CENTRONIC

Centronorm

Catalogue No.: CNORM005 CNORM010 CNORM020
Pack.-Size: 5 x 5 ml 10 x 5 ml 20 x 5 ml

CE

LOT 300900
09/2026

Constituent	Method	Conv.-Units	Target Value	Control Range	S.I.-Units	Target Value	Control Range
Total acid phosphatase	1-naphthylphosphate, 37°C	U/l	10,3	7,5 - 13,1	µkat/l	0,17	0,13 - 0,22
Albumin	Bromcresol green	g/dl	3,42	2,6 - 4,2	g/l	34,2	28,0 - 40,4
Aldolase	UV Method. 20 min.	U/l	2,0	1,5 - 2,5	µkat/l	0,03	0,03 - 0,04
Alk. Phosphatase	DGKC, 37°C	U/l	134	100,5 - 167,5	µkat/l	2,24	1,68 - 2,80
	IFCC, 37°C	U/l	74,4	55,8 - 93,0	µkat/l	1,24	0,93 - 1,55
ALT / GPT	IFCC (with pyridoxal phosphate), 37°C	U/l	50,0	38,5 - 61,5	µkat/l	0,84	0,64 - 1,03
	IFCC (without pyridoxal phosphate), 37°C	U/l	50,0	38,5 - 61,5	µkat/l	0,84	0,64 - 1,03
α-Amylase , total	IFCC, 37°C	U/l	77	60,8 - 93,2	µkat/l	1,29	1,02 - 1,56
a-Amylase, pancreatic	IFCC, 37°C	U/l	30,0	23,7 - 36,3	µkat/l	0,50	0,40 - 0,61
AST / GOT	IFCC (with pyridoxal phosphate), 37°C	U/l	40,5	31,2 - 49,8	µkat/l	0,68	0,52 - 0,83
	IFCC (without pyridoxal phosphate), 37°C	U/l	40,5	31,2 - 49,8	µkat/l	0,68	0,52 - 0,83
Bilirubin, total	Diazo	mg/dl	1,56	1,15 - 1,97	µmol/l	26,7	19,7 - 33,6
	Jendrassik-Grof	mg/dl	2,36	1,75 - 2,97	µmol/l	40,4	29,86 - 50,85
	Vanadate	mg/dl	1,69	1,25 - 2,13	µmol/l	28,9	21,39 - 36,41
Bilirubin, direct	Jendrassik-Grof	mg/dl	0,89	0,66 - 1,12	µmol/l	15,2	11,26 - 19,18
	Vanadate	mg/dl	0,84	0,62 - 1,06	µmol/l	14,4	10,63 - 18,10
BUN	Urease UV	mg/dl	15,2	11,87 - 18,57	mmol/l	5,4	4,24 - 6,63
Calcium	o-cresolphthaleine complexone	mg/dl	9,22	8,21 - 10,24	mmol/l	2,3	2,05 - 2,55
	Arsenazo/MTB	mg/dl	8,32	7,40 - 9,24	mmol/l	2,08	1,85 - 2,31
Chloride	ISE, indirect potentiometry	mg/dl	355	322,6 - 386,4	mmol/l	100	91,0 - 109,0
Cholesterol, total	CHOD-PAP	mg/dl	141	121 - 161	mmol/l	3,67	3,15 - 4,18
HDL-Cholesterol	Direct, homogen, 37°C	mg/dl	42,5	31,0 - 54,0	mmol/l	1,11	0,8 - 1,4
LDL-Cholesterol	Direct, homogen, 37°C	mg/dl	85,1	64,7 - 105,5	mmol/l	2,21	1,7 - 2,7
Cholinesterase	butyrylthiocholine, 37°C	U/l	6270	5141 - 7399	µkat/l	104,71	85,9 - 124
CK-NAC	IFCC, 37°C	U/l	170	136 - 204	µkat/l	2,84	2,27 - 3,41
Copper	bathocuproin with deproteinization	µg/dl	124,5	107 - 142	µmol/l	19,5	16,8 - 22,3
Creatinine	Crea Plus	mg/dl	1,28	1,00 - 1,56	µmol/l	113,2	88,3 - 138,0
	Jaffe (rate-blanked and compensated)	mg/dl	1,35	1,05 - 1,65	µmol/l	119,3	93,1 - 145,6
Glucose	GOD-PAP / HK/G6P-DH	mg/dl	93,7	78,7 - 108,7	mmol/l	5,20	4,37 - 6,03
GGT	Szasz Method, 37°C	U/l	26,5	20,7 - 32,3	µkat/l	0,44	0,3 - 0,5
	IFCC, 37°C	U/l	30,4	23,7 - 37,1	µkat/l	0,51	0,4 - 0,6
GLDH	Opt. DGKC	U/l	12,6	9,2 - 16,0	µkat/l	0,21	0,2 - 0,3
HBDH	Kin. UV Test, Opt. DGKC 37°C	U/l	127	100,3 - 153,7	µkat/l	2,12	1,7 - 2,6
IgA	immunoturbidimetry	mg/dl	193	147 - 239	g/l	1,93	1,47 - 2,39
IgG	immunoturbidimetry	mg/dl	874	699 - 1048,8	g/l	8,74	6,99 - 10,5
IgM	immunoturbidimetry	mg/dl	70	50 - 90	g/l	0,70	0,50 - 0,90
Iron	ferrozine without deproteinization	µg/dl	82,2	71 - 94	µmol/l	14,7	12,7 - 16,8
Lactate	enzym. UV	mg/dl	13,5	10,7 - 16,3	mmol/l	1,50	1,18 - 1,81
Lithium	ISE, direct potentiometry	mg/dl	0,66	0,57 - 0,75	mmol/l	0,96	0,83 - 1,09
LDH-P	DGKC, 37°C	U/l	289	237,0 - 341,0	µkat/l	4,83	4,0 - 5,7
	IFCC, 37°C	U/l	150	123 - 177	µkat/l	2,51	2,05 - 2,96
LDH-L	IFCC,DGKC, 37°C	U/l	148,6	121,9 - 175,3	µkat/l	2,48	2,0 - 2,9
Lipase	enzym. colorimetric assay, 37°C	U/l	50,0	40,0 - 60	µkat/l	0,84	0,67 - 1,00
Magnesium	xylidyl blue method	mg/dl	1,75	1,47 - 2,03	mmol/l	0,72	0,60 - 0,84
Phosphate, inorganic	molybdate UV	mg/dl	3,00	2,46 - 3,54	mmol/l	0,97	0,80 - 1,14
Potassium	ISE, indirect potentiometry	mg/dl	16,0	12,8 - 19,2	mmol/l	4,10	3,3 - 4,9
Protein, total	biuret	g/dl	5,5	4,90 - 6,11	g/l	55,0	49,0 - 61,1
Sodium	ISE, indirect potentiometry	mg/dl	299	281 - 317	mmol/l	130	122,1 - 137,9
Transferrin	immunoturbidimetry	mg/dl	219	180 - 258	µmol/l	27,6	22,6 - 32,6
Triglycerides	GPO-PAP	mg/dl	86,9	71 - 103	mmol/l	0,99	0,81 - 1,17
Uric Acid	uricase-PAP Plus	mg/dl	4,9	4,2 - 5,6	µmol/l	291,6	250,7 - 332,4
Urea	urease, UV	mg/dl	32,6	25,4 - 39,8	mmol/l	5,44	4,25 - 6,64
Zinc	5-Brom-PAPS	µg/dl	164,7	141,6 - 188	µmol/l	25,2	21,7 - 28,7

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CamScanner

Centronorm

Control Serum for Quality Control for Chemical/ Biochemical Measurands

REF	CNORM005	CNORM010	CNORM020	IVD	*For In Vitro Diagnostic Use*
	5 x 5 ml	10 x 5 ml	20 x 5 ml		

Intended Use

The lyophilized assayed Centronorm is intended for use as an assayed quality control serum for Internal Quality Control (IQC) in the medical laboratory.[1)2)]

Principle

The use of quality control materials is indicated as an objective assessment of precision and accuracy and is an integral part of Good Laboratory Practices (GLP). Two levels of control are available to allow performance monitoring within the clinical range.

Reagent

Centronorm is a lyophilized control material based on human plasma, defibrinated for the following measurands: Total Acid Phosphatase, Albumin, Aldolase, Alk. Phosphatase, ALT/GPT, α-Amylase total, α-Amylase pancreatic, AST/GOT, Bilirubin total, Bilirubin direct, BUN, Calcium, Chloride, Cholesterol total, HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, CK-NAC, Copper, Creatinine, GGT, Glucose, GLDH, HBDH, IgA, IgG, IgM, Iron, Lactate, LDH-P, LDH-L, Lipase, Lithium, Magnesium, Phosphate inorganic, Potassium, Sodium, Total Protein, Transferrin, Triglycerides, TIBC, Urea, Uric Acid, Zn.

Target Values and Ranges

Target values were derived from replicate analysis in several laboratories and are specific for the lot of Centronorm. Ranges were calculated as target value ± the maximal allowed deviation of the single measured value.[2)]

The traceability to reference methods/ selected methods is described in the appered routine methods. Target values may slightly differ due to various test kits and methods. The indicated target values and ranges are valid only for the indicated test system.

Procedure

The reconstituted Centronorm should be treated the same as patient specimens and run in accordance with the instructions accompanying the instrument, kit or reagent being used.

Reconstitution

Remove screw cape from the vial and pipette exactly 5 ml dest. water to the lyophilisate.
Keep the vial at rest (for about 30 min) in a light-protected place until the lyophilisate has completely solved. Swing carefully- do not shake. Avoid developing of foam.

Storage and Stability

Centronorm is stable until the expiration date when stored unopened at 2-8 °C After reconstitution:

1 day at 18 – 25 °C
2 days at 2 – 8 °C
1 month at – 20 °C

Warnings and Precautions

The blood donations used for production are tested with CE-marked test kits and found to be non-reactive for HBsAg, anti- HIV-1/2 und anti-HCV. In addition HIV and HCV is tested by PCR. Despite of that the danger of infection cannot be excluded with certainty. Due to that the control material has to be treated with the same care as patient samples. [3)]

Waste Management

Dispose of any discarded materials in accordance with the requirements of local regulations authorities.

Limitations

This product should not be used past the expiration date. This product is not intended for use as a standard.

Bibliography

1) Röhle G, Siekmann L. Quality assurance of quantitative determation. In: Thomas L., editor Clinical laboratory diagnostics, 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998.p.1393-1401
2) Richtlinien der Bundesärztekammer: Deutsches Ärzteblatt 1988; 85: B519-532
3) Biosafety in Microbiological and Biomedical Laboratories. U.S. Department of Health and Human Services, Washington 1993 (HHS Publication No. [CDC] 93-8395)

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Distributor

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