

CAT.NO. HE1532
LOT.NO. 1066UE

**HUMAN ASSAYED MULTI-SERA - LEVEL 3
(HUM ASY CONTROL 3)**

**EXPIRY: 2023-01-28
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 3 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 3 (HUMAN ASY CONTROL 3)

Lot. No. 1066UE Cat. No HE1532

Size	20 x 5ml	Expiry	2023-01-28		Range			
Analyte	Unit	Target	Low	High	1SD	2SD	Methods	
Acid Phosphatase (Total)	U/l	30.5	20.4	40.6	5.05	10.1	1-Naphthyl Phosphate Substrate Kinetic 37°C	
Albumin	g/dl	2.96	2.52	3.4	0.22	0.44	Bromocresol Green	
Alkaline Phosphatase	U/l	495	421	569	37	74	Diethanolamine buffer DEA 37°C(DGKC)	
ALT(GPT)	U/l	138	111	165	13.5	27	Tris buffer without P5P 37°C	
Amylase Total	U/l	308	262	354	23	46	pNP Maltotriose substrates 37°C (CNPG3)	
	U/l	314	267	361	23.5	47	Liquid Ethylidene pNPG7 37°C (EPSG7)	
Apolipoprotein A-1	mg/dl	121	99.2	143	10.9	21.8	Immunoturbidimetric	
Apolipoprotein B	mg/dl	58.2	47.7	68.7	5.25	10.5	Immunoturbidimetric	
AST(GOT)	U/l	150	120	180	15	30	Tris buffer without P5P 37°C	
Bilirubin Direct	mg/dl	1.64	1.29	1.99	0.18	0.35	Diazo with Sulphanilic Acid	
	mg/dl	1.6	1.27	1.93	0.17	0.33	Diazo with Dichloroaniline (DCA)	
Bilirubin Total	mg/dl	5.7	4.5	6.9	0.6	1.2	Diazo with Dichloroaniline (DCA)	
	mg/dl	5.06	4	6.12	0.53	1.06	Diazo with Sulphanilic Acid	
	mg/dl	4.79	3.78	5.8	0.51	1.01	Dichlorophenyl Diazonium (DPD)	
Calcium	mg/dl	12.8	11.5	14.1	0.65	1.3	Cresolphthalein complexone (CPC)	
	mg/dl	12.8	11.5	14.1	0.65	1.3	Arsenazo III	
Cholesterol	mg/dl	273	237	309	18	36	Cholesterol Oxidase	
Chloride	mmol/l	116	107	125	4.5	9	Colorimetric	
	mmol/l	118	109	127	4.5	9	ISE indirect	
	mmol/l	118	109	127	4.5	9	ISE direct	
CK Total	U/l	507	416	598	45.5	91	CK-NAC (IFCC) 37°C	
Copper	µg/dl	169	135	203	17	34	Colorimetric	
Creatinine	mg/dl	4.33	3.46	5.2	0.44	0.87	Enzymatic UV method	
	mg/dl	4.25	3.4	5.1	0.43	0.85	Jaffe rate blanked	
D-3-Hydroxybutyrate	mmol/l	1.18	1.01	1.35	0.09	0.17	Tris buffer 100mmol pH 8.5	
gamma-GT	U/l	160	136	184	12	24	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C (SZASZ)	
Glucose	mg/dl	281	240	322	20.5	41	Glucose oxidase	
HDL - Cholesterol	mg/dl	77.6	66	89.2	5.8	11.6	Direct Clearance Method	
	mg/dl	70.3	59.8	80.8	5.25	10.5	Direct precipitation	
Immunoglobulin A	mg/dl	155	116	194	19.5	39	Immunoturbidimetric	
Immunoglobulin G	mg/dl	641	526	756	57.5	115	Immunoturbidimetric	
Immunoglobulin M	mg/dl	65.1	52.1	78.1	6.5	13	Immunoturbidimetric	
Iron	µg/dl	219	179	259	20	40	Colorimetric without ppt.	
Lactate	mg/dl	50.8	41.6	60	4.6	9.2	Colorimetric Lactate Oxidase	
	mg/dl	49.6	40.7	58.5	4.45	8.9	UV LDH	
LDH	U/l	688	585	791	51.5	103	P->L German methods 37°C (DGKC)	
Lipase	U/l	53	42	64	5.5	11	Roche Colorimetric 37°C	
	U/l	85	69	101	8	16	Randox Colorimetric 37°C	
Lithium	mmol/l	2.23	1.96	2.5	0.14	0.27	Ion selective electrode	
Magnesium	mg/dl	4.2	3.72	4.68	0.24	0.48	Calmagite	
	mg/dl	4.35	3.82	4.88	0.27	0.53	Xylidyl Blue	
NEFA	mmol/l	0.52	0.45	0.6	0.04	0.08	Colorimetric	
Phosphorus	mg/dl	6.88	5.83	7.93	0.53	1.05	Phosphomolybdate UV	
Potassium	mmol/l	6.02	5.53	6.51	0.25	0.49	ISE method - direct	
	mmol/l	6.08	5.59	6.57	0.25	0.49	ISE method - indirect	
Protein Total	g/dl	4.49	3.59	5.39	0.45	0.9	Biuret reaction end point	
Sodium	mmol/l	160	152	168	4	8	ISE method - direct	
	mmol/l	162	154	170	4	8	ISE method - indirect	
TIBC	µg/dl	234	185	283	24.5	49	Direct Colorimetric	
Transferrin	mg/dl	177	142	212	17.5	35	Immunoturbidimetric	
Triglycerides	mg/dl	258	218	298	20	40	Lipase/GPO-PAP no correction	
Uric Acid (Urate)	mg/dl	9.34	8.13	10.6	0.61	1.21	Uricase peroxidase no ascorbate oxidase (TOOS)	
	mg/dl	9.27	8.06	10.5	0.61	1.21	Uricase Peroxidase with ascorbate oxidase@546nm(TBHBA)	
Urea	mg/dl	117	99.8	134	8.6	17.2	Urease kinetic	
	mg/dl	54.7	46.5	62.9	4.1	8.2	BUN	
Zinc	µmol/l	36.4	29.2	43.6	3.6	7.2	Colorimetric	
	µg/dl	238	191	285	23.5	47		