

PRODUCT INFORMATION

HE1532 / HS2611

1439UE

Please note that in Human Assayed Multi-Sera Level 3, lot 1439UE:

- Total Bilirubin is stable for **3 days** at +2°C to +8°C.
Do not store at +15°C to +25°C. Do not freeze.
- Total PSA is stable for **3 days** at +2°C to +8°C.
Aliquots are stable for 28 days when frozen at -18°C to -24°C.

CCS INC1510

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

CAT. NO.	HE1532	GTIN:	05055273203608	SIZE	20 x 5ml
CAT. NO.	HS2611	GTIN:	05055273203813	SIZE	5 x 5ml
LOT NO.	1439UE	EXPIRY:	2028-11-28		

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, Direct Bilirubin is stable for 4 days and Total Bilirubin is stable for 3 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 3 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.

Lipase may generate error flags when run on Dry Chemistry systems. If error flags are generated, the control should be diluted 1:1 with distilled water.

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.

MATERIALS PROVIDED

Human Assayed Multi-sera - Level 3 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.

EC	REP
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Table of Content

Method

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Method		Human Assayed Multi-Sera - Level 3					
Lot. No: 1439UE Cat. No: HE1532 Expiry: 2028/11/28							
Size: 20 x 5ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Albumin	g/dl	3.03	2.58	3.48	0.225	0.450	Bromocresol Green
	g/l	30.3	25.8	34.8	2.25	4.50	
Alkaline Phosphatase	U/l	593	504	682	44.5	89.0	Diethanolamine buffer, DEA
alpha - HBDH	U/l	388	307	469	40.5	81.0	Oxobutyrate < 10 mmol/l
ALT (GPT)	U/l	132	106	158	13.0	26.0	Colorimetric
	U/l	131	105	157	13.0	26.0	Tris Buffer Without P5P
Amylase Total	U/l	276	235	317	20.5	41.0	Beckman CNPG3 (Master Cal)
Apolipoprotein A1	g/l	1.09	0.894	1.29	0.100	0.200	Immunoturbidimetric
	mg/dl	109	89.4	129	10.0	20.0	
Apolipoprotein B	g/l	0.586	0.481	0.691	0.053	0.105	Immunoturbidimetric
	mg/dl	58.6	48.1	69.1	5.25	10.5	
AST (GOT)	U/l	138	110	166	14.0	28.0	Colorimetric
	U/l	139	111	167	14.0	28.0	Tris Buffer Without P5P
Bile Acids	µmol/l	46.1	36.9	55.3	4.60	9.20	Enzymatic Colorimetric
Bilirubin Direct	mg/dl	1.78	1.41	2.15	0.185	0.370	Diazo With Sulphanilic Acid
	µmol/l	30.5	24.1	36.9	3.20	6.40	
Bilirubin Total	mg/dl	4.97	3.93	6.01	0.520	1.04	Diazo With Sulphanilic Acid
	µmol/l	84.9	67.1	103	9.05	18.1	
	mg/dl	4.60	3.63	5.57	0.485	0.970	Dichlorophenyl Diazonium
	µmol/l	78.6	62.1	95.1	8.25	16.5	
Calcium	mg/dl	12.3	11.1	13.5	0.600	1.20	Arsenazo III
	mmol/l	3.06	2.75	3.37	0.155	0.310	
Chloride	mmol/l	112	103	121	4.50	9.00	Colorimetric
	mmol/l	113	104	122	4.50	9.00	ISE Direct
Cholesterol	mg/dl	302	263	341	19.5	39.0	Cholesterol Oxidase - IDMS
	mmol/l	7.83	6.81	8.85	0.510	1.02	
CK Total	U/l	562	461	663	50.5	101	CK-NAC (IFCC)
Copper	µg/dl	167	134	200	16.5	33.0	Colorimetric
	µmol/l	26.3	21.0	31.6	2.65	5.30	
Creatinine	mg/dl	3.93	3.14	4.72	0.395	0.790	Jaffe Rate Blanked
	µmol/l	348	278	418	35.0	70.0	
D-3-Hydroxybutyrate	mmol/l	1.12	0.952	1.29	0.085	0.170	Tris buffer 100mmol pH 8.5
Digoxin	ng/ml	3.05	2.44	3.66	0.305	0.610	Immunoturbidimetric
	nmol/l	3.91	3.13	4.69	0.390	0.780	
gamma-GT	U/l	163	139	187	12.0	24.0	Gamma glut'3-carb'4-nitro(IFCC)
GLDH	U/l	30	24	36	3.00	6.00	Triethanolamine buffer
Glucose	mg/dl	281	239	323	21.0	42.0	Glucose Oxidase
	mmol/l	15.6	13.3	17.9	1.15	2.30	

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Analyte	Unit	Target	Low	High	1SD	2SD	Method
HDL - Cholesterol	mg/dl	91.5	77.8	105	6.75	13.5	Direct HDL, Clearance method
	mmol/l	2.37	2.01	2.73	0.180	0.360	
	mg/dl	98.1	83.4	113	7.45	14.9	HDL Ultra/Accel Selective Detergent
	mmol/l	2.54	2.16	2.92	0.190	0.380	
Immunoglobulin A	g/l	1.71	1.28	2.14	0.215	0.430	Turbidimetric (IFCC Cal.)
	mg/dl	171	128	214	21.5	43.0	
Immunoglobulin G	g/l	6.83	5.60	8.06	0.615	1.23	Turbidimetric (IFCC Cal.)
	mg/dl	683	560	806	61.5	123	
Immunoglobulin M	g/l	0.792	0.634	0.950	0.079	0.158	Turbidimetric (IFCC Cal.)
	mg/dl	79.2	63.4	95.0	7.90	15.8	
Iron	µg/dl	230	189	271	20.5	41.0	Colorimetric without ppt.
	µmol/l	41.2	33.8	48.6	3.70	7.40	
Lactate	mg/dl	55.5	45.5	65.5	5.00	10.0	UV-LDH
	mmol/l	6.16	5.05	7.27	0.555	1.11	
LD (LDH)	U/l	740	629	851	55.5	111	P to L Scandinavian & Dutch
	U/l	733	623	843	55.0	110	P to L, German methods
Lipase	U/l	72	58	86	7.00	14.0	Colorimetric Roche
Magnesium	mg/dl	4.20	3.70	4.70	0.250	0.500	Arsenazo III
	mmol/l	1.73	1.52	1.94	0.105	0.210	
	mg/dl	4.18	3.68	4.68	0.250	0.500	Xylidyl Blue
	mmol/l	1.72	1.51	1.93	0.105	0.210	
NEFA	mmol/l	0.440	0.352	0.528	0.044	0.088	Colorimetric
Phosphate Inorganic	mg/dl	7.16	6.09	8.23	0.535	1.07	Phosphomolybdate UV
	mmol/l	2.31	1.96	2.66	0.175	0.350	
Potassium	mmol/l	5.94	5.46	6.42	0.240	0.480	Colorimetric
	mmol/l	5.97	5.49	6.45	0.240	0.480	ISE Direct
	mmol/l	5.93	5.46	6.40	0.235	0.470	ISE method - direct
Protein Total	g/dl	4.72	3.78	5.66	0.470	0.940	Biuret reaction, end point
	g/l	47.2	37.8	56.6	4.70	9.40	
Sodium	mmol/l	161	153	169	4.00	8.00	ISE Direct
	mmol/l	157	149	165	4.00	8.00	ISE method - direct
TIBC	µg/dl	271	214	328	28.5	57.0	Direct Colorimetric
	µmol/l	48.5	38.3	58.7	5.10	10.2	
Transferrin	g/l	1.73	1.38	2.08	0.175	0.350	Immunoturbidimetric
	mg/dl	173	138	208	17.5	35.0	
Triglycerides	mg/dl	252	212	292	20.0	40.0	Lipase/GPO-PAP No Correction
	mmol/l	2.85	2.39	3.31	0.230	0.460	

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Size: 20 x 5ml		Range					
Analyte	Unit	Target	Low	High	1SD	2SD	Method
Urea	mg/dl	110	93.5	127	8.50	17.0	Urease, kinetic
	mg/dl (BUN)	51.2	43.5	58.9	3.85	7.70	
	mmol/l	18.3	15.6	21.0	1.35	2.70	
Uric Acid (Urate)	mg/dl	8.91	7.75	10.1	0.595	1.19	Uricase Perox. with ascorb. ox @ 546nm
	mmol/l	0.530	0.461	0.599	0.035	0.069	
Zinc	µg/dl	211	169	253	21.0	42.0	Colorimetric with deprot.
	µmol/l	32.3	25.8	38.8	3.25	6.50	