clonatest®

HUMAN MULTISERA NORMAL CE

PRESENTACION / CONTENTS		
REF	CT19800 HUMAN MULTISERA Normal	8 x 5 mL
Sólo para uso diagnóstico *in Vitro* Only for *in Vitro* diagnostic use		

HUMAN MULTISERA NORMAL

APLICACIONES

Suero control multiparamétrico liofilizado de origen humano, para el control de calidad en la verificación de la exactitud y precisión de los métodos cuantitativos.
Los componentes tienen concentraciones y actividades situadas dentro del intervalo de valores normales.

COMPOSICION

Suero humano. Aditivos biológicos y químicos.
La concentración/actividad de los componentes son específicos de cada lote. Los valores de cada parámetro están incluidos en la hoja de valores de cada lote.

RECONSTITUCION

1. Abrir el vial cuidadosamente, evitar la pérdida de liofilizado y pipetear exactamente **5.0 mL** de agua destilada.
2. Cerrar el vial cuidadosamente y disolver el contenido completamente mezclando suavemente, evitando la formación de espuma. No agitar. Dejarlo en reposo durante 30 minutos.

Una reconstitución inexacta puede causar resultados erróneos en los ensayos.

ESTABILIDAD

Estable hasta la fecha de caducidad indicada en el envase si se mantiene el vial cerrado a 2-8ºC y se evita la contaminación durante su uso.

No usar controles caducados o con signos de contaminación microbiana. Conservar los viales bien cerrados y protegidos de la luz después de su uso.

Estabilidad después de la reconstitución: 1 mes a –20 ºC*, 5 días a 2-8 ºC o 12 h a 15-25 ºC.

Estabilidad de la Bilirrubina T (conservado protegido de la luz) : 2 semanas a -20 ºC*, 24 h a 2-8 ºC o 8 h a 15-25 ºC.

Estabilidad de la Bilirrubina D (conservado protegido de la luz) : 2 semanas a -20 ºC*, 8 h a 2-8 ºC o 4 h a 15-25 ºC.

Estabilidad de la Fosfatasa Acida: 2 semanas a -20 ºC*, 24 h a 2-8 ºC o 4 h a 15-25 ºC.

*Congelado una sola vez

PRECAUCIONES

- Todos los componentes de origen humano han resultado ser negativos para el antígeno HBsAg, HCV y para el anti-HIV (1/2). Sin embargo, deben tratarse con precaución como potencialmente infecciosos.
- La contaminación bacteriana del control reconstituido puede causar disminución de la estabilidad de sus componentes.

INTENDED USE

Lyophilized multiparametric control on human serum, for use in quality control by monitoring accuracy and precision for quantitative methods.
With most constituent concentration and activities in the normal range.

COMPOSITION

Human serum. Biological and chemical additives.
The concentration/activities of the components are lot-specific. The exact values and ranges are given in the enclosed value sheets.

RECONSTITUTION

1. Careffully open one bottle, avoid the loss of lyophilizate and pipette in exactly **5.0 mL** of distilled water.
2. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling with 30 minutes. Avoid the formation of foam. Do not shake.

Inaccurate reconstitution can cause erroneous results.

STABILITY

The Control serum is stable until the expiration date on the label when stored tightly closed at 2-8ºC and contaminations are prevented during their use.

Do not use reagents over the expiration date or if there is visible evidence of microbial grown. Store tightly capped and protected from light when not in use.

Stability of the components in the reconstituted control: 1 month at -20ºC*, 5 days to 2-8ºC or 12 hours at 15-25ºC.

Stability of the Bilirubin T (stored protected from light): 2 weeks at -20ºC*, 24 hours to 2-8ºC or 8 hours at 15-25ºC.

Stability of the Bilirubin D (stored protected from light): 2 weeks at -20ºC*, 8 hours to 2-8ºC or 8 hours at 15-25ºC.

Stability of the Acid phosphatase: 2 weeks at -20ºC*, 24 hours to 2-8ºC or 4 hours at 15-25ºC.

*When frozen once

PRECAUTIONS

- Components from human origin have been tested and found negative for the presence of HBsAg, HCV and antibody to HIV (1/2). However handle cautiously as potentially infectious.
- The bacterial contamination of the reconstituted control will cause reductions in the stability of its components.

QUALITY SYSTEM CERTIFIED
ISO 9001 ISO 13485

LINEAR CHEMICALS S.L.
08390 Montgat, SPAIN (EU)

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CE

MEAN OF INSTRUMENTS

REF CT19800	LOT Nº 19777	EXP 2019-09

SUSTRATOS / SUBSTRATES

COMPONENTE *COMPONENT*	VALOR *TARGET*	RANGO *RANGE*	Analytical uncertainty		UNIDAD *UNIT*	MÉTODO *METHOD*
			1 SD	2 SD		
Albúmina *Albumin*	41.9 4.19	35.5 – 48.3 3.55 – 4.83	3.20 0.32	6.40 0.64	g/L g/dL	Colorimetric method Bromocresol Green (BCG)
Bilirrubina Directa *Direct Bilirubin*	13.68 0.80	10.73 – 16.63 0.63 – 0.97	1.48 0.09	2.95 0.17	µmol/L mg/dL	Colorimetric method with sample blank Modified Jendrassik & Grof
	8.72 0.51	6.84 – 10.60 0.40 – 0.62	1.94 0.06	1.88 0.11	µmol/L mg/dL	Colorimetric method without sample blank Modified Jendrassik & Grof
Bilirrubina Total *Total Bilirubin*	27.36 1.6	21.50 – 33.22 1.26 – 1.94	2.92 0.17	5.86 0.34	µmol/L mg/dL	Colorimetric method Modified Jendrassik & Grof
Calcio Arsenazo Calcium Arsenazo	2.36 9.46	2.12 – 2.60 8.50 – 10.4	0.12 0.48	0.24 0.96	mmol/L mg/dL	Colorimetric , Arsenazo III
Cloruros *Chloride*	97.8	90 – 105.6	3.9	7.80	mmol/L	Colorimetric method
Colesterol total *Total Cholesterol*	4.44 171	3.86 – 5.02 149– 193	0.29 11.0	0.58 22.0	mmol/L mg/dL	Enzymatic colorimetric method Cholesterol Oxidase
Creatinina *Creatinine*	116 1.31	92.8 – 139 1.05 – 1.57	11.60 0.13	23.20 0.26	µmol/L mg/dL	Kinetic colorimetric method. Creatinine Enzymatic
Fósforo inorgánico *Phosphorus inorganic*	1.41 4.37	1.13 – 1.69 3.50 – 5.24	0.14 0.44	0.28 0.87	mmol/L mg/dL	Phosphomolybdate UV method / Colorimetric method
Glucosa *Glucose*	6.64 120	5.64 – 7.64 102 – 138	0.50 9.00	1.00 18.00	mmol/L mg/dL	Glucose Oxidase. Endpoint. Enzymatic colorimetric method.
Hierro Ferrozine *Iron Ferrozine*	19.1 107	15.7 – 22.5 87.8 – 126.2	1.71 9.60	3.42 19.20	µmol/L µg/dL	Colorimetric method. Endpoint.
Hierro Cromazurol *Iron Cromazurol*	20.76 116	17.02 – 24.5 95.1– 136.9	1.87 10.5	3.74 20.9	µmol/L µg/dL	Colorimetric method. Endpoint.
Magnesio *Magnesium*	0.78 1.90	0.66 – 0.90 1.61 – 2.19	0.06 0.14	0.12 0.29	mmol/L mg/dL	Colorimetric method Calmagita
Potasio *Potassium*	4.20 3.97	3.86 – 4.54 3.65 – 4.29	0.17 0.16	0.34 0.32	mmol/L mmol/L	ISE method-direct ISE method-indirect
Potasio *Potassium*	4.48	4.02 – 4.95	0.23	0.47	mmol/L	Colorimetric method KINETIC
Proteínas Totales *Total Protein*	60.1 6.01	48.1 – 72.1 4.81 – 7.21	6.0 0.60	12.0 1.20	g/L g/dL	Colorimetric method Biuret endpoint
Sodio *Sodium*	149 138	142 – 156 131 – 145	3.5 3.5	7.0 7.0	mmol/L mmol/L	ISE method-direct ISE method-indirect

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COMPONENTE *COMPONENT*	VALOR *VALUE*	RANGO *RANGE*	Analytical uncertainty		UNIDAD *UNIT*	MÉTODO *METHOD*
			1 SD	2 SD		
Sodio *Sodium*	142.1	130.8 – 153.5	5.68	11.37	mmol/L	Colorimetric method KINETIC
Triglicéridos *Triglycerides*	1.13 100	0.95 – 1.31 84.0 – 116	0.09 8.0	0.18 16.0	mmol/L mg/dL	Enzymatic colorimetric method Lipase/GOD-PAP no correction
Urea *Urea*	7.06 42.4	5.89 – 8.23 35.4 – 49.5	0.59 3.52	1.17 7.04	mmol/L mg/dL	Enzymatic colorimetric. Berthelot UV Enzymatic method
Ácido úrico *Uric acid*	340 5.66	290 – 380 4.92 – 6.40	20 0.37	40 0.74	µmol/L mg/dL	Enzymatic colorimetric method Uricase / Peroxidase

ENZIMAS / ENZYMES

COMPONENTE *COMPONENT*	VALOR *VALUE*	RANGO *RANGE*	Analytical uncertainty		UNIDAD *UNIT*	MÉTODO *METHOD*
			1 SD	2 SD		
Fosfatasa alcalina *Alkaline phosphatase*	272	231 – 313	20.4	41	U/L	Diethanolamine buffer DEA, 37ºC. Colorimetric
ALT/GPT	37.5	29.9 – 44.9	3.75	7.5	U/L	TRIS no P5PIFCC/SFBC 37ºC. UV
α–Amilasa *α–Amylase*	88	74.8 – 101.2	6.6	13.2	U/L	Total. R. Liquid stable pNPG 37ºC
AST/GOT	41.7	33.2 – 50.2	4.25	8.5	U/L	TRIS no P5PIFCC/SFBC 37ºC. UV
CK Total	270	221 – 319	24.5	49.0	U/L	CK-NAC substrate start (DGKC) 37ºC. UV enzymatic
GGT *GGT*	44	37.51 – 50.75	3.3	6.6	U/L	G Glutamyl-3-Carbo-4-nitroanilide 37ºC.
LDH *LDH*	367	312 – 422	27.5	55	U/L	Pyruvate→Lactate SFBC 37ºC
Lipasa *Lipase*	46	36.7 – 55.3	4.6	9.3	U/L	Enzymatic colorimetric 37ºC

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