

HUMAN ASSAYED MULTI-SERA - LEVEL 2 (HUM ASY CONTROL 2)

CAT. NO. HNI530	GTIN: 05055273203783	SIZE: 20 x 5ml
CAT. NO. HS2611	GTIN: 05055273203813	SIZE: 5 x 5ml
LOT NO. 1738UN	EXPIRY: 2028-01-28	

INTENDED USE

This product is intended for *in vitro* diagnostic use, in the quality control of diagnostic assays. The Human Assayed Multi-sera is for the control of accuracy.

DEVICE DESCRIPTION

The Human Assayed Multi-sera is supplied at 2 levels, level 2 and 3. Target values and ranges are supplied for the analytes listed in the values section at both levels.

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly.

Health and Safety Data Sheets are available on request.

STORAGE AND STABILITY

OPENED: Store refrigerated (+2°C to +8°C). Reconstituted serum is stable for 8 hours at +15°C to +25°C or 7 days at +2°C to +8°C, and 28 days when frozen once at -18°C to -24°C. (See Limitations)

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

LIMITATIONS

For Total & Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25µl - 30µl) of 0.7M Acetic acid solution to 1ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total and Prostatic Acid Phosphatase is stable for 2 hours at +15°C to +25°C, 2 days at +2°C to +8°C, and 28 days when frozen once at -18°C to -24°C.

Alkaline Phosphatase levels in the reconstituted serum will rise over the stability period. It is recommended that the reconstituted serum is allowed to stand for 1 hour at +15°C to +25°C before measurement.

Bilirubin in the serum is light sensitive and it is recommended that the serum is stored in the dark. Stored in the dark, it is stable for 4 days at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.

GLDH is stable for 2 days at +2°C to +8°C.

NEFA is stable for 1 day at +2°C to +8°C.

Total PSA is stable for 4 days at +2°C to +8°C, or 28 days in aliquots frozen at -18°C to -24°C.

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components.

Different lot numbers of this control should not be interchanged, as the values assigned to the controls vary from lot to lot.

The control should not be used as a calibration material.

Due to the zinc content in some batches of rubber stoppers, the QC and calibrator material should be aliquoted into polypropylene tubes and stored at +2°C to +8°C to ensure stable zinc levels throughout the stability period.

PREPARATION FOR USE

The Human Assayed Multi-sera is supplied lyophilised.

- Carefully reconstitute each vial of lyophilised serum with exactly 5ml of distilled water at +15°C to +25°C. Close the bottle and allow to stand for 30 minutes before use. Ensure contents are completely dissolved by swirling gently. Avoid formation of foam. Do not shake.
- Refer to the Control section of the individual analyser application.
- Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

MATERIALS PROVIDED

Human Assayed Multi-sera - Level 2 20 x 5ml / 5 x 5ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

Due to the variation caused by test equipment, test reagents and laboratory technique, the quoted ranges are provided for guidance. It is recommended that these ranges are used until each laboratory has established its own ranges, based on individual laboratory requirements.

Each batch of Assayed Human Serum Control is assigned at Randox Laboratories and a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories.

With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean $\pm 2S.D.$

If an instrument specific value is not available, refer to the Method section. If necessary, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

NOTES

- ® All trademarks recognised.
- (1) Applies only in Germany. Ranges established according to the Guidelines of the Federal Chamber of Physicians in Germany.
- (2) Values established by reference laboratories officially recognised by the Federal Chamber of Physicians in Germany.
- (3) DGKC: German Society for Clinical Chemistry.
- (4) IFCC: International Federation of Clinical Chemistry.
- (5) SCE: Scandinavian Committee on Enzymes.

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Table of Content

Method

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Method		Human Assayed Multi-Sera - Level 2					
Lot. No: 1738UN Cat. No: HN1530 Expiry: 2028/01/28							
Size: 20 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Acid Phosphatase (Total)	U/l	15	10	20	2.50	5.00	Naphthyl phos. sub., kinetic
Albumin	g/dl	3.97	3.37	4.57	0.300	0.600	Bromocresol Green
	g/l	39.7	33.7	45.7	3.00	6.00	
Alkaline Phosphatase	U/l	267	227	307	20.0	40.0	Diethanolamine buffer, DEA
alpha - HBDH	U/l	208	164	252	22.0	44.0	Oxobutyrate < 10 mmol/l
ALT (GPT)	U/l	40	32	48	4.00	8.00	Colorimetric
	U/l	40	32	48	4.00	8.00	Tris Buffer Without P5P
Amylase Total	U/l	77	65	89	6.00	12.0	I.L. 2-chloro-pNPG3
Apolipoprotein A1	g/l	1.14	0.935	1.35	0.105	0.210	Immunoturbidimetric
	mg/dl	114	93.5	135	10.5	21.0	
Apolipoprotein B	g/l	0.691	0.567	0.815	0.062	0.124	Immunoturbidimetric
	mg/dl	69.1	56.7	81.5	6.20	12.4	
AST (GOT)	U/l	37	30	44	3.50	7.00	Colorimetric
	U/l	37	30	44	3.50	7.00	Tris Buffer Without P5P
Bicarbonate	mmol/l	13.2	10.5	15.9	1.35	2.70	Manometric
Bile Acids	µmol/l	24.1	19.3	28.9	2.40	4.80	4th Generation Colorimetric
	µmol/l	25.7	20.6	30.8	2.55	5.10	5th Generation Colorimetric
Bilirubin Direct	mg/dl	1.16	0.916	1.40	0.120	0.240	Dichlorophenyl Diazonium
	µmol/l	19.9	15.7	24.1	2.10	4.20	
Bilirubin Total	mg/dl	1.85	1.46	2.24	0.195	0.390	Diazo With Sulphanilic Acid
	µmol/l	31.6	25.0	38.2	3.30	6.60	
	mg/dl	1.74	1.37	2.11	0.185	0.370	Dichlorophenyl Diazonium
	µmol/l	29.8	23.5	36.1	3.15	6.30	
Calcium	mg/dl	8.62	7.76	9.48	0.430	0.860	Arsenazo III
	mmol/l	2.15	1.94	2.36	0.105	0.210	
	mg/dl	8.66	7.79	9.53	0.435	0.870	Ion Selective Electrode
	mmol/l	2.16	1.94	2.38	0.110	0.220	
Calcium Ionised	mg/dl	4.17	3.75	4.59	0.210	0.420	Ion Selective Electrode
	mmol/l	1.04	0.936	1.14	0.050	0.100	
	mg/dl	4.33	3.90	4.76	0.215	0.430	Spectrophotometric
	mmol/l	1.08	0.972	1.19	0.055	0.110	
Chloride	mmol/l	100	92.0	108	4.00	8.00	Colorimetric
	mmol/l	99.1	91.2	107	3.95	7.90	ISE Direct
Cholesterol	mg/dl	153	133	173	10.0	20.0	Cholesterol Oxidase - IDMS
	mmol/l	3.95	3.44	4.46	0.255	0.510	
Cholinesterase	U/l	5620	4496	6744	562	1124	Colorimetric - Benzoylcholine
CK Total	U/l	199	163	235	18.0	36.0	CK-NAC (IFCC)

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Size: 20 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Copper	µg/dl	106	84.8	127	10.5	21.0	Colorimetric
	µmol/l	16.6	13.3	19.9	1.65	3.30	
Creatinine	mg/dl	1.41	1.13	1.69	0.140	0.280	Jaffe Rate Blanked
	µmol/l	125	100	150	12.5	25.0	
D-3-Hydroxybutyrate	mmol/l	0.300	0.255	0.345	0.023	0.045	Tris buffer 100mmol pH 8.5
Digoxin	ng/ml	1.23	0.984	1.48	0.125	0.250	Immunoturbidimetric
	nmol/l	1.57	1.26	1.88	0.155	0.310	
gamma-GT	U/l	59	50	68	4.50	9.00	Gamma glut'3-carb'4-nitro(IFCC)
Glucose	mg/dl	110	93.5	127	8.50	17.0	Glucose Oxidase
	mmol/l	6.13	5.21	7.05	0.460	0.920	
HDL - Cholesterol	mg/dl	47.9	40.7	55.1	3.60	7.20	Direct HDL, PEGME
	mmol/l	1.24	1.05	1.43	0.095	0.190	
	mg/dl	51.0	43.4	58.6	3.80	7.60	HDL Ultra/Accel Selective Detergent
	mmol/l	1.32	1.12	1.52	0.100	0.200	
Immunoglobulin A	g/l	1.94	1.46	2.42	0.240	0.480	Turbidimetric (IFCC Cal.)
	mg/dl	194	146	242	24.0	48.0	
Immunoglobulin G	g/l	7.08	5.81	8.35	0.635	1.27	Turbidimetric (IFCC Cal.)
	mg/dl	708	581	835	63.5	127	
Immunoglobulin M	g/l	0.839	0.671	1.01	0.086	0.171	Turbidimetric (IFCC Cal.)
	mg/dl	83.9	67.1	101	8.55	17.1	
Iron	µg/dl	108	88.6	127	9.50	19.0	Colorimetric without ppt.
	µmol/l	19.3	15.8	22.8	1.75	3.50	
Lactate	mg/dl	12.3	10.1	14.5	1.10	2.20	Ion Selective Electrode
	mmol/l	1.36	1.12	1.60	0.120	0.240	
	mg/dl	11.9	9.76	14.0	1.05	2.10	UV-LDH
	mmol/l	1.32	1.08	1.56	0.120	0.240	
LD (LDH)	U/l	408	347	469	30.5	61.0	P to L Scandinavian & Dutch
	U/l	397	337	457	30.0	60.0	P to L, German methods
Lipase	U/l	38	30	46	4.00	8.00	Colorimetric Dimension (LIP Kit)
	U/l	35	28	42	3.50	7.00	Colorimetric Roche
Lithium	mg/dl	0.672	0.591	0.753	0.041	0.081	Ion Selective Electrode
	mmol/l	0.968	0.852	1.08	0.056	0.112	
	mg/dl	0.685	0.603	0.767	0.041	0.082	Spectrophotometric
	mmol/l	0.987	0.869	1.11	0.062	0.123	
Magnesium	mg/dl	2.29	2.02	2.56	0.135	0.270	Arsenazo III
	mmol/l	0.942	0.829	1.06	0.059	0.118	
	mg/dl	2.32	2.04	2.60	0.140	0.280	Xylidyl Blue
	mmol/l	0.956	0.841	1.07	0.057	0.114	
NEFA	mmol/l	1.27	1.02	1.52	0.125	0.250	Colorimetric

Method		Human Assayed Multi-Sera - Level 2					
Lot. No: 1738UN Cat. No: HN1530 Expiry: 2028/01/28							
Size: 20 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Phosphate Inorganic	mg/dl	5.02	4.27	5.77	0.375	0.750	Phosphomolybdate UV
	mmol/l	1.62	1.38	1.86	0.120	0.240	
Potassium	mmol/l	3.79	3.49	4.09	0.150	0.300	Colorimetric
	mmol/l	3.78	3.48	4.08	0.150	0.300	ISE method - direct
Protein Total	g/dl	5.70	4.56	6.84	0.570	1.14	Biuret reaction, end point
	g/l	57.0	45.6	68.4	5.70	11.4	
Sodium	mmol/l	139	132	146	3.50	7.00	ISE method - direct
TIBC	µg/dl	241	190	292	25.5	51.0	Calculated from Transferrin
	µmol/l	43.1	34.0	52.2	4.55	9.10	
	µg/dl	246	194	298	26.0	52.0	Direct Colorimetric
	µmol/l	44.0	34.8	53.2	4.60	9.20	
Transferrin	g/l	1.94	1.55	2.33	0.195	0.390	Immunoturbidimetric
	mg/dl	194	155	233	19.5	39.0	
Triglycerides	mg/dl	99.1	83.2	115	7.95	15.9	Lipase/GPO-PAP No Correction
	mmol/l	1.12	0.941	1.30	0.090	0.180	
Urea	mg/dl	46.3	39.4	53.2	3.45	6.90	Urease, kinetic
	mg/dl (BUN)	21.6	18.4	24.8	1.60	3.20	
	mmol/l	7.71	6.55	8.87	0.580	1.16	
Uric Acid (Urate)	mg/dl	5.98	5.20	6.76	0.390	0.780	Uricase Perox. with ascorb. ox @ 546nm
	mmol/l	0.356	0.310	0.402	0.023	0.046	
Zinc	µg/dl	167	134	200	16.5	33.0	Colorimetric with deprot.
	µmol/l	25.6	20.5	30.7	2.55	5.10	