

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. 1711UN	EXPIRY: 2028-06-28	

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

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- (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.

EC	REP	Randox Teoranta, Meenmore, Dungloe, Donegal, F94 TV06, Ireland
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Method		Human Assayed Multi-Sera - Level 2					
Lot. No: 1711UN Cat. No: HN1530 / HS2611 Expiry: 2028/06/28							
Size: 20 x 5 ml / 5 x 5ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Albumin	g/dl	4.00	3.40	4.60	0.300	0.600	Bromocresol Green
	g/l	40.0	34.0	46.0	3.00	6.00	
Alkaline Phosphatase	U/l	175	149	201	13.0	26.0	Colorimetric
	U/l	266	226	306	20.0	40.0	Diethanolamine buffer, DEA
alpha - HBDH	U/l	211	167	255	22.0	44.0	Oxobutyrate < 10 mmol/l
ALT (GPT)	U/l	36	29	43	3.50	7.00	Tris Buffer Without P5P
Amylase Total	U/l	77	65	89	6.00	12.0	Beckman CNPG3 (Master Cal)
Apolipoprotein A1	g/l	1.06	0.869	1.25	0.095	0.190	Immunoturbidimetric
	mg/dl	106	86.9	125	9.50	19.0	
Apolipoprotein B	g/l	0.626	0.513	0.739	0.057	0.113	Immunoturbidimetric
	mg/dl	62.6	51.3	73.9	5.65	11.3	
AST (GOT)	U/l	36	29	43	3.50	7.00	Tris Buffer Without P5P
Bicarbonate	mmol/l	12.1	9.60	14.6	1.25	2.50	Enzymatic
Bile Acids	µmol/l	24.2	19.4	29.0	2.40	4.80	5th Generation Colorimetric
	µmol/l	24.1	19.3	28.9	2.40	4.80	Enzymatic Colorimetric
Bilirubin Direct	mg/dl	1.04	0.822	1.26	0.110	0.220	Diazo With Sulphanilic Acid
	µmol/l	17.8	14.1	21.5	1.85	3.70	
	mg/dl	1.07	0.845	1.30	0.115	0.230	Dichlorophenyl Diazonium
	µmol/l	18.3	14.5	22.1	1.90	3.80	
Bilirubin Total	mg/dl	1.73	1.37	2.09	0.180	0.360	Diazo With Sulphanilic Acid
	µmol/l	29.5	23.3	35.7	3.10	6.20	
	mg/dl	1.60	1.26	1.94	0.170	0.340	Dichlorophenyl Diazonium
	µmol/l	27.3	21.6	33.0	2.85	5.70	
Calcium	mg/dl	8.46	7.61	9.31	0.425	0.850	Arsenazo III
	mmol/l	2.11	1.90	2.32	0.105	0.210	
Chloride	mmol/l	102	93.8	110	4.00	8.00	Colorimetric
	mmol/l	96.3	88.6	104	3.85	7.70	ISE Direct
Cholesterol	mg/dl	158	137	179	10.5	21.0	Cholesterol Oxidase - IDMS
	mmol/l	4.08	3.55	4.61	0.265	0.530	
CK Total	U/l	181	148	214	16.5	33.0	CK-NAC (IFCC)
Copper	µg/dl	107	85.6	128	10.5	21.0	Colorimetric
	µmol/l	16.8	13.4	20.2	1.70	3.40	
Creatinine	mg/dl	1.27	1.02	1.52	0.125	0.250	Enzymatic
	µmol/l	112	89.6	134	11.0	22.0	
	mg/dl	1.27	1.02	1.52	0.125	0.250	Jaffe Rate Blanked
	µmol/l	112	89.6	134	11.0	22.0	
D-3-Hydroxybutyrate	mmol/l	0.270	0.230	0.310	0.020	0.040	Tris buffer 100mmol pH 8.5
Digoxin	ng/ml	1.30	1.04	1.56	0.130	0.260	Immunoturbidimetric
	nmol/l	1.66	1.33	1.99	0.165	0.330	

Method		Human Assayed Multi-Sera - Level 2					
Lot. No: 1711UN Cat. No: HN1530 / HS2611 Expiry: 2028/06/28							
Size: 20 x 5 ml / 5 x 5ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
gamma-GT	U/l	50	43	57	3.50	7.00	Gamma glut'3-carb'4-nitro(IFCC)
Glucose	mg/dl	108	91.8	124	8.00	16.0	Glucose Oxidase
	mmol/l	6.00	5.10	6.90	0.450	0.900	
HDL - Cholesterol	mg/dl	47.5	40.4	54.6	3.55	7.10	Direct HDL, Clearance method
	mmol/l	1.23	1.05	1.41	0.090	0.180	
	mg/dl	54.4	46.2	62.6	4.10	8.20	HDL Ultra/Accel Selective Detergent
	mmol/l	1.41	1.20	1.62	0.105	0.210	
Immunoglobulin A	g/l	1.96	1.47	2.45	0.245	0.490	Turbidimetric (IFCC Cal.)
	mg/dl	196	147	245	24.5	49.0	
Immunoglobulin G	g/l	7.65	6.27	9.03	0.690	1.38	Turbidimetric (IFCC Cal.)
	mg/dl	765	627	903	69.0	138	
Immunoglobulin M	g/l	0.914	0.731	1.10	0.093	0.186	Turbidimetric (IFCC Cal.)
	mg/dl	91.4	73.1	110	9.30	18.6	
Iron	µg/dl	105	86.1	124	9.50	19.0	Colorimetric without ppt.
	µmol/l	18.7	15.3	22.1	1.70	3.40	
Lactate	mg/dl	15.0	12.3	17.7	1.35	2.70	Colorimetric - Lactate oxidase
	mmol/l	1.66	1.36	1.96	0.150	0.300	
LD (LDH)	U/l	415	353	477	31.0	62.0	P to L Scandinavian & Dutch
	U/l	403	343	463	30.0	60.0	
Lipase	U/l	37	30	44	3.50	7.00	Colorimetric Roche
	U/l	39	31	47	4.00	8.00	Other Colorimetric
Magnesium	mg/dl	2.21	1.94	2.48	0.135	0.270	Arsenazo III
	mmol/l	0.911	0.802	1.02	0.055	0.109	
	mg/dl	2.21	1.94	2.48	0.135	0.270	Enzymatic
	mmol/l	0.908	0.799	1.02	0.056	0.112	
	mg/dl	2.24	1.97	2.51	0.135	0.270	Xylidyl Blue
	mmol/l	0.922	0.811	1.03	0.054	0.108	
NEFA	mmol/l	1.20	0.960	1.44	0.120	0.240	Colorimetric
Osmolality	mOsm/ Kg	298	238	358	30.0	60.0	Calculated
Phosphate Inorganic	mg/dl	4.46	3.79	5.13	0.335	0.670	Phosphomolybdate UV
	mmol/l	1.44	1.22	1.66	0.110	0.220	
Potassium	mmol/l	4.10	3.77	4.43	0.165	0.330	Enzymatic
	mmol/l	3.93	3.62	4.24	0.155	0.310	ISE method - direct
Protein Total	g/dl	5.64	4.51	6.77	0.565	1.13	Biuret reaction, end point
	g/l	56.4	45.1	67.7	5.65	11.3	
Sodium	mmol/l	145	138	152	3.50	7.00	Enzymatic
	mmol/l	139	132	146	3.50	7.00	ISE method - direct

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Size: 20 x 5 ml / 5 x 5ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
TIBC	µg/dl	268	212	324	28.0	56.0	Direct Colorimetric
	µmol/l	47.9	37.8	58.0	5.05	10.1	
Transferrin	g/l	1.96	1.57	2.35	0.195	0.390	Immunoturbidimetric
	mg/dl	196	157	235	19.5	39.0	
Triglycerides	mg/dl	98.2	82.5	114	7.90	15.8	Lipase/GPO-PAP No Correction
	mmol/l	1.11	0.932	1.29	0.090	0.180	
Urea	mg/dl	42.1	35.8	48.4	3.15	6.30	Urease, kinetic
	mg/dl (BUN)	19.6	16.7	22.5	1.45	2.90	
	mmol/l	7.01	5.96	8.06	0.525	1.05	
Uric Acid (Urate)	mg/dl	5.55	4.83	6.27	0.360	0.720	Uricase Perox. with ascorb. ox @ 546nm
	mmol/l	0.330	0.287	0.373	0.022	0.043	
Zinc	µg/dl	153	122	184	15.5	31.0	Colorimetric without deprot.
	µmol/l	23.5	18.8	28.2	2.35	4.70	