RANDOX 2797 CE

ASSAYED BOVINE MULTI-SERA - LEVEL 3 (BOV ASY CONTROL 3)

CAT. NO. AE1032 **LOT NO.** 355SE
SIZE: 20 x 5 ml **EXPIRY:** 2025-09-28
GTIN: 05055273200119

INTENDED USE
This product is intended for *in vitro* diagnostic use, in the quality control of diagnostic assays. The Assayed Bovine Multi-sera is for the control of accuracy.

DEVICE DESCRIPTION
The Assayed Bovine Multi-sera is supplied at 3 levels, level 1, 2 and 3. Target values and ranges are supplied for the analytes listed in the value section at 3 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.

Assayed Bovine Multi-sera is manufactured from bovine sera. Human source material, which has been added, 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 –20°C (see Limitations).

UNOPENED: Store refrigerated (+2°C to +8°C). Stable to expiration date printed on individual vials.

LIMITATIONS
For Total and Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25 - 30 µl) of 0.7M Acetic acid solution to 1 ml of the serum. After stabilisation Total & 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 –20°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, Bilirubin is stable for 2 days at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.
GLDH is stable for 1 day at 2 - 8°C.
PSA is stable for 4 days at +2°C to +8°C, or 28 days in aliquots frozen at –20°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 Assayed Bovine Multi-sera is supplied lyophilised.

1. Carefully reconstitute each vial of lyophilised serum with exactly 5 ml 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
Assayed Bovine Multi-sera - Level 3 20 x 5 ml

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 lot of serum is submitted to a number of external laboratories. Values are assigned from a consensus of results obtained by these laboratories and internal testing conducted at Randox Laboratories Ltd. With each batch, a control range is provided for individual parameters and each parameter method. The control range is equivalent to the assigned mean ±2 S.D.

EC REP Randox Teoranta, Meenmore,
Dungloe, Donegal,
F94 TV06, Ireland

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ASSAYED BOVINE MULTI SERA - LEVEL 3 (BOV ASY CONTROL 3)

Cat. No. AE1032 Lot. No. 355SE Size 20 x 5ml Expiry 2025-09-28

MEAN OF ALL INSTRUMENTS			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Alpha-HBDH	U/l	422	333	511	Oxobutyrate < 10 mmol/l 37°C
	U/l	319	251	386	Oxobutyrate < 10 mmol/l 30°C
	U/l	239	188	289	Oxobutyrate < 10 mmol/l 25°C
Acid Phosphatase (Total)	U/l	44.9	30.1	59.7	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	45.3	38.5	52.1	Bromocresol Green
	g/dl	4.53	3.85	5.21	
Alkaline Phosphatase	U/l	587	499	675	Diethanolamine buffer DEA 37°C
	U/l	457	389	525	Diethanolamine buffer DEA 30°C
	U/l	375	319	431	Diethanolamine buffer DEA 25°C
	U/l	343	292	394	AMP optimised to IFCC 37°C
	U/l	267	227	307	AMP optimised to IFCC 30°C
	U/l	219	187	252	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	153	122	184	Tris buffer without P5P 37°C
	U/l	113	90	136	Tris buffer without P5P 30°C
	U/l	86	69	103	Tris buffer without P5P 25°C
Amylase Total	U/l	575	489	661	Randox Lyo. Ethylidene pNPG7 37°C
	U/l	617	524	710	Randox Liquid Ethylidene pNPG7 37°C
AST (GOT)	U/l	199	159	239	Tris buffer without P5P 37°C
	U/l	135	107	163	Tris buffer without P5P 30°C
	U/l	95	76	114	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	26.9	21.3	32.5	Enzymatic
Bile Acids	µmol/l	98.6	78.9	118	5th Generation Colorimetric
	µmol/l	117	93.6	140	4th Generation Colorimetric
Bilirubin Direct	µmol/l	33.3	26.3	40.3	Diazo with Sulphanilic Acid
	mg/dl	1.95	1.54	2.36	
	µmol/l	32.2	25.4	39.0	Oxidation to Biliverdin/Vanadate
	mg/dl	1.88	1.49	2.27	
	µmol/l	28.3	22.4	34.2	Modified Jendrassik
	mg/dl	1.66	1.31	2.01	
Bilirubin Total	µmol/l	78.4	61.9	94.9	Diazo with Sulphanilic Acid
	mg/dl	4.59	3.62	5.56	
	µmol/l	82.8	65.4	100	Oxidation to Biliverdin/Vanadate
	mg/dl	4.84	3.83	5.85	
	µmol/l	88.8	70.2	107	Modified Jendrassik
	mg/dl	5.19	4.11	6.26	
Calcium	mmol/l	3.14	2.83	3.45	Arsenazo III
	mg/dl	12.6	11.3	13.9	
	mmol/l	3.13	2.82	3.44	Cresolphthalein complexone
	mg/dl	12.5	11.3	13.7	
Chloride	mmol/l	114	105	123	ISE indirect
	mmol/l	109	100	118	ISE direct
Cholesterol	mmol/l	6.60	5.74	7.46	Cholesterol Oxidase - Abell Kendall
	mg/dl	255	222	288	

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ASSAYED BOVINE MULTI SERA - LEVEL 3 (BOV ASY CONTROL 3)

Cat. No. AE1032 Lot. No. 355SE Size 20 x 5ml Expiry 2025-09-28

MEAN OF ALL INSTRUMENTS			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK Total	U/l	514	421	607	CK-NAC substrate start (DGKC) 37°C
	U/l	322	264	380	CK-NAC substrate start (DGKC) 30°C
	U/l	218	179	257	CK-NAC substrate start (DGKC) 25°C
	U/l	532	436	628	CK-NAC (IFCC) 37°C
	U/l	333	273	393	CK-NAC (IFCC) 30°C
	U/l	226	185	267	CK-NAC (IFCC) 25°C
Copper	µmol/l	24.8	19.8	29.8	Colorimetric
	µg/dl	158	126	190	
Cortisol	nmol/l	392	294	490	Roche Cobas e801
	µg/dl	14.1	10.6	17.6	
Creatinine	µmol/l	458	366	550	Alkaline picrate no deproteinization
	mg/dl	5.18	4.14	6.22	
	µmol/l	492	394	590	Enzymatic UV method
	mg/dl	5.56	4.45	6.67	
D-3-Hydroxybutyrate	mmol/l	2.44	2.07	2.81	Tris buffer 100mmol pH 8.5
Free T4	pmol/l	>100	-	-	Roche Cobas e801
	ng/dl	>7.80	-	-	
	pg/ml	>78.0	-	-	
Gamma-GT	U/l	143	122	164	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	113	96	130	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	88	75	101	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
GLDH	U/l	22	17	27	Triethanolamine buffer 50 mmol 37°C
	U/l	17	13	21	Triethanolamine buffer 50 mmol 30°C
	U/l	14	11	17	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	15.2	12.9	17.5	Hexokinase
	mg/dl	274	232	316	
	mmol/l	16.5	14.0	19.0	Glucose oxidase
	mg/dl	297	252	342	
Iron	µmol/l	34.1	28.0	40.2	Colorimetric without ppt.
	µg/dl	191	157	225	
Lactate	mmol/l	8.13	6.67	9.59	Colorimetric Lactate Oxidase
	mg/dl	73.3	60.1	86.4	
LD (LDH)	U/l	798	678	918	P->L German methods 37°C
	U/l	576	490	662	P->L German methods 30°C
	U/l	405	344	466	P->L German methods 25°C
	U/l	350	298	403	L->P IFCC 37°C
	U/l	253	215	291	L->P IFCC 30°C
	U/l	177	151	204	L->P IFCC 25°C
Lipase	U/l	89	71	107	Randox Colorimetric 37°C
Lithium	mmol/l	1.85	1.63	2.07	Spectrophotometric
	mg/dl	1.28	1.13	1.44	
Magnesium	mmol/l	1.41	1.24	1.58	Xylidyl Blue
	mg/dl	3.43	3.01	3.85	
NEFA	mmol/l	2.78	2.22	3.34	Colorimetric
Osmolality	mOsm/kg	463	370	556	Freezing point depression

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ASSAYED BOVINE MULTI SERA - LEVEL 3 (BOV ASY CONTROL 3)

Cat. No. AE1032 Lot. No. 355SE Size 20 x 5ml Expiry 2025-09-28

MEAN OF ALL INSTRUMENTS			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Phosphate Inorganic	mmol/l	2.31	1.96	2.66	Phosphomolybdate UV
	mg/dl	7.16	6.08	8.24	
Potassium	mmol/l	6.39	5.88	6.90	ISE method - indirect
	mmol/l	6.40	5.89	6.91	Enzymatic
	mmol/l	6.33	5.82	6.84	ISE direct
Protein Total	g/l	70.3	56.2	84.4	Biuret reaction end point
	g/dl	7.03	5.62	8.44	
PSA Total	ng/ml = µg/l	45.6	34.2	57.0	Roche Cobas e801
Sodium	mmol/l	149	142	156	Enzymatic
	mmol/l	151	143	159	ISE direct
	mmol/l	151	143	159	ISE indirect
TIBC	µmol/l	43.4	34.3	52.5	Randox Direct
	µg/dl	243	192	293	
Total T3	nmol/l	3.51	2.63	4.39	Roche Cobas e801
	ng/ml	2.29	1.71	2.86	
	ng/dl	229	171	286	
Total T4	nmol/l	214	161	268	Roche Cobas e801
	µg/dl	16.7	12.6	20.9	
	ng/ml	167	126	209	
Triglycerides	mmol/l	2.87	2.41	3.33	Lipase/GPO-PAP no correction
	mg/dl	254	213	295	
UIBC	µmol/l	9.30	7.63	11.0	TIBC - FE
	µg/dl	52.0	42.7	61.5	
Urea	mmol/l	23.4	19.9	26.9	Urease kinetic
	mg/dl	141	120	162	
	mmol/l	23.0	19.6	26.5	Urease hypochlorite
	mg/dl	138	118	158	
	mmol/l	23.4	19.9	26.9	BUN
	mg/dl	65.7	55.8	75.6	
Uric Acid (Urate)	mmol/l	0.593	0.516	0.670	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.96	8.67	11.3	
	mmol/l	0.563	0.490	0.636	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.46	8.23	10.7	
Vitamin B12	pmol/l	110	88.0	132	Roche Cobas e801
	pg/ml	149	119	179	
Zinc	µmol/l	31.2	25.0	37.4	Colorimetric with deproteinisation
	µg/dl	204	163	245	

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ASSAYED BOVINE MULTI SERA - LEVEL 3 (BOV ASY CONTROL 3)

Cat. No. AE1032 Lot. No. 355SE Size 20 x 5ml Expiry 2025-09-28

RX SERIES®			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	45.3	38.5	52.1	Bromocresol Green
	g/dl	4.53	3.85	5.21	
Alkaline Phosphatase	U/l	587	499	675	Diethanolamine buffer DEA 37°C
	U/l	343	292	394	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	153	122	184	Tris buffer without P5P 37°C
Amylase Total	U/l	617	524	710	Randox Liquid Ethylidene pNPG7
AST (GOT)	U/l	199	159	239	Tris buffer without P5P 37°C
Bicarbonate	mmol/l	26.9	21.3	32.5	Enzymatic
Bile Acids	µmol/l	98.6	78.9	118	5th Generation Colorimetric
Bilirubin Direct	µmol/l	30.7	24.3	37.1	Diazo with Sulphanilic Acid
	mg/dl	1.80	1.42	2.18	
	µmol/l	32.2	25.4	39.0	Oxidation to Biliverdin/Vanadate
	mg/dl	1.88	1.49	2.27	
Bilirubin Total	µmol/l	78.7	62.2	95.2	Diazo with Sulphanilic Acid
	mg/dl	4.60	3.64	5.56	
	µmol/l	82.8	65.4	100	Oxidation to Biliverdin/Vanadate
	mg/dl	4.84	3.83	5.85	
Calcium	mmol/l	3.14	2.83	3.45	Arsenazo III
	mg/dl	12.6	11.3	13.9	
Chloride	mmol/l	109	100	118	ISE direct
Cholesterol	mmol/l	6.60	5.74	7.46	Cholesterol Oxidase - Abell Kendall
	mg/dl	255	222	288	
CK Total	U/l	514	421	607	CK-NAC substrate start (DGKC) 37°C
	U/l	532	436	628	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	458	366	550	Alkaline picrate no deproteinization
	mg/dl	5.18	4.14	6.22	
	µmol/l	492	394	590	Enzymatic UV method
	mg/dl	5.56	4.45	6.67	
Gamma-GT	U/l	143	122	164	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
Glucose	mmol/l	15.2	12.9	17.5	Hexokinase
	mg/dl	274	232	316	
	mmol/l	16.5	14.0	19.0	Glucose oxidase
	mg/dl	297	252	342	
Iron	µmol/l	34.1	28.0	40.2	Colorimetric without ppt.
	µg/dl	191	157	225	
Lactate	mmol/l	8.13	6.67	9.59	Colorimetric Lactate Oxidase
	mg/dl	73.3	60.1	86.4	
LD (LDH)	U/l	798	678	918	P->L German methods 37°C
	U/l	350	298	403	L->P IFCC 37°C
Lipase	U/l	89	71	107	Randox Colorimetric
Magnesium	mmol/l	1.41	1.24	1.58	Xylidyl Blue
	mg/dl	3.43	3.01	3.85	

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ASSAYED BOVINE MULTI SERA - LEVEL 3 (BOV ASY CONTROL 3)

Cat. No. AE1032 Lot. No. 355SE Size 20 x 5ml Expiry 2025-09-28

RX SERIES®			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Phosphate Inorganic	mmol/l	2.31	1.96	2.66	Phosphomolybdate UV
	mg/dl	7.16	6.08	8.24	
Potassium	mmol/l	6.33	5.82	6.84	ISE method - direct
	mmol/l	6.40	5.89	6.91	Enzymatic
Protein Total	g/l	70.3	56.2	84.4	Biuret reaction end point
	g/dl	7.03	5.62	8.44	
Sodium	mmol/l	151	143	159	ISE method - direct
	mmol/l	149	142	156	Enzymatic
TIBC	µmol/l	43.4	34.3	52.5	Direct Colorimetric
	µg/dl	243	192	294	
Triglycerides	mmol/l	2.87	2.41	3.33	Lipase/GPO-PAP no correction
	mg/dl	254	213	295	
Urea	mmol/l	23.4	19.9	26.9	Urease kinetic
	mg/dl	141	120	162	
	mmol/l	23.4	19.9	26.9	BUN
	mg/dl	65.7	55.8	75.6	
Uric Acid (Urate)	mmol/l	0.593	0.520	0.670	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	10.0	8.74	11.3	
	mmol/l	0.563	0.490	0.640	Uricase peroxidase no ascorbate oxidase
	mg/dl	9.46	8.23	10.8	

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