

PRODUCT INFORMATION

HN1530

Lot: 1706UN

Please note the concentration of analytes Total and Prostatic Acid Phosphatase is low and undetectable in Lot 1706UN compared to previous normal controls. Targets and Ranges have not been provided.

For any queries regarding this, please contact technical.services@randox.com

qCCS 670

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

CAT. NO. HNI1530	GTIN: 05055273203783	SIZE: 20 x 5ml
CAT. NO. HS2611	GTIN: 05055273203813	SIZE: 5 x 5ml
LOT NO. 1706UN	EXPIRY: 2028-02-28	

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

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: 1706UN Cat. No: HN1530 Expiry: 2028-02-28							
Size: 20 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Albumin	g/dl	4.06	3.45	4.67	0.305	0.610	Bromocresol Green
	g/l	40.6	34.5	46.7	3.05	6.10	
Alkaline Phosphatase	U/l	314	267	361	23.5	47.0	Diethanolamine buffer, DEA
ALT (GPT)	U/l	38	30	46	4.00	8.00	Tris Buffer Without P5P
Amylase Total	U/l	87	74	100	6.50	13.0	Agappe - CNPG3
	U/l	83	71	95	6.00	12.0	I.L. 2-chloro-pNPG3
AST (GOT)	U/l	34	27	41	3.50	7.00	Tris Buffer Without P5P
Bilirubin Direct	mg/dl	1.35	1.07	1.63	0.140	0.280	Dichlorophenyl Diazonium
	µmol/l	23.0	18.2	27.8	2.40	4.80	
Bilirubin Total	mg/dl	1.65	1.30	2.00	0.175	0.350	Dichlorophenyl Diazonium
	µmol/l	28.2	22.3	34.1	2.95	5.90	
Calcium	mg/dl	8.82	7.94	9.70	0.440	0.880	Agappe - ARSENAZO
	mmol/l	2.20	1.98	2.42	0.110	0.220	
	mg/dl	8.58	7.72	9.44	0.430	0.860	Arsenazo III
	mmol/l	2.14	1.93	2.35	0.105	0.210	
	mg/dl	8.62	7.76	9.48	0.430	0.860	Ion Selective Electrode
	mmol/l	2.15	1.94	2.36	0.105	0.210	
Chloride	mmol/l	95.5	87.9	103	3.75	7.50	ISE Direct
Cholesterol	mg/dl	164	143	185	10.5	21.0	Cholesterol Oxidase - IDMS
	mmol/l	4.25	3.70	4.80	0.275	0.550	
CK Total	U/l	199	163	235	18.0	36.0	CK-NAC (IFCC)
Creatinine	mg/dl	1.45	1.16	1.74	0.145	0.290	Alkaline picrate no deproteinisation
	µmol/l	128	102	154	13.0	26.0	
gamma-GT	U/l	51	43	59	4.00	8.00	Gamma glut'3-carb'4-nitro(IFCC)
Glucose	mg/dl	107	91.0	123	8.00	16.0	Agappe - GOD-PAP
	mmol/l	5.92	5.03	6.81	0.445	0.890	
	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	49.8	42.3	57.3	3.75	7.50
mmol/l		1.29	1.10	1.48	0.095	0.190	
	mg/dl	56.0	47.6	64.4	4.20	8.40	HDL Ultra/Accel Selective Detergent
	mmol/l	1.45	1.23	1.67	0.110	0.220	
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	13.2	10.8	15.6	1.20	2.40	Ion Selective Electrode
	mmol/l	1.46	1.20	1.72	0.130	0.260	
	mg/dl	13.2	10.8	15.6	1.20	2.40	UV-LDH
	mmol/l	1.46	1.20	1.72	0.130	0.260	

Method		Human Assayed Multi-Sera - Level 2					
Lot. No: 1706UN Cat. No: HN1530 Expiry: 2028-02-28							
Size: 20 x 5 ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
LD (LDH)	U/l	418	355	481	31.5	63.0	Agappe - SCE
	U/l	394	335	453	29.5	59.0	P to L Scandinavian & Dutch
Lipase	U/l	41	33	49	4.00	8.00	Colorimetric Dimension (LIP Kit)
	U/l	37	30	44	3.50	7.00	Colorimetric Roche
Lithium	mg/dl	0.624	0.549	0.699	0.038	0.075	Ion Selective Electrode
	mmol/l	0.899	0.791	1.01	0.056	0.111	
Magnesium	mg/dl	2.41	2.12	2.70	0.145	0.290	Agappe - XYLIDYL BLUE
	mmol/l	0.991	0.872	1.11	0.060	0.119	
	mg/dl	2.18	1.92	2.44	0.130	0.260	Arsenazo III
	mmol/l	0.897	0.789	1.01	0.057	0.113	
	mg/dl	2.24	1.97	2.51	0.135	0.270	Xylidyl Blue
	mmol/l	0.921	0.810	1.03	0.055	0.109	
Phosphate Inorganic	mg/dl	4.43	3.77	5.09	0.330	0.660	Phosphomolybdate UV
	mmol/l	1.43	1.22	1.64	0.105	0.210	
Potassium	mmol/l	3.89	3.58	4.20	0.155	0.310	ISE method - direct
Protein Total	g/dl	5.80	4.64	6.96	0.580	1.16	Biuret reaction, end point
	g/l	58.0	46.4	69.6	5.80	11.6	
Sodium	mmol/l	138	131	145	3.50	7.00	ISE method - direct
	mmol/l	137	130	144	3.50	7.00	
	mmol/l	138	131	145	3.50	7.00	
TIBC	µg/dl	249	197	301	26.0	52.0	Calculated from Transferrin
	µmol/l	44.5	35.2	53.8	4.65	9.30	
Triglycerides	mg/dl	96.5	81.1	112	7.75	15.5	Lipase/GPO-PAP No Correction
	mmol/l	1.09	0.916	1.26	0.085	0.170	
Urea	mg/dl	47.1	40.0	54.2	3.55	7.10	Urease, kinetic
	mg/dl (BUN)	21.9	18.6	25.2	1.65	3.30	
	mmol/l	7.83	6.66	9.00	0.585	1.17	
Uric Acid (Urate)	mg/dl	5.60	4.87	6.33	0.365	0.730	Uricase Perox. with ascorb. ox @ 546nm
	mmol/l	0.333	0.290	0.376	0.022	0.043	
Zinc	µg/dl	149	119	179	15.0	30.0	Colorimetric with deprot.
	µmol/l	22.8	18.2	27.4	2.30	4.60	