HUMAN MULTISERA NORMAL

PRESENTACIÓN		
REF 1980005	HUMAN MULTISERA Normal	5 x 5 mL
Sólo para uso diagnóstico *in vitro*		

HUMAN MULTISERA NORMAL

APLICACIONES

LINEAR Human Multisera Normal es un suero estabilizado y liofilizado de origen humano. Este control está elaborado a partir de sangre de donantes voluntarios de diferentes Bancos de Sangre. Los datos analíticos del **Human Multisera Normal** se han elaborado en colaboración entre laboratorios de reconocido prestigio, utilizando métodos de referencia.

COMPOSICIÓN

Human Multisera Normal no contiene conservantes. Contiene oligoelementos y polipéptidos, que aseguran que el control y las muestras se analizan bajo las mismas condiciones. El control, después de su reconstitución, tiene un aspecto claro (absorbancia a 700 nm <0.278).
Human Multisera se presenta con dos niveles de concentración: *Normal and Abnormal*.

ESTABILIDAD

- Liofilizado, estable hasta la fecha de caducidad indicada en la etiqueta conservado a 2-8 ºC.
- Después de su reconstitución: 1 mes a –20 ºC, 7 días a 2-8 ºC o 8 horas a 15-25 ºC.
- Características diferentes de estabilidad se aplicarán a:
  - Fosfatasa Acida, Bilirrubina, CK y LDH, 1-2% de pérdida por semana a –20 ºC.
  - Fosfatasa Alcalina, 1-2% pérdida por día a 2-8 ºC.
  - Fosfatasa Acida y LDH, 1-2% incremento por día a 2-8ºC.
  - Fósforo y Triglicéridos, 0.5% incremento por día a 2-8ºC.
  - Fosfatasa Acida, 1% incremento por hora a 15-25 ºC.
  - Fosfatasa Alcalina, 1% incremento por hora a 15-25ºC.
  - Bilirrubina y CK son sensibles a la luz.

RECONSTITUCIÓN

1. Abrir el tapón del vial, tirar cuidadosamente del obturador sin sacarlo completamente, y dejar que el aire entre por las ranuras situadas en la parte inferior del obturador. Evitar pérdidas del material liofilizado. Retirar completamente el obturador y adicionar (**5 mL**) de agua destilada.
2. Cerrar el vial y dejarlo reposar durante 30 minutos en la oscuridad. Disolver el contenido por mezcla suave, evitando la formación de espuma. No agitar. Entonces, el contenido del vial se utilizará como si fuera una muestra de suero.

VALORES ASIGNADOS

Los valores y los intervalos de concentración asignados a cada componente se han determinado usando el método analítico especificado en la tabla y solo se indican a título orientativo. Los resultados obtenidos pueden diferir ligeramente de los indicados como consecuencia de las técnicas e instrumentos utilizados en cada laboratorio. Es conveniente que cada laboratorio establezca sus propios parámetros de precisión.

PRECAUCIONES

Todos los componentes de origen humano han resultado ser negativos para el antígeno HBs, 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

LINEAR Human Multisera Normal is a stable and lyophilized serum of human origin. This control is produced from blood collected from thoroughly controlled voluntary blood donors of Blood Banks. The analytical data of **Human Multisera Normal** are eleborated in collaboration between expert laboratories in part using accepted reference methods.

COMPOSITION

Human Multisera Normal contains no preservatives. Contains trace elements and polypeptides, which ensure that control and test samples are analyzed under the same conditions. The control is clear after reconstitution (absorbance at 700 nm <0.278).
Human Multisera offers two different levels of concentration: *Normal and Abnormal*.

STABILITY

- In lyophilized stable until the expiration date printed on the label stored at 2-8 ºC.
- After reconstitution, unless otherwise specified: 1 month at –20 ºC, 7 days at 2-8 ºC or 8 hours at 15-25 ºC.
- Shorter stability characteristics apply to:
  - Acid Phosphatase, Bilirubin, CK and LDH, 1- 2% decrease per week at –20 ºC.
  - Phosphatase Alkaline, 1-2% increase per day at 2-8ºC.
  - Acid Phosphatase and LDH, 1-2% increase per day at 2-8 ºC.
  - Phosphatase and Triglycerides,0.5% increase per day (2-8ºC).
  - Acid Phosphatase, 1% decrease per hour at 15-25 ºC.
  - Phosphatase Alkaline, 1% increase per hour at 15-25 ºC.
  - Bilirubin and CK are sensitive to light.

RECONSTITUTION

1. Open the screw cap and carefully lift the rubber stopper without removing it completely and let the air enter the vial through the groove of the lower part of the stopper. Avoid loss of dried material. Then remove the rubber stopper and add exactly the (**5 mL**) of pure water.
2. Close the vial carefully and let it stand for 30 minutes in the dark. Dissolve the content completely by swirling gently, avoiding formation of foam. Do not shake.
   From now on the vial contents should be handled as an ordinary serum.

ASSIGNED VALUES

The assigned concentration values of each parameter and its intervals have been assigned using the method specified in the table below and are given for orientation only. Results may slightly differ from these values because of the different methods and instruments used in the different laboratories. It is useful that every laboratory establishes its own precision parameters.

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

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Cromatest

LINEAR

HUMAN MULTISERA NORMAL

REF **1980005**	LOT Nº **19839**	EXP **2021-01**

SUSTRATOS / SUBSTRATES

COMPONENTE *COMPONENT*	VALOR *TARGET*	RANGO *RANGE*	Analytical uncertainty		UNIDAD *UNIT*	MÉTODO *METHOD*
			1 SD	2 SD		
Albúmina *Albumin*	41.7 4.17	35.4 – 48.0 3.54 – 4.80	3.15 0.32	6.30 0.63	g/L g/dL	Colorimetric method Bromocresol Green (BCG)
Bilirrubina Directa *Direct Bilirubin*	12.83 0.75	11.47 – 14.19 0.67 – 0.83	0.68 0.04	1.36 0.08	µmol/L mg/dL	Colorimetric method with sample blank Modified Jendrassik & Grof
	9.58 0.56	8.56 – 10.60 0.50 – 0.62	0.51 0.03	1.02 0.06	µmol/L mg/dL	Colorimetric method without sample blank Modified Jendrassik & Grof
Bilirrubina Total *Total Bilirubin*	25.99 1.52	23.25 – 28.73 1.36 – 1.68	1.37 0.08	2.74 0.16	µmol/L mg/dL	Colorimetric method Modified Jendrassik & Grof
Calcio OCC *Calcium OCC*	2.00 8.02	1.80 – 2.20 7.21 – 8.83	0.10 0.41	0.20 0.81	mmol/L mg/dL	Cresolphtalein complexone OC
Calcio Arsenazo Calcium Arsenazo	2.11 8.45	1.91 – 2.31 7.61 – 9.29	0.1 0.42	0.2 0.84	mmol/L mg/dL	Colorimetric , Arsenazo III
Cloruros *Chloride*	100	92.0 - 108	4.0	8.0	mmol/L	Colorimetric method
Colesterol total *Total Cholesterol*	4.48 173	3.90 – 5.06 151– 195	0.29 11.00	0.58 22.00	mmol/L mg/dL	Enzymatic colorimetric method Cholesterol Oxidase
Creatinina *Creatinine*	123 1.39	98.4 – 148 1.11 – 1.67	12.30 0.14	24.60 0.28	µmol/L mg/dL	Kinetic colorimetric method. Creatinine Enzymatic
Fósforo inorgánico *Phosphorus inorganic*	1.31 4.06	1.11 – 1.51 3.38 – 4.74	0.1 0.34	0.2 0.68	mmol/L mg/dL	Phosphomolybdate UV method / Colorimetric method
Glucosa *Glucose*	6.52 117	5.54 – 7.50 99.8 – 134	0.49 8.60	0.98 17.20	mmol/L mg/dL	Glucose Oxidase. Endpoint. Enzymatic colorimetric method.
Hierro Ferrozine *Iron Ferrozine*	16.8 93.7	13.8 – 19.8 76.9 – 110.5	1.5 8.4	3.0 16.8	µmol/L µg/dL	Colorimetric method. Endpoint.
Hierro Cromazurol *Iron Cromazurol*	18.6 104	15.3 – 21.9 85.5 – 122.5	1.65 9.25	3.30 18.50	µmol/L µg/dL	Colorimetric method. Endpoint.
Magnesio *Magnesium*	0.83 2.02	0.71 – 0.95 1.72 – 2.32	0.06 0.15	0.12 0.30	mmol/L mg/dL	Colorimetric method Calmagita
Potasio *Potassium*	4.16 3.92	3.83 – 4.49 3.61 – 4.23	0.17 0.16	0.33 0.31	mmol/L mmol/L	ISE method-direct ISE method-indirect
Potasio *Potassium*	4.43	3.97 – 4.89	0.23	0.46	mmol/L	Colorimetric method KINETIC
Proteínas Totales *Total Protein*	58.4 5.84	46.7 – 70.1 4.67 – 7.01	5.85 0.59	11.70 1.17	g/L g/dL	Colorimetric method Biuret endpoint
Sodio *Sodium*	153 143	145 - 161 136 – 150	4.0 3.5	8.0 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*	146.2	134.6 – 157.8	5.8	11.6	mmol/L	Colorimetric method KINETIC
TIBC	38.6 216	30.5 – 46.8 170.6 – 261.4	4.05 22.6	8.1 45.2	µmol/L µg/dL	Colorimetric method Saturation
Triglicéridos *Triglycerides*	1.11 98.2	0.93 – 1.29 82.5 – 114	0.09 7.85	0.18 15.70	mmol/L mg/dL	Enzymatic colorimetric method Lipase/GOD-PAP no correction
Urea *Urea*	7.2 43.4	6.0 – 8.4 36.2 – 50.6	0.6 3.6	1.2 7.2	mmol/L mg/dL	Enzymatic colorimetric. Berthelot UV Enzymatic method
Ácido úrico *Uric acid*	330 5.48	290 – 370 4.77 – 6.19	20 0.36	40 0.71	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 ácida *Acid phosphatase*	23.02 27.80	15.42 – 30.62 18.6– 37	3.8 4.6	7.6 9.2	U/L U/L	Prostatic. 1-Naphthyl Phosphatase Kinetic 37ºC Total. 1-Naphthyl Phosphatase Kinetic 37ºC With Pentane diol Activation. Colorimetric method
Fosfatasa alcalina *Alkaline phosphatase*	279 218 179	237 – 321 185 – 251 152 - 206	20.9 16 13	41.8 33 27	U/L	Diethanolamine buffer DEA, 37ºC. Colorimetric Diethanolamine buffer DEA, 30ºC. Colorimetric Diethanolamine buffer DEA, 25ºC. Colorimetric
ALT/GPT	37.9 28.0 21.4	30.3 – 45.5 22.4 – 33.6 17.1 – 25.7	3.8 2.8 2.1	7.6 5.6 4.3	U/L	TRIS no P5PIFCC/SFBC 37ºC. UV TRIS no P5PIFCC/SFBC 30ºC. UV TRIS no P5PIFCC/SFBC 25ºC. UV
α–Amilasa *α–Amylase*	94	80 – 108	7	14	U/L	Total. R. Liquid stable pNPG 37ºC
AST/GOT	42.3 28.8 20.3	33.7 – 51.0 22.9 – 34.7 16.2 – 24.5	4.3 2.9 2.1	8.6 5.8 4.1	U/L	TRIS no P5PIFCC/SFBC 37ºC. UV TRIS no P5PIFCC/SFBC 30ºC. UV TRIS no P5PIFCC/SFBC 25ºC. UV
Colinesterasa *Cholinesterase*	4373	3498 - 5248	437.50	875.00	U/L	Enzymatic colorimetric Butyrylthiocholin (37ºC)
CK Total	302 189 128	248 – 356 155 – 223 105 - 151	27 17 11.50	54 34 23	U/L	CK-NAC substrate start (DGKC) 37ºC. UV enzymatic CK-NAC substrate start (DGKC) 30ºC. UV enzymatic CK-NAC substrate start (DGKC) 25ºC. UV enzymatic
GGT *GGT*	48.5 38.1 30.3	41.3 – 55.7 32.4 – 43.8 25.8 – 34.9	3.6 2.8 2.3	7.2 5.7 4.5	U/L	G Glutamyl-3-Carbo-4-nitroanilide 37ºC. G Glutamyl-3-Carbo-4-nitroanilide 30ºC. G Glutamyl-3-Carbo-4-nitroanilide 25ºC. Colorimetric enzymatic method
LDH *LDH*	443 320 225	377 – 509 272 – 368 191 – 259	33 24 17	66 48 34	U/L	Pyruvate→Lactate SFBC 37ºC Pyruvate→Lactate SFBC 30ºC Pyruvate→Lactate SFBC 25ºC
Lipasa *Lipase*	43.9	35.1 – 52.7	4.4	8.8	U/L	Enzymatic colorimetric 37ºC

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