytical method, it is advisable to run a Normal as well an Abnormal control serum samples.

SYMBOLS ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCE

Hyltoft Petersen, P.; RicoS, C.; Stockl, D. Proposed guidelines for the internal Quality Control of analytical results in the medical laboratory. Eur J Clin Chem Biochem, 1996, 34, 983: 999.

Lawson, NS. ; Haven GT.; Williams, GW. Analyte stability in clinical chemistry Quality Control materials. CRC Crit Rev Clin Lab Sci, 1982, 17, 1: 50.

Proteins				
Component	**Method**	**Value**	**Range**	**Units**
Albumin	BCG Method	2.80 28.0	2.40 – 3.20 24.0 – 32.0	g/dl g/l
Total protein	biuret	4.40 44.0	3.80 – 5.00 38.0 – 50.0	g/dl g/l

Other metabolites				
Component	**Method**	**Value**	**Range**	**Units**
Uric Acid	Uricase POD	9.00 536	5.80-12.20 345-726	mg/dl µmol/L
Total Bilirubin	Jendrassik - Grof /Manual	5.00 85.5	4.15-5.85 70.9-100	mg/dl µmol/L
	Jendrassik - Grof /Automatic	5.00 85.5	4.25-5.75 72.7-98.3	mg/dl µmol/L
Direct Bilirubin	Jendrassik - Grof /Manual	1.90 32.5	1.37-2.43 23.5-41.6	mg/dl µmol/L
	Jendrassik - Grof /Automatic	2.30 39.3	1.80-2.80 30.8-47.9	mg/dl µmol/L
Creatinine	Kinetic jaffe	4.15 367	3.50-4.80 309-424	mg/dl µmol/L
Glucose	GOD-POD	276 15.3	247-305 13.7-17.0	mg/dl µmol/L
Urea	Urease GLDH	113 18.8	88-138 14.7-23.0	mg/dl µmol/L
	Urease Berthelot	126 21.0	97-155 16.2-25.8	mg/dl µmol/L

Enzymes					
Component	**Method**	**T (°c)**	**value**	**range**	**units**

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a-Amylase	IFCC method	37 °c	278	256-300	U/L
	Substrate BPS-blocked maltoheptaoside	37 °c	310	270-350	U/L
CK NAC activated	IFCC	37 °c	563	511-615	U/L
CK-MB	Immunological	37 °c	38.4	23.4-53.4	U/L
Cholinesterase	Butyrylthiocholine iodide	37 °c	4700	3760-5640	U/L
Acid phosphatase	a-naphthyl phosphate	37 °c	36	32-40	U/L
Prostatic acid phos.	a-naphthyl phosphate	37 °c	19.7	13.4-27.0	U/L
Alkaline phosphatase	DGKC (p-NPP)	37 °c	518	467-569	U/L
	IFCC liquid	37 °c	355	300-410	U/L
	Phenolphthalein monophosphate	37 °c	170	136-204	U/L
Gamma gt	Szasz 405nm	37 °c	160	131-189	U/L
GLDH	DGKC	37 °c	23.4	18.0-28.8	U/L
GOT/AST	IFCC	37 °c	158	126-190	U/L
	Reitman-Frankel	37 °c	80	56-104	U/mL
GPT/ALT	IFCC	37 °c	134	112-156	U/L
	Reitman-Frankel	37 °c	84	62-106	U/mL
LDH	SFBC (Pir.- Lact.)	37 °c	720	613-827	U/L
Lipase	color	37 °c	84	72-96	U/L

	o-Cresolphthalein	2.63	8.5-13.5 2.10-3.32	mg/dl mmol/L
Chloride	Ion-selective electrode	111	93.0-129	mEq/L mmol/L
	Thiocyanate method	115	105-125	mEq/L mmol/L
Copper	Direct colorimetric method	82 12.9	67-97 10.5-15.2	µg/dl µmol/L
Inorganic phosphorus	Phosphomolybdate	7.24 2.34	5.54-8.94 1.79-2.89	mg/dl mmol/L
Iron	FerroZine	192 34.4	162-222 29.0-39.8	µg/dl µmol/L
	CAB method	178 32.0	132-224 23.6-40.1	µg/dl µmol/L
Magnesium	Calmagite dye	4.20 1.73	3.25-5.15 1.34-2.12	mg/dl mmol/L
	Xylidyl blue	3.90 1.60	3.20-4.60 1.32-1.90	mg/dl mmol/L
Potassium	Ion-selective electrode	5.20	4.50-5.90	mEq/L mmol/L
	Turbidimetric method / TPB-Na	5.50	4.70-6.30	mEq/L mmol/L
Sodium	Ion-selective electrode	154	132-176	mEq/L mmol/L
TIBC	$FeCl_3;MgCO_3$	334 59.8	292-376 52.3-67.3	µg/dl µmol/L
Zn	Br-PAPS method	234 35.8	177-291 27.1-44.5	µg/dl µmol/L

LIPIDS				
Component	**Method**	**value**	**range**	**units**
Cholesterol	CHOD-POD	286 7.41	232-304 6.00-7.87	mg/dl mmol/L
HDL- Cholesterol	Enzymatic	127 3.29	102-152 2.64-3.94	mg/dl mmol/L
LDL-cholesterol	Enzymatic	165 4.27	133-197 3.44-5.10	mg/dl mmol/L
triglycerides	GPO	245 2.80	205-285 2.34-3.26	mg/dl mmol/L

IONS				
Component	**Method**	**value**	**range**	**units**
Calcium	Arsenazo III	10.7	8.6-12.8 2.12-3.15	mg/dl mmol/L

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