

CAT.NO. HN1530
LOT.NO. 1416UN

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

EXPIRY: 2023-06-28
SIZE: 20 x 5ml

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.

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 or 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. 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.

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

ASSIGNED VALUES

Each batch of assayed human serum is submitted to reference laboratories for assignment against international Reference Standards. Where international Reference Standards are unavailable, Reference Methods are used. Values are also collected from approx. 3000 laboratories worldwide and using a unique statistical analysis, a value is assigned.

With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean $\pm 2S.D.$ This results in an assayed serum with extremely accurate values, which may be confidently used by laboratories to ensure the accuracy of their methods. If an instrument specific value is not available, refer to the Mean of all Instruments section. If necessary, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

MEAN OF ALL INSTRUMENT

ASSAYED HUMAN SERA 2 (HUMAN ASY CONTROL 2)

Lot. No. 1416UN Cat. No. HN1530

Size 20 x 5ml Expiry 2023-06-28

Range

Analyte	Unit	Target	Low	High	1SD	2SD	Methods
Acid Phosphatase (Total)	U/l	12/2	8/17	16/2	2/02	4/03	1-Naphthyl Phosphate Substrate Kinetic 37°C
Albumin	g/dl	4/14	3/52	4/76	0/31	0/62	Bromocresol Green
Alkaline Phosphatase	U/l	279	237	321	21/00	42/00	Diethanolamine buffer DEA 37°C(DGKC)
ALT(GPT)	U/l	36	29	43	3/50	7/00	Tris buffer without P5P 37°C
Amylase Total	U/l	93	79	107	7/00	14/00	pNP Maltotriose substrates 37°C (CNP63)
	U/l	100	85	115	7/50	15/00	Liquid Ethylidene pNPG7 37°C (EP6G7)
Apolipoprotein A-1	mg/dl	98/6	80/9	116	8/85	17/70	Immunoturbidimetric
Apolipoprotein B	mg/dl	64/2	52/6	75/8	5/80	11/60	Immunoturbidimetric
AST(GOT)	U/l	35	28	42	3/50	7/00	Tris buffer without P5P 37°C
Bilirubin Direct	mg/dl	1/29	1/01	1/57	0/14	0/28	Dichlorophenyl Diazonium (DPD)
	mg/dl	1/25	0/989	1/51	0/13	0/26	Diazo with Sulphanilic Acid
	mg/dl	1/29	1/01	1/57	0/14	0/28	Diazo with Dichloroaniline (DCA)
Bilirubin Total	mg/dl	2/12	1/68	2/56	0/22	0/44	Diazo with Dichloroaniline (DCA)
	mg/dl	1/73	1/36	2/1	0/19	0/37	Diazo with Sulphanilic Acid
	mg/dl	1/57	1/24	1/9	0/17	0/33	Dichlorophenyl Diazonium (DPD)
Calcium	mg/dl	8/74	7/86	9/62	0/44	0/88	Cresolphthalein complexone (CPC)
	mg/dl	8/86	7/98	9/74	0/44	0/88	Arsenazo III
Chloride	mmol/l	102	93/8	110	4/10	8/20	Colorimetric
	mmol/l	97/4	89/6	105	3/90	7/80	ISE indirect
	mmol/l	98/8	90/9	107	3/95	7/90	ISE direct
Cholesterol	mg/dl	156	135	177	10/50	21/00	Cholesterol Oxidase
CK Total	U/l	186	153	219	16/50	33/00	CK-NAC (IFCC) 37°C
Copper	µg/dl	96/7	77/6	116	9/55	19/10	Colorimetric
Creatinine	mg/dl	1/57	1/25	1/89	0/16	0/32	Enzymatic UV method
	mg/dl	1/55	1/23	1/87	0/16	0/32	Jaffe rate blanked
D-3-Hydroxybutyrate	mmol/l	0/28	0/24	0/32	0/02	0/04	Tris buffer 100mmol pH 8.5
gamma-GT	U/l	49	42	56	3/50	7/00	Gamma glutamyl-3-carboxy-4-nitroanilide 37°C (SZASZ)
Glucose	mg/dl	113	96	130	8/50	17/00	Glucose oxidase
HDL - Cholesterol	mg/dl	51/0	43/2	58/8	3/90	7/80	Direct Clearance Method
	mg/dl	50/6	42/8	58/4	3/90	7/80	Direct precipitation
Immunoglobulin A	mg/dl	174	131	217	21/50	43/00	Immunoturbidimetric
Immunoglobulin G	mg/dl	682	559	805	61/50	123/00	Immunoturbidimetric
Immunoglobulin M	mg/dl	84/6	67/7	102	8/45	16/90	Immunoturbidimetric
Iron	µg/dl	108	88/9	127	9/55	19/10	Colorimetric without ppt.
Lactate	mg/dl	14/0	11/4	16/6	1/30	2/60	Colorimetric Lactate Oxidase
	mg/dl	14/1	11/5	16/7	1/30	2/60	UV LDH
LD (LDH)	U/l	408	347	469	30/50	61/00	P->L German methods 37°C (DGKC)
Lipase	U/l	32	26	38	3/00	6/00	Other Colorimetric 37°C
	U/l	44	35	53	4/50	9/00	Randox Colorimetric 37°C
Lithium	mmol/l	1/01	0/89	1/14	0/06	0/13	Ion selective electrode
Magnesium	mg/dl	2/10	1/85	2/35	0/13	0/25	Calmagite
	mg/dl	2/09	1/84	2/34	0/13	0/25	Xylidyl Blue
NEFA	mmol/l	1/28	1/09	1/47	0/10	0/19	Colorimetric
Phosphorus	mg/dl	4/28	3/63	4/93	0/33	0/65	Phosphomolybdate UV
Potassium	mmol/l	3/95	3/63	4/27	0/16	0/32	ISE method - direct
	mmol/l	4/00	3/68	4/32	0/16	0/32	ISE method - indirect
Protein Total	g/dl	5/78	4/63	6/93	0/58	1/15	Biuret reaction end point
Sodium	mmol/l	141	134	148	3/50	7/00	ISE method - direct
	mmol/l	143	136	150	3/50	7/00	ISE method - indirect
TIBC	µg/dl	268	211	325	28/50	57/00	Direct Colorimetric
Transferrin	mg/dl	196	157	235	19/50	39/00	Immunoturbidimetric
Triglycerides	mg/dl	93/8	78/6	109	7/60	15/20	Lipase/GPO-PAP no correction
Urea	mg/dl	42/9	36/5	49/3	3/20	6/40	Urease kinetic
	mg/dl	20/0	17	23	1/50	3/00	BUN
Uric Acid (Urate)	mg/dl	5/81	5/06	6/56	0/38	0/75	Uricase peroxidase no ascorbate oxidase (TOOS)
	mg/dl	5/80	5/04	6/56	0/38	0/76	Uricase Peroxidase with ascorbate oxidase@546nm(TBHBA)
Zinc	µmol/l	26/90	21/5	32/3	2/70	5/40	Colorimetric
	µg/dl	176	140	212	18/00	36/00	