

**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, 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's 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.

1. 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.
2. Refer to the Control section of the individual analyser application.
3. Refrigerate any unused material. Prior to reuse, mix contents thoroughly.

**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.

Analyte	unit	Target	low	high	1SD	2SD	methods
alpha-HBDH	U/l	409	323	495	43.00	86.00	Oxobutyrate < 10 mmol/l 37°C
Acid Phosphatase (Total)	U/l	24.2	16.2	32.2	4.00	8.00	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	28.7	24.4	33.0	2.15	4.30	Bromocresol Green
	g/dl	2.87	2.44	3.30	0.22	0.43	
Alkaline Phosphatase	U/l	515	438	592	38.50	77.00	Diethanolamine buffer DEA 37°C (DGKC)
	U/l	356	303	409	26.50	53.00	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	143	115	171	14.00	28.00	Tris buffer without P5P 37°C
Amylase Pancreatic	U/l	260	221	299	19.50	39.00	Immunoinhibition EPS substrate 37°C
Amylase Total	U/l	294	250	338	22.00	44.00	pNP Maltotrioxide substrates 37°C (CNPG3)
	U/l	295	251	339	22.00	44.00	Siemens - blocked pNPG7 37°C
	U/l	316	269	363	23.50	47.00	Randox Liquid Ethylidene pNPG7 37°C (EPG7)
Apolipoprotein A-1	g/l	0.95	0.78	1.12	0.09	0.17	Immunoturbidimetric
	mg/dl	94.6	77.6	112	8.50	17.00	
Apolipoprotein B	g/l	0.61	0.50	0.72	0.05	0.11	Immunoturbidimetric
	mg/dl	60.7	49.8	71.6	5.45	10.90	
AST (GOT)	U/l	157	125	189	16.00	32.00	Tris buffer without P5P 37°C
Bicarbonate	mmol/l	16.6	13.2	20.0	1.70	3.40	Colorimetric
	mmol/l	16.8	13.3	20.3	1.75	3.50	Enzymatic
	mmol/l	17.0	13.5	20.5	1.75	3.50	Ion selective electrode
Bile Acids	mp/l	47.0	37.6	56.4	4.70	9.40	4th Generation Colorimetric
	µmol/l	46.4	37.1	55.7	4.65	9.30	5th Generation Colorimetric
Bilirubin Direct	mg/dl	1.66	1.30	2.02	0.18	0.36	Dichlorophenyl Diazonium (DPD)
	mg/dl	1.74	1.37	2.11	0.19	0.37	Diazo with Sulphanilic Acid
	mg/dl	1.77	1.39	2.15	0.19	0.38	Diazo with Dichloroaniline (DCA)
	mg/dl	1.65	1.30	2.00	0.18	0.35	Oxidation to Biliverdin/Vanadate
	mg/dl	1.89	1.49	2.29	0.20	0.40	Modified Jendrassik
Bilirubin Total	mg/dl	5.08	4.01	6.15	0.54	1.07	Diazo with Dichloroaniline (DCA)
	mg/dl	4.87	3.84	5.90	0.52	1.03	Diazo with Sulphanilic Acid
	mg/dl	4.57	3.62	5.52	0.48	0.95	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.70	3.71	5.69	0.50	0.99	Diazonium ion
	mg/dl	5.49	4.33	6.65	0.58	1.16	Oxidation to Biliverdin/Vanadate
	mg/dl	5.46	4.31	6.61	0.58	1.15	Modified Jendrassik
Calcium	mg/dl	12.5	11.3	13.7	0.60	1.20	Cresolphthalein complexone (CPC)
	mg/dl	12.0	10.8	13.2	0.60	1.20	Ion selective electrode
	mg/dl	12.5	11.2	13.8	0.65	1.30	Arsenazo III
Chloride	mmol/l	116	107	125	4.50	9.00	Colorimetric
	mmol/l	113	104	122	4.50	9.00	ISE indirect
	mmol/l	113	104	122	4.50	9.00	ISE direct

Analyte	unit	Target	low	high	1SD	2SD	methods
Cholesterol	mg/dl	293	255	331	19.00	38.00	Cholesterol Oxidase
Cholinesterase	U/l	4990	3992	5988	499.50	998.00	Colorimetric Butyrylthiocholine 37°C
CK Total	U/l	527	432	622	47.50	95.00	CK-NAC serum start (DGKC) 37°C
	U/l	512	420	604	46.00	92.00	CK-NAC substrate start (DGKC) 37°C
	U/l	504	414	594	45.00	90.00	CK-NAC (IFCC) 37°C
Copper	µg/dl	172	138	206	17.00	34.00	Atomic absorption
	µg/dl	169	135	203	17.00	34.00	Colorimetric
Cortisol	µg/dl	34.4	25.8	43.0	4.30	8.60	Roche Cobas E411
Creatinine	mg/dl	4.38	3.50	5.26	0.44	0.88	Jaffe rate blanked
	mg/dl	4.47	3.58	5.36	0.45	0.89	Enzymatic UV method
	mg/dl	4.46	3.57	5.35	0.45	0.89	Creatinine PAP method
D-3-Hydroxybutyrate	mmol/l	1.13	0.96	1.30	0.08	0.17	Tris buffer 100mmol pH 8.5
Digoxin	ng/ml	3.22	2.58	3.86	0.32	0.64	Immunoturbidimetric
Folate	nmol/l	10.8	8.24	13.4	1.30	2.60	Roche Cobas 6000/8000
	ng/ml	4.78	3.63	5.93	0.58	1.15	
Free T4	ng/dl	3.61	2.71	4.51	0.45	0.90	Abbott Architect
	pg/ml	36.1	27.1	45.1	4.50	9.00	
	ng/dl	6.79	5.09	8.49	0.85	1.70	Siemens Centaur XP/XPT/Classic
	pg/ml	67.9	50.9	84.9	8.50	17.00	
	ng/dl	5.09	3.81	6.37	0.64	1.28	Roche Elecsys
	pg/ml	50.9	38.1	63.7	6.40	12.80	
	ng/dl	7.00	5.26	8.74	0.87	1.74	Vitros ECi
	pg/ml	70.0	52.6	87.4	8.70	17.40	
	ng/dl	4.52	3.39	5.65	0.57	1.13	Beckman Access
	pg/ml	45.2	33.9	56.5	5.65	11.30	
	ng/dl	5.19	3.89	6.49	0.65	1.30	Roche Cobas E411
	pg/ml	51.9	38.9	64.9	6.50	13.00	
Gentamicin	µg/ml	9.75	7.79	11.7	0.98	1.96	Immunoturbidimetric
gamma-GT	U/l	168	143	193	12.50	25.00	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C (SZASZ)
	U/l	178	152	204	13.00	26.00	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
GLDH	U/l	36	28	44	3.50	7.00	Triethanolamine buffer 50 mmol 37°C
Glucose	mg/dl	281	240	322	20.50	41.00	Glucose dehydrogenase
	mg/dl	285	241	329	22.00	44.00	Hexokinase
	mg/dl	283	240	326	21.50	43.00	Glucose oxidase
HDL - Cholesterol	mg/dl	117	100	134	8.50	17.00	Direct HDL PPD
	mg/dl	146	124	168	11.00	22.00	Direct HDL Roche 3rd generation

Analyte	unit	Target	low	high	1SD	2SD	methods
HDL - Cholesterol	mg/dl	145	123	167	11.00	22.00	Direct HDL Roche 4rd generation
	mg/dl	109	93.0	125	8.00	16.00	Direct Clearance Method
Immunoglobulin A	g/l	1.45	1.09	1.81	0.18	0.36	Immunoturbidimetric
	mg/dl	145	109	181	18.00	36.00	
Immunoglobulin G	g/l	6.13	5.03	7.23	0.55	1.10	Immunoturbidimetric
	mg/dl	613	503	723	55.00	110.00	
Immunoglobulin M	g/l	0.73	0.59	0.88	0.07	0.15	Immunoturbidimetric
	mg/dl	73.4	58.7	88.1	7.35	14.70	
Iron	µmol/l	38.0	31.2	44.8	3.40	6.80	Colorimetric without ppt.
	µg/dl	212	174	250	19.00	38.00	
Lactate	mmol/l	5.39	4.42	6.36	0.49	0.97	Colorimetric Lactate Oxidase
	mg/dl	48.6	39.8	57.4	4.40	8.80	
	mmol/l	4.95	4.06	5.84	0.45	0.89	Ortho Vitros Microslide Systems
	mg/dl	44.6	36.6	52.6	4.00	8.00	
LAP	mmol/l	5.35	4.39	6.31	0.48	0.96	Enzymatic Electrode
	mg/dl	48.2	39.6	56.8	4.30	8.60	
LAP	U/l	15	13	17	1.00	2.00	NAGEL 37°C
	U/l	333	283	383	25.00	50.00	L->P 37°C
	U/l	710	603	817	53.50	107.00	P->L German methods 37°C (DGKC)
	U/l	706	600	812	53.00	106.00	P->L SFBC 37°C
Lipase	U/l	373	317	429	28.00	56.00	L->P I FCC 37°C
	U/l	707	567	847	70.00	140.00	Ortho Vitros Microslide System 37°C
	U/l	58	47	69	5.50	11.00	Roche Colorimetric 37°C
	U/l	63	50	76	6.50	13.00	Other Colorimetric 37°C
Lithium	U/l	83	66	100	8.50	17.00	Randox Colorimetric 37°C
	mmol/l	2.08	1.83	2.33	0.13	0.25	Ion selective electrode
	mmol/l	2.01	1.77	2.25	0.12	0.24	Spectrophotometric
Magnesium	mmol/l	2.03	1.79	2.27	0.12	0.24	Randox Colorimetric
	mg/dl	3.99	3.52	4.46	0.24	0.47	Arsenazo III
	mg/dl	4.01	3.52	4.50	0.25	0.49	Calmagite
	mg/dl	4.13	3.62	4.64	0.26	0.51	Xylidyl Blue
NEFA	mg/dl	4.03	3.55	4.51	0.24	0.48	Enzymatic
	mmol/l	0.43	0.37	0.50	0.03	0.07	Colorimetric
Osmolality	mOsm/kg	349	279	419	35.00	70.00	Calculated
	mOsm/kg	384	307	461	38.50	77.00	Freezing point depression
Paracetamol	mg/l	93.6	74.9	112	9.35	18.70	Colorimetric

Analyte	unit	Target	low	high	1SD	2SD	methods
Phosphate Inorganic (PHOS)	mg/dl	7.07	6.01	8.13	0.53	1.06	Phosphomolybdate enzymatic
	mg/dl	7.07	6.01	8.13	0.53	1.06	Phosphomolybdate UV
Potassium	mmol/l	6.20	5.70	6.70	0.25	0.50	Enzymatic
	mmol/l	6.11	5.62	6.60	0.25	0.49	Ortho Vitros Microslide Systems
	mmol/l	6.11	5.62	6.60	0.25	0.49	ISE method - direct
	mmol/l	6.19	5.70	6.68	0.25	0.49	ISE method - indirect
Protein Total	g/l	43.7	34.9	52.5	4.40	8.80	Biuret reaction end point
	g/dl	4.37	3.49	5.25	0.44	0.88	
	g/l	43.0	34.4	51.6	4.30	8.60	Biuret reaction kinetic
	g/dl	4.30	3.44	5.16	0.43	0.86	
PSA Total	ng/ml	24.9	18.7	31.1	3.10	6.20	Roche Elecsys Modular E170
	ng/ml	25.6	19.2	32.0	3.20	6.40	bioMerieux VIDAS TPSA
	ng/ml	20.4	15.3	25.5	2.55	5.10	Abbott Architect
	ng/ml	26.0	19.5	32.5	3.25	6.50	Cobas E411
	ng/ml	25.2	18.9	31.5	3.15	6.30	Roche Cobas 6000/8000
Salicylate	mg/dl	12.0	9.59	14.4	1.21	2.41	Gravimetric
Sodium	mmol/l	161	153	169	4.00	8.00	Enzymatic
	mmol/l	156	148	164	4.00	8.00	Ortho Vitros Microslide Systems
	mmol/l	158	150	166	4.00	8.00	ISE method - direct
	mmol/l	160	152	168	4.00	8.00	ISE method - indirect
Theophylline	µg/ml	25.0	20.0	30.0	2.50	5.00	Gravimetric
Thyroid Stimulating Hormone	µU/ml	1.06	0.85	1.27	0.11	0.21	Abbott Architect
	µU/ml	1.35	1.08	1.62	0.14	0.27	bioMerieux VIDAS TSH
	µU/ml	1.48	1.18	1.78	0.15	0.30	Roche Cobas E411
	µU/ml	1.48	1.18	1.78	0.15	0.30	Roche Cobas 6000/8000
TIBC	µg/dl	226	178	274	24.00	48.00	Removal of excess free iron
	µg/dl	240	190	290	25.00	50.00	FE+UIBC(saturation with iron)
	µg/dl	243	192	294	25.50	51.00	Direct Colorimetric
	µg/dl	225	177	273	24.00	48.00	Calculated from Transferrin
	µg/dl	240	190	290	25.00	50.00	Randox Direct
Tobramycin	µg/ml	7.30	5.85	8.75	0.73	1.45	Gravimetric

Analyte	unit	Target	low	high	1SD	2SD	methods	
Total T3	ng/ml	2.02	1.51	2.53	0.26	0.51	Abbott Architect	
	ng/dl	202	151	253	25.50	51.00		
	ng/ml	2.99	2.24	3.74	0.38	0.75	Siemens Centaur XP/XPT/Classic	
	ng/dl	299	224	374	37.50	75.00		
	ng/ml	2.64	1.98	3.30	0.33	0.66	Roche Cobas E411	
	ng/dl	264	198	330	33.00	66.00		
	ng/ml	2.66	1.99	3.33	0.34	0.67	Roche Cobas 6000/8000	
	ng/dl	266	199	333	33.50	67.00		
	Total T4	µg/dl	16.8	12.6	21.0	2.10	4.20	Abbott Architect
		ng/ml	168	126	210	21.00	42.00	
µg/dl		16.8	12.6	21.0	2.10	4.20	Siemens Centaur XP/XPT/Classic	
ng/ml		168	126	210	21.00	42.00		
µg/dl		15.9	11.9	19.9	2.00	4.00	Siemens Immulite 2000/2500	
ng/ml		159	119	199	20.00	40.00		
µg/dl		13.4	10.1	16.7	1.65	3.30	Roche Cobas E411	
ng/ml		134	101	167	16.50	33.00		
µg/dl		13.4	10.1	16.7	1.65	3.30	Roche Cobas 6000/8000	
ng/ml		134	101	167	16.50	33.00		
Transferrin	g/l	1.65	1.32	1.98	0.17	0.33	Immunoturbidimetric	
	mg/dl	165	132	198	16.50	33.00		
Triglycerides	mg/dl	257	215	299	21.00	42.00	Lipase/GPO-PAP no correction	
	mg/dl	259	218	300	20.50	41.00	L/G Kinase EP. no correction	
Urea	mg/dl	122	104	140	9.00	18.00	Urease end point	
	mg/dl	121	103	139	9.00	18.00	Urease kinetic	
	mg/dl	114	96.8	131	8.60	17.20	Ortho Vitros Microslide Systems	
	mg/dl	56.7	48.2	65.2	4.25	8.50	BUN	
Uric Acid (Urate)	mg/dl	9.49	8.25	10.7	0.62	1.24	Uricase peroxidase no ascorbate oxidase (TOOS)	
	mg/dl	9.44	8.22	10.7	0.61	1.22	Uricase Peroxidase with ascorbate oxidase @ 546nm	
Vitamin B12	pmol/l	195	156	234	19.50	39.00	Roche Cobas E411	
	pg/ml	264	211	317	26.50	53.00		
Zinc	µg/dl	248	199	297	24.50	49.00	Colorimetric with deproteinisation	