RANDOX 2797 CE

ASSAYED BOVINE MULTI-SERA - LEVEL 2 (BOV ASY CONTROL 2)

CAT. NO. AN1026
SIZE: 20 x 5 ml
GTIN: 05055273200294
LOT NO. 491SN
EXPIRY: 2025-09-28

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).

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.

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

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 2 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,
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Cat. No. AN1026 Lot. No. 491SN Size 20 x 5ml Expiry 2025-09-28

MEAN OF ALL INSTRUMENTS			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Alpha-HBDH	U/l	152	120	184	Oxobutyrate < 10 mmol/l 37°C
	U/l	115	91	139	Oxobutyrate < 10 mmol/l 30°C
	U/l	86	68	104	Oxobutyrate < 10 mmol/l 25°C
Acid Phosphatase (Total)	U/l	17.4	11.7	23.1	1-Naphthyl Phosphate substrate Kinetic 37°C
Albumin	g/l	39.2	33.3	45.1	Bromocresol Green
	g/dl	3.92	3.33	4.51	
Alkaline Phosphatase	U/l	198	168	228	Diethanolamine buffer DEA 37°C
	U/l	154	131	177	Diethanolamine buffer DEA 30°C
	U/l	127	107	147	Diethanolamine buffer DEA 25°C
	U/l	111	94	128	AMP optimised to IFCC 37°C
	U/l	86	73	100	AMP optimised to IFCC 30°C
	U/l	71	60	82	AMP optimised to IFCC 25°C
ALT (GPT)	U/l	54	43	65	Tris buffer without P5P 37°C
	U/l	40	32	48	Tris buffer without P5P 30°C
	U/l	30	24	36	Tris buffer without P5P 25°C
Amylase Total	U/l	171	145	197	Randox Lyo. Ethylidene pNPG7 37°C
	U/l	133	113	153	Randox Liquid Ethylidene pNPG7 37°C
AST (GOT)	U/l	41	33	49	Tris buffer without P5P 37°C
	U/l	28	22	34	Tris buffer without P5P 30°C
	U/l	20	16	24	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	22.4	17.8	27.0	Enzymatic
Bile Acids	µmol/l	30.1	24.1	36.1	5th Generation Colorimetric
	µmol/l	31.7	25.4	38.0	4th Generation Colorimetric
Bilirubin Direct	µmol/l	21.9	17.3	26.5	Diazo with Sulphanilic Acid
	mg/dl	1.28	1.01	1.55	
	µmol/l	20.3	16.0	24.6	Oxidation to Biliverdin/Vanadate
	mg/dl	1.19	0.940	1.44	
	µmol/l	15.1	11.9	18.3	Modified Jendrassik
	mg/dl	0.880	0.700	1.07	
Bilirubin Total	µmol/l	28.6	22.6	34.6	Diazo with Sulphanilic Acid
	mg/dl	1.67	1.32	2.02	
	µmol/l	29.1	23.0	35.2	Oxidation to Biliverdin/Vanadate
	mg/dl	1.70	1.35	2.06	
	µmol/l	33.4	26.4	40.4	Modified Jendrassik
	mg/dl	1.95	1.54	2.36	
Calcium	mmol/l	2.42	2.18	2.66	Arsenazo III
	mg/dl	9.70	8.74	10.7	
	mmol/l	2.37	2.13	2.61	Cresolphthalein complexone
	mg/dl	9.50	8.54	10.5	
Chloride	mmol/l	97.7	89.9	106	ISE indirect
	mmol/l	94.6	87.0	102	ISE direct
Cholesterol	mmol/l	5.21	4.53	5.89	Cholesterol Oxidase - Abell Kendall
	mg/dl	201	175	227	

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ASSAYED BOVINE MULTI-SERA - LEVEL 2 (BOV ASY CONTROL 2)

Cat. No. AN1026 Lot. No. 491SN Size 20 x 5ml Expiry 2025-09-28

MEAN OF ALL INSTRUMENTS			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
CK Total	U/l	198	162	234	CK-NAC substrate start (DGKC) 37°C
	U/l	124	101	147	CK-NAC substrate start (DGKC) 30°C
	U/l	84	69	99	CK-NAC substrate start (DGKC) 25°C
	U/l	211	173	249	CK-NAC (IFCC) 37°C
	U/l	132	108	156	CK-NAC (IFCC) 30°C
	U/l	90	74	106	CK-NAC (IFCC) 25°C
Copper	µmol/l	19.5	15.6	23.4	Colorimetric
	µg/dl	124	99.2	149	
Cortisol	nmol/l	230	173	288	Roche Cobas e801
	µg/dl	8.28	6.23	10.4	
Creatinine	µmol/l	139	111	167	Alkaline picrate no deproteinization
	mg/dl	1.57	1.25	1.89	
	µmol/l	147	118	176	Enzymatic UV method
	mg/dl	1.66	1.33	1.99	
D-3-Hydroxybutyrate	mmol/l	1.58	1.34	1.82	Tris buffer 100mmol pH 8.5
Free T4	pmol/l	51.9	38.9	64.9	Roche Cobas e801
	ng/dl	4.05	3.03	5.06	
	pg/ml	40.5	30.3	50.6	
Gamma-GT	U/l	57	48	66	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	45	38	52	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	35	30	40	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
GLDH	U/l	18	14	22	Triethanolamine buffer 50 mmol 37°C
	U/l	14	11	17	Triethanolamine buffer 50 mmol 30°C
	U/l	11	9	13	Triethanolamine buffer 50 mmol 25°C
Glucose	mmol/l	5.80	4.93	6.67	Hexokinase
	mg/dl	105	88.8	121	
	mmol/l	6.28	5.34	7.22	Glucose oxidase
	mg/dl	113	96.2	130	
Iron	µmol/l	27.2	22.3	32.1	Colorimetric without ppt.
	µg/dl	152	125	179	
Lactate	mmol/l	5.87	4.81	6.93	Colorimetric Lactate Oxidase
	mg/dl	52.9	43.3	62.4	
LD (LDH)	U/l	288	245	331	P->L German methods 37°C
	U/l	208	177	239	P->L German methods 30°C
	U/l	146	124	168	P->L German methods 25°C
	U/l	139	118	160	L->P IFCC 37°C
	U/l	100	85	116	L->P IFCC 30°C
	U/l	70	60	81	L->P IFCC 25°C
Lipase	U/l	48	38	58	Randox Colorimetric 37°C
Lithium	mmol/l	1.23	1.08	1.38	Spectrophotometric
	mg/dl	0.850	0.750	0.960	
Magnesium	mmol/l	0.888	0.781	0.995	Xylidyl Blue
	mg/dl	2.16	1.90	2.42	
NEFA	mmol/l	2.46	1.97	2.95	Colorimetric
Osmolality	mOsm/kg	350	280	420	Freezing point depression

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ASSAYED BOVINE MULTI-SERA - LEVEL 2 (BOV ASY CONTROL 2)

Cat. No. AN1026 Lot. No. 491SN Size 20 x 5ml Expiry 2025-09-28

MEAN OF ALL INSTRUMENTS			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Phosphate Inorganic	mmol/l	1.26	1.07	1.45	Phosphomolybdate UV
	mg/dl	3.91	3.32	4.50	
Potassium	mmol/l	4.28	3.94	4.62	ISE method - indirect
	mmol/l	4.30	3.96	4.64	Enzymatic
	mmol/l	4.29	3.95	4.63	ISE direct
Protein Total	g/l	58.7	47.0	70.4	Biuret reaction end point
	g/dl	5.87	4.70	7.04	
PSA Total	ng/ml = µg/l	9.97	7.48	12.5	Roche Cobas e801
Sodium	mmol/l	142	135	149	Enzymatic
	mmol/l	137	130	144	ISE direct
	mmol/l	139	132	146	ISE indirect
TIBC	µmol/l	35.5	28.0	43.0	Randox Direct
	µg/dl	198	157	240	
Total T3	nmol/l	2.02	1.52	2.53	Roche Cobas e801
	ng/ml	1.32	0.990	1.65	
	ng/dl	132	99.0	165	
Total T4	nmol/l	114	85.5	143	Roche Cobas e801
	µg/dl	8.89	6.67	11.2	
	ng/ml	88.9	66.7	112	
Triglycerides	mmol/l	1.13	0.949	1.31	Lipase/GPO-PAP no correction
	mg/dl	100	84.0	116	
UIBC	µmol/l	8.30	6.81	9.79	TIBC - FE
	µg/dl	46.4	38.1	54.7	
Urea	mmol/l	6.78	5.76	7.80	Urease kinetic
	mg/dl	40.7	34.6	46.8	
	mmol/l	10.6	9.01	12.2	Urease hypochlorite
	mg/dl	63.7	54.2	73.2	
	mmol/l	6.78	5.76	7.80	BUN
	mg/dl	19.0	16.2	21.8	
Uric Acid (Urate)	mmol/l	0.340	0.296	0.384	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.71	4.97	6.45	
	mmol/l	0.314	0.273	0.355	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.28	4.59	5.97	
Vitamin B12	pmol/l	183	146	220	Roche Cobas e801
	pg/ml	248	198	298	
Zinc	µmol/l	25.2	20.2	30.2	Colorimetric with deproteinisation
	µg/dl	165	132	198	

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Cat. No. AN1026 Lot. No. 491SN Size 20 x 5ml Expiry 2025-09-28

RX SERIES®			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Albumin	g/l	39.2	33.3	45.1	Bromocresol Green
	g/dl	3.92	3.33	4.51	
Alkaline Phosphatase	U/l	198	168	228	Diethanolamine buffer DEA 37°C
	U/l	111	94	128	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	54	43	65	Tris buffer without P5P 37°C
Amylase Total	U/l	133	113	153	Randox Liquid Ethylidene pNPG7 37°C
AST (GOT)	U/l	41	33	49	Tris buffer without P5P 37°C
Bicarbonate	mmol/l	22.4	17.8	27.0	Enzymatic
Bile Acids	µmol/l	30.1	24.1	36.1	5th Generation Colorimetric
Bilirubin Direct	µmol/l	20.9	16.5	25.3	Diazo with Sulphanilic Acid
	mg/dl	1.22	0.965	1.48	
	µmol/l	20.3	16.0	24.6	Oxidation to Biliverdin/Vanadate
	mg/dl	1.19	0.940	1.44	
Bilirubin Total	µmol/l	29.4	23.2	35.6	Diazo with Sulphanilic Acid
	mg/dl	1.72	1.36	2.08	
	µmol/l	29.1	23.0	35.2	Oxidation to Biliverdin/Vanadate
	mg/dl	1.70	1.35	2.06	
Calcium	mmol/l	2.42	2.18	2.66	Arsenazo III
	mg/dl	9.70	8.74	10.7	
Chloride	mmol/l	94.6	87.0	102	ISE direct
Cholesterol	mmol/l	5.21	4.53	5.89	Cholesterol Oxidase - Abell Kendall
	mg/dl	201	175	227	
CK Total	U/l	198	162	234	CK-NAC substrate start (DGKC) 37°C
	U/l	211	173	249	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	139	111	167	Alkaline picrate no deproteinization
	mg/dl	1.57	1.25	1.89	
	µmol/l	147	118	176	Enzymatic UV method
	mg/dl	1.66	1.33	1.99	
Gamma-GT	U/l	57	48	66	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
Glucose	mmol/l	5.80	4.93	6.67	Hexokinase
	mg/dl	105	88.8	121	
	mmol/l	6.28	5.34	7.22	Glucose oxidase
	mg/dl	113	96.2	130	
Iron	µmol/l	27.2	22.3	32.1	Colorimetric without ppt.
	µg/dl	152	125	179	
Lactate	mmol/l	5.87	4.81	6.93	Colorimetric Lactate Oxidase
	mg/dl	52.9	43.3	62.4	
LD (LDH)	U/l	288	245	331	P->L German methods 37°C
	U/l	139	118	160	L->P IFCC 37°C
Lipase	U/l	48	38	58	Randox Colorimetric
Magnesium	mmol/l	0.888	0.781	0.995	Xylidyl Blue
	mg/dl	2.16	1.90	2.42	

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RX SERIES®			Range		
Analyte	**unit**	**Target**	**low**	**high**	**methods**
Phosphate Inorganic	mmol/l	1.26	1.07	1.45	Phosphomolybdate UV
	mg/dl	3.91	3.32	4.50	
Potassium	mmol/l	4.29	3.95	4.63	ISE method - direct
	mmol/l	4.30	3.96	4.64	Enzymatic
Protein Total	g/l	58.7	47.0	70.4	Biuret reaction end point
	g/dl	5.87	4.70	7.04	
Sodium	mmol/l	137	130	144	ISE method - direct
	mmol/l	142	135	149	Enzymatic
TIBC	µmol/l	35.5	28.0	43.0	Direct Colorimetric
	µg/dl	198	157	239	
Triglycerides	mmol/l	1.13	0.949	1.31	Lipase/GPO-PAP no correction
	mg/dl	100	84.0	116	
Urea	mmol/l	6.78	5.76	7.80	Urease kinetic
	mg/dl	40.7	34.6	46.8	
	mmol/l	6.78	5.76	7.80	BUN
	mg/dl	19.0	16.2	21.8	
Uric Acid (Urate)	mmol/l	0.340	0.300	0.380	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	5.71	5.04	6.38	
	mmol/l	0.314	0.270	0.350	Uricase peroxidase no ascorbate oxidase
	mg/dl	5.28	4.54	5.88	

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