

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

Cat. No. AEI032
Size: 20 x 5 ml

Lot No. 342SE
Expiry: 2018-04

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 stabilization 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.

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.

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 3 20 x 5 ml

MATERIALS REQUIRED BUT NOT PROVIDED

Volumetric pipette

ASSIGNED VALUES

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.

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.

Rev. 08 Sep '15 ne

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

Beckman Coulter AU 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	386	328	444	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	129	103	155	Tris buffer without P5P 37°C
AST (GOT)	U/l	203	162	244	Tris buffer without P5P 37°C
Bicarbonate	mmol/l	29.1	23.1	35.1	Enzymatic
Bilirubin Direct	µmol/l	25.1	19.8	30.4	Diazo with Sulphanilic Acid
	mg/dl	1.47	1.16	1.78	
Bilirubin Total	µmol/l	80.8	63.8	97.8	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.73	3.73	5.72	
Calcium	mmol/l	3.09	2.78	3.40	Arsenazo III
	mg/dl	12.4	11.1	13.7	
Chloride	mmol/l	115	106	124	ISE indirect
CK Total	U/l	530	435	625	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	499	399	599	Jaffe rate blanked
	mg/dl	5.64	4.51	6.77	
Gamma-GT	U/l	121	103	139	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	15.6	13.3	17.9	Hexokinase
	mg/dl	281	240	322	
Iron	µmol/l	38.2	31.3	45.1	Colorimetric without ppt.
	µg/dl	214	175	253	
LD (LDH)	U/l	365	310	420	L->P IFCC 37°C
Magnesium	mmol/l	1.46	1.28	1.64	Xylidyl Blue
	mg/dl	3.55	3.11	3.99	
Phosphate Inorganic	mmol/l	2.33	1.98	2.68	Phosphomolybdate UV
	mg/dl	7.22	6.14	8.30	
Potassium	mmol/l	6.13	5.64	6.62	ISE indirect
Protein Total	g/l	70.1	56.1	84.1	Biuret reaction end point
	g/dl	7.01	5.61	8.41	
Sodium	mmol/l	151	143	159	ISE indirect
Urea	mmol/l	21.3	18.1	24.5	Urease kinetic
	mg/dl	128	109	147	
	mmol/l	21.3	18.1	24.5	BUN
	mg/dl	59.8	50.8	68.8	
Uric Acid (Urate)	mmol/l	0.566	0.490	0.640	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.51	8.23	10.8	

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

COBAS INTEGRA®

Range

Analyte	unit	Target	low	high	methods
Albumin	g/l	51.2	43.5	58.9	Bromocresol Green
	g/dl	5.12	4.35	5.89	
Alkaline Phosphatase	U/l	252	214	290	p-Nitrophenylphosphate AMP 37°C
	U/l	196	167	225	p-Nitrophenylphosphate AMP 30°C
	U/l	161	137	185	p-Nitrophenylphosphate AMP 25°C
ALT (GPT)	U/l	125	100	150	Tris buffer without P5P 37°C
	U/l	93	74	112	Tris buffer without P5P 30°C
	U/l	70	56	84	Tris buffer without P5P 25°C
Amylase Total	U/l	517	439	595	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	186	149	223	Tris buffer without P5P 37°C
	U/l	126	101	151	Tris buffer without P5P 30°C
	U/l	89	71	107	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	27.0	21.4	32.6	Enzymatic
Bilirubin Direct	µmol/l	23.2	18.3	28.1	Diazo with Sulphanilic Acid
	mg/dl	1.36	1.07	1.65	
Bilirubin Total	µmol/l	76.7	60.6	92.8	Diazo with Sulphanilic Acid
	mg/dl	4.49	3.55	5.43	
Calcium	mmol/l	3.26	2.93	3.59	NM-BAPTA
	mg/dl	13.1	11.7	14.4	
Chloride	mmol/l	114	105	123	ISE indirect
Cholesterol	mmol/l	6.27	5.45	7.09	Cholesterol Oxidase
	mg/dl	242	210	274	
CK Total	U/l	545	447	643	CK-NAC (IFCC) 37°C
	U/l	341	280	403	CK-NAC (IFCC) 30°C
	U/l	232	190	273	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	497	398	596	Alkaline picrate no deproteinization
	mg/dl	5.62	4.50	6.73	
Gamma-GT	U/l	120	102	138	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	95	80	110	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	74	63	85	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
Glucose	mmol/l	15.9	13.5	18.3	Hexokinase
	mg/dl	287	243	331	
Iron	µmol/l	38.7	31.7	45.7	Colorimetric without ppt.
	µg/dl	216	177	255	
LD (LDH)	U/l	378	321	435	L->P IFCC 37°C
	U/l	273	232	314	L->P IFCC 30°C
	U/l	192	163	221	L->P IFCC 25°C
Lithium	mmol/l	1.80	1.58	2.02	Ion selective electrode
	mg/dl	1.25	1.10	1.40	
Magnesium	mmol/l	1.47	1.29	1.65	Chlorphosphonazo III
	mg/dl	3.57	3.13	4.01	
Phosphate Inorganic	mmol/l	2.46	2.09	2.83	Phosphomolybdate UV
	mg/dl	7.63	6.48	8.78	

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

COBAS INTEGRA®

Range

Analyte	unit	Target	low	high	methods
Potassium	mmol/l	6.13	5.64	6.62	ISE indirect
Protein Total	g/l	70.2	56.2	84.2	Biuret reaction end point
	g/dl	7.02	5.62	8.42	
Sodium	mmol/l	150	143	158	ISE indirect
Triglycerides	mmol/l	2.60	2.18	3.02	Lipase/GPO-PAP no correction
	mg/dl	230	193	267	
Urea	mmol/l	21.3	18.1	24.5	Urease kinetic
	mg/dl	128	109	147	
	mmol/l	21.3	18.1	24.5	BUN
	mg/dl	59.8	50.8	68.8	
Uric Acid (Urate)	mmol/l	0.547	0.480	0.620	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.19	8.06	10.4	

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

HITACHI SERIES®		Range			
Analyte	unit	Target	low	high	methods
Acid Phosphatase (non-prostatic)	U/l	19.2	12.9	25.5	1-Naphthyl Phosphate substrate Kinetic 37°C
	U/l	15.1	10.1	20.1	1-Naphthyl Phosphate, Kinetic with Pentane diol Activation 37°C
Acid Phosphatase (Prostatic)	U/l	27.0	18.1	35.9	1-Naphthyl Phosphate substrate Kinetic 37°C
	U/l	45.2	30.3	60.1	1-Naphthyl Phosphate, Kinetic with Pentane diol Activation 37°C
Acid Phosphatase (Total)	U/l	46.2	31.0	61.4	1-Naphthyl Phosphate substrate Kinetic 37°C
	U/l	60.3	40.4	80.2	1-Naphthyl Phosphate, Kinetic with Pentane diol Activation 37°C
Albumin	g/l	49.5	42.1	56.9	Bromocresol Green
	g/dl	4.95	4.21	5.69	
Alkaline Phosphatase	U/l	212	180	244	p-Nitrophenylphosphate AMP 37°C
	U/l	165	140	190	p-Nitrophenylphosphate AMP 30°C
	U/l	135	115	155	p-Nitrophenylphosphate AMP 25°C
	U/l	326	277	375	Randox AMP 37°C
	U/l	254	216	292	Randox AMP 30°C
	U/l	208	177	240	Randox AMP 25°C
ALT (GPT)	U/l	124	99	149	Tris buffer without P5P 37°C
	U/l	92	73	111	Tris buffer without P5P 30°C
	U/l	70	56	84	Tris buffer without P5P 25°C
Amylase Total	U/l	486	413	559	Roche liquid stable pNPG7 37°C
	U/l	568	483	653	Randox liquid stable pNPG7 37°C
AST (GOT)	U/l	180	144	216	Tris buffer without P5P 37°C
	U/l	122	97	147	Tris buffer without P5P 30°C
	U/l	86	69	103	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	26.8	21.3	32.3	Enzymatic
Bile Acids	µmol/l	87.5	70.0	105	5th Generation Colorimetric
Bilirubin Direct	µmol/l	24.8	19.6	30.0	Oxidation to Biliverdin
	mg/dl	1.45	1.15	1.76	
Bilirubin Total	µmol/l	77.7	61.4	94.0	Diazo with Sulphanilic Acid
	mg/dl	4.55	3.59	5.51	
	µmol/l	81.2	64.1	98.3	Dichlorophenyl Diazonium (DPD)
	mg/dl	4.75	3.75	5.75	
Calcium	mmol/l	3.07	2.76	3.38	NM-BAPTA
	mg/dl	12.3	11.1	13.5	
Chloride	mmol/l	113	104	122	ISE indirect
Cholesterol	mmol/l	5.96	5.19	6.73	Cholesterol Oxidase
	mg/dl	230	200	260	
CK Total	U/l	470	385	555	CK-NAC (IFCC) 37°C
	U/l	294	241	347	CK-NAC (IFCC) 30°C
	U/l	200	164	236	CK-NAC (IFCC) 25°C
	U/l	470	385	555	CK-NAC substrate start (DGKC) 37°C
	U/l	294	241	347	CK-NAC substrate start (DGKC) 30°C
	U/l	200	164	236	CK-NAC substrate start (DGKC) 25°C
Creatinine	µmol/l	510	408	612	Alkaline picrate no deproteinization
	mg/dl	5.76	4.61	6.91	

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

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HITACHI SERIES®

Range

Analyte	unit	Target	low	high	methods
Gamma-GT	U/l	123	105	141	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	97	83	111	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	76	65	87	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	127	108	146	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	100	85	115	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	78	67	89	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	16.5	14.0	19.0	Glucose oxidase
	mg/dl	297	252	342	
	mmol/l	16.0	13.6	18.4	Hexokinase
	mg/dl	288	245	332	
Iron	µmol/l	38.0	31.2	44.8	Colorimetric without ppt.
	µg/dl	212	174	250	
LD (LDH)	U/l	728	619	837	P->L German methods 37°C
	U/l	526	447	605	P->L German methods 30°C
	U/l	369	314	424	P->L German methods 25°C
	U/l	330	281	380	L->P IFCC 37°C
	U/l	238	203	274	L->P IFCC 30°C
	U/l	167	142	193	L->P IFCC 25°C
Lipase	U/l	76	61	91	Randox Colorimetric 37°C
Magnesium	mmol/l	1.47	1.29	1.65	Xylidyl Blue
	mg/dl	3.57	3.13	4.01	
	mmol/l	1.39	1.22	1.56	Chlorphosphonazo III
	mg/dl	3.38	2.96	3.79	
Phosphate Inorganic	mmol/l	2.26	1.92	2.60	Phosphomolybdate UV
	mg/dl	7.01	5.95	8.07	
Potassium	mmol/l	6.19	5.69	6.69	ISE indirect
Protein Total	g/l	69.7	55.8	83.6	Biuret reaction end point
	g/dl	6.97	5.58	8.36	
Sodium	mmol/l	152	144	160	ISE indirect
TIBC	µmol/l	45.7	36.1	55.3	Randox Direct
	µg/dl	255	202	309	
Triglycerides	mmol/l	2.58	2.17	2.99	Lipase/GPO-PAP no correction
	mg/dl	228	192	264	
Urea	mmol/l	21.3	18.1	24.5	Urease kinetic
	mg/dl	128	109	147	
	mmol/l	21.3	18.1	24.5	BUN
	mg/dl	59.8	50.8	68.8	
Uric Acid (Urate)	mmol/l	0.535	0.465	0.605	Uricase peroxidase with ascorbate oxidase
	mg/dl	8.99	7.81	10.2	

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

MEAN OF ALL INSTRUMENTS

			Range		
Analyte	unit	Target	low	high	methods
Alpha-HBDH	U/l	452	357	547	Oxobutyrate < 10 mmol/l 37°C
	U/l	341	270	413	Oxobutyrate < 10 mmol/l 30°C
	U/l	256	202	310	Oxobutyrate < 10 mmol/l 25°C
Acid Phosphatase (non-prostatic)	U/l	19.2	12.9	25.5	1-Naphthyl Phosphate substrate Kinetic 37°C
	U/l	15.1	10.1	20.1	1-Naphthyl Phosphate, Kinetic with Pentane diol Activation 37°C
Acid Phosphatase (Prostatic)	U/l	27.0	18.1	35.9	1-Naphthyl Phosphate substrate Kinetic 37°C
	U/l	45.2	30.3	60.1	1-Naphthyl Phosphate, Kinetic with Pentane diol Activation 37°C
Acid Phosphatase (Total)	U/l	46.2	31.0	61.4	1-Naphthyl Phosphate substrate Kinetic 37°C
	U/l	60.3	40.4	80.2	1-Naphthyl Phosphate, Kinetic with Pentane diol Activation 37°C
Albumin	g/l	47.7	40.5	54.9	Bromocresol Green
	g/dl	4.77	4.05	5.49	
	g/l	21.7	18.4	25.0	Bromocresol Purple
	g/dl	2.17	1.84	2.50	
Alkaline Phosphatase	U/l	326	277	375	p-Nitrophenylphosphate AMP 37°C
	U/l	254	216	292	p-Nitrophenylphosphate AMP 30°C
	U/l	208	177	239	p-Nitrophenylphosphate AMP 25°C
	U/l	512	435	589	Diethanolamine buffer DEA 37°C
	U/l	399	339	459	Diethanolamine buffer DEA 30°C
	U/l	327	278	376	Diethanolamine buffer DEA 25°C
ALT (GPT)	U/l	151	121	181	Tris buffer with P5P 37°C
	U/l	112	90	134	Tris buffer with P5P 30°C
	U/l	85	68	102	Tris buffer with P5P 25°C
	U/l	127	102	152	Tris buffer without P5P 37°C
	U/l	94	75	113	Tris buffer without P5P 30°C
	U/l	72	57	87	Tris buffer without P5P 25°C
Amylase Total	U/l	563	479	647	Randox - Ethylidene pNPG7 37°C
	U/l	568	483	653	Randox liquid stable pNPG7 37°C
	U/l	500	425	575	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	251	201	301	Tris buffer with P5P 37°C
	U/l	170	136	204	Tris buffer with P5P 30°C
	U/l	119	96	142	Tris buffer with P5P 25°C
	U/l	198	158	238	Tris buffer without P5P 37°C
	U/l	134	107	161	Tris buffer without P5P 30°C
	U/l	94	75	113	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	27.8	22.0	33.6	Enzymatic
Bile Acids	µmol/l	104	83.2	125	4th Generation Colorimetric
	µmol/l	87.5	70.0	105	5th Generation Colorimetric
Bilirubin Direct	µmol/l	35.4	28.0	42.8	Diazo with Sulphanilic Acid
	mg/dl	2.07	1.64	2.50	
	µmol/l	26.3	20.8	31.8	Modified Jendrassik
	mg/dl	1.54	1.22	1.86	
Bilirubin Total	µmol/l	86.4	68.3	105	Diazo with Sulphanilic Acid
	mg/dl	5.05	4.00	6.10	

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MEAN OF ALL INSTRUMENTS

Range

Analyte	unit	Target	low	high	methods
Bilirubin Total	μmol/l	91.1	72.0	110	Dichlorophenyl Diazonium (DPD)
	mg/dl	5.33	4.21	6.45	
	μmol/l	97.1	76.7	117	Diazo with Dichloroaniline (DCA)
	mg/dl	5.68	4.49	6.84	
	μmol/l	96.9	76.6	117	Modified Jendrassik
	mg/dl	5.67	4.48	6.84	
Calcium	mmol/l	3.11	2.80	3.42	Arsenazo III
	mg/dl	12.5	11.2	13.8	
	mmol/l	3.26	2.93	3.59	Cresolphthalein complexone
	mg/dl	13.1	11.7	14.5	
	mmol/l	3.13	2.82	3.44	NM-BAPTA
	mg/dl	12.5	11.3	13.8	
Chloride	mmol/l	112	103	121	Colorimetric
	mmol/l	113	104	122	ISE indirect
	mmol/l	113	104	122	ISE direct
Cholesterol	mmol/l	6.06	5.27	6.85	Cholesterol Oxidase
	mg/dl	234	203	265	
CK Total	U/l	467	383	551	CK-NAC substrate start (DGKC) 37°C
	U/l	292	240	344	CK-NAC substrate start (DGKC) 30°C
	U/l	198	163	233	CK-NAC substrate start (DGKC) 25°C
	U/l	505	414	596	CK-NAC (IFCC) 37°C
	U/l	316	259	373	CK-NAC (IFCC) 30°C
	U/l	215	176	254	CK-NAC (IFCC) 25°C
Copper	μmol/l	27.1	21.7	32.5	Colorimetric
	μg/dl	172	138	206	
Cortisol	nmol/l	422	317	528	Roche Cobas E411
	μg/dl	15.2	11.4	19.0	
Creatinine	μmol/l	493	394	592	Alkaline picrate no deproteinization
	mg/dl	5.57	4.45	6.69	
	μmol/l	520	416	624	Randox Enzymatic UV method
	mg/dl	5.88	4.70	7.06	
	μmol/l	499	399	599	Jaffe rate blanked
	mg/dl	5.64	4.51	6.77	
	μmol/l	512	410	614	Jaffe rate blanked comp. (-26 μmol/l)
	mg/dl	5.79	4.63	6.94	
D-3-Hydroxybutyrate	mmol/l	2.47	2.10	2.84	Tris buffer 100mmol pH 8.5
Free T4	pmol/l	68.7	51.5	85.9	Roche Cobas E411
	ng/dl	5.36	4.02	6.70	
	pg/ml	53.6	40.2	67.0	
Gamma-GT	U/l	122	104	140	Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	96	82	110	Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	75	64	86	Gamma glutamyl.-3-carboxy-4-nitroanilide 25°C
	U/l	124	105	143	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	98	83	113	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	77	65	89	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

MEAN OF ALL INSTRUMENTS

Range

Analyte	unit	Target	low	high	methods
Gamma-GT	U/l	123	105	141	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 37°C
	U/l	97	83	111	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 30°C
	U/l	76	65	87	Randox Gamma glutamyl.-3-carboxy-4-nitroanilide 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	15.7	13.3	18.1	Hexokinase
	mg/dl	283	240	326	
	mmol/l	16.2	13.8	18.6	Glucose oxidase
	mg/dl	292	249	335	
Iron	µmol/l	38.0	31.2	44.8	Colorimetric without ppt.
	µg/dl	212	174	250	
Lactate	mmol/l	4.47	3.67	5.27	Colorimetric Lactate Oxidase
	mg/dl	40.3	33.1	47.5	
LD (LDH)	U/l	710	604	817	P->L German methods 37°C
	U/l	513	436	590	P->L German methods 30°C
	U/l	360	306	414	P->L German methods 25°C
	U/l	367	312	422	L->P IFCC 37°C
	U/l	265	225	305	L->P IFCC 30°C
	U/l	186	158	214	L->P IFCC 25°C
Lipase	U/l	76	61	91	Randox Colorimetric 37°C
	U/l	554	444	664	Randox Turbidimetric with colipase 37°C
Lithium	mmol/l	1.87	1.65	2.09	Colorimetric
	mg/dl	1.30	1.15	1.45	
	mmol/l	1.80	1.58	2.02	Ion selective electrode
	mg/dl	1.25	1.10	1.40	
Magnesium	mmol/l	1.44	1.27	1.61	Xylidyl Blue
	mg/dl	3.50	3.09	3.91	
	mmol/l	1.43	1.26	1.60	Chlorphosphonazo III
	mg/dl	3.47	3.06	3.89	
NEFA	mmol/l	2.37	2.01	2.73	Colorimetric
Osmolality	mOsm/kg	445	356	534	Freezing point depression
Phosphate Inorganic	mmol/l	2.30	1.96	2.65	Phosphomolybdate UV
	mg/dl	7.13	6.08	8.18	
Potassium	mmol/l	5.91	5.44	6.38	Enzymatic
	mmol/l	6.23	5.73	6.73	ISE direct
	mmol/l	6.19	5.69	6.69	ISE indirect
Protein Total	g/l	71.1	56.9	85.3	Biuret reaction end point
	g/dl	7.11	5.69	8.53	
PSA Total	ng/ml = µg/l	51.6	38.7	64.5	Roche Cobas E411
Sodium	mmol/l	148	141	155	Enzymatic
	mmol/l	151	143	159	ISE direct
	mmol/l	152	144	160	ISE indirect
TIBC	µmol/l	45.7	36.1	55.3	Randox Direct
	µg/dl	255	202	309	
Total T3	nmol/l	5.06	3.80	6.33	Roche Cobas E411
	ng/ml	3.29	2.47	4.12	
	ng/dl	329	247	412	

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

MEAN OF ALL INSTRUMENTS

Range

Analyte	unit	Target	low	high	methods
Total T4	nmol/l	199	149	249	Roche Cobas E411
	µg/dl	15.5	11.6	19.4	
	ng/ml	155	116	194	
Triglycerides	mmol/l	2.58	2.17	2.99	Lipase/GPO-PAP no correction
	mg/dl	228	192	264	
Urea	mmol/l	21.3	18.1	24.5	Urease kinetic
	mg/dl	128	109	147	
	mmol/l	20.6	17.5	23.7	Urease hypochlorite
	mg/dl	124	105	143	
	mmol/l	7.69	6.54	8.84	Urease Berthelot
	mg/dl	46.2	39.3	53.1	
	mmol/l	21.3	18.1	24.5	BUN
	mg/dl	59.8	50.8	68.8	
Uric Acid (Urate)	mmol/l	0.536	0.466	0.606	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.00	7.83	10.2	
	mmol/l	0.511	0.445	0.577	Uricase peroxidase no ascorbate oxidase
	mg/dl	8.58	7.48	9.68	
	mmol/l	0.542	0.472	0.612	Uricase peroxidase with ascorbate oxidase
	mg/dl	9.11	7.93	10.3	
Vitamin B12	pmol/l	204	164	245	Roche Cobas E411
	pg/ml	277	222	332	
Zinc	µmol/l	34.6	27.7	41.5	Colorimetric with deproteinisation
	µg/dl	226	181	271	

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

Roche Cobas 6000 c501 e601

Range

Analyte	unit	Target	low	high	methods
Albumin	g/l	21.7	18.4	25.0	Bromocresol Purple
	g/dl	2.17	1.84	2.50	
Alkaline Phosphatase	U/l	210	179	242	p-Nitrophenylphosphate AMP 37°C
	U/l	164	139	189	p-Nitrophenylphosphate AMP 30°C
	U/l	134	114	155	p-Nitrophenylphosphate AMP 25°C
ALT (GPT)	U/l	130	104	156	Tris buffer without P5P 37°C
	U/l	96	77	115	Tris buffer without P5P 30°C
	U/l	73	59	88	Tris buffer without P5P 25°C
Amylase Total	U/l	511	434	588	Roche liquid stable pNPG7 37°C
AST (GOT)	U/l	215	172	258	Tris buffer without P5P 37°C
	U/l	145	116	174	Tris buffer without P5P 30°C
	U/l	102	82	123	Tris buffer without P5P 25°C
Bicarbonate	mmol/l	29.1	23.1	35.1	Enzymatic
Bilirubin Direct	µmol/l	22.3	17.6	27.0	Diazo with Sulphanilic Acid
	mg/dl	1.30	1.03	1.58	
Bilirubin Total	µmol/l	77.8	61.5	94.1	Diazo with Sulphanilic Acid
	mg/dl	4.55	3.60	5.50	
Calcium	mmol/l	3.13	2.82	3.44	Arsenazo III
	mg/dl	12.5	11.3	13.8	
Chloride	mmol/l	113	104	122	ISE indirect
Cholesterol	mmol/l	5.97	5.19	6.75	Cholesterol Oxidase
	mg/dl	230	200	261	
CK Total	U/l	536	440	632	CK-NAC (IFCC) 37°C
	U/l	336	275	396	CK-NAC (IFCC) 30°C
	U/l	228	187	269	CK-NAC (IFCC) 25°C
Creatinine	µmol/l	550	440	660	Randox Enzymatic UV method
	mg/dl	6.22	4.97	7.46	
Gamma-GT	U/l	132	112	152	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
	U/l	104	88	120	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 30°C
	U/l	81	69	94	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 25°C
Glucose	mmol/l	15.1	12.8	17.4	Hexokinase
	mg/dl	272	231	314	
Iron	µmol/l	38.0	31.2	44.8	Colorimetric without ppt.
	µg/dl	212	174	250	
LD (LDH)	U/l	693	589	797	P->L German methods 37°C
	U/l	500	425	575	P->L German methods 30°C
	U/l	351	299	404	P->L German methods 25°C
Magnesium	mmol/l	1.42	1.25	1.59	Xylidyl Blue
	mg/dl	3.45	3.04	3.86	
Phosphate Inorganic	mmol/l	2.24	1.90	2.58	Phosphomolybdate UV
	mg/dl	6.94	5.89	8.00	
Potassium	mmol/l	6.30	5.80	6.80	ISE indirect

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

Roche Cobas 6000 c501 e601

Range

Analyte	unit	Target	low	high	methods
Protein Total	g/l	69.3	55.4	83.2	Biuret reaction end point
	g/dl	6.93	5.54	8.32	
Sodium	mmol/l	154	146	162	ISE indirect
Triglycerides	mmol/l	2.55	2.14	2.96	Lipase/GPO-PAP no correction
	mg/dl	226	189	262	
Urea	mmol/l	20.8	17.7	23.9	Urease kinetic
	mg/dl	125	106	144	
	mmol/l	20.8	17.7	23.9	BUN
	mg/dl	58.4	49.6	67.2	
Uric Acid (Urate)	mmol/l	0.525	0.460	0.590	Uricase peroxidase with ascorbate oxidase
	mg/dl	8.82	7.73	9.91	

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

RX SERIES®

Range

Analyte	unit	Target	low	high	methods
Albumin	g/l	45.6	38.8	52.4	Bromocresol Green
	g/dl	4.56	3.88	5.24	
Alkaline Phosphatase	U/l	512	435	589	Diethanolamine buffer DEA 37°C
	U/l	326	277	375	AMP optimised to IFCC 37°C
ALT (GPT)	U/l	134	107	161	Tris buffer without P5P 37°C
Amylase Total	U/l	568	483	653	Randox liquid stable pNPG7 37°C
AST (GOT)	U/l	216	173	259	Tris buffer without P5P 37°C
Bicarbonate	mmol/l	28.2	22.4	34.0	Enzymatic
Bile Acids	µmol/l	87.5	70.0	105	5th Generation Colorimetric
Bilirubin Direct	µmol/l	28.6	22.6	34.6	Diazo with Sulphanilic Acid
	mg/dl	1.67	1.32	2.02	
Bilirubin Total	µmol/l	85.1	67.2	103	Diazo with Sulphanilic Acid
	mg/dl	4.98	3.93	6.03	
Calcium	mmol/l	3.10	2.79	3.41	Arsenazo III
	mg/dl	12.4	11.2	13.6	
Chloride	mmol/l	113	104	122	ISE direct
Cholesterol	mmol/l	6.14	5.34	6.94	Cholesterol Oxidase
	mg/dl	237	206	268	
CK Total	U/l	464	380	548	CK-NAC substrate start (DGKC) 37°C
	U/l	490	402	578	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	457	366	548	Alkaline picrate no deproteinization
	mg/dl	5.16	4.14	6.18	
	µmol/l	481	385	577	Randox Enzymatic UV method
	mg/dl	5.44	4.35	6.52	
Gamma-GT	U/l	123	105	141	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	15.5	13.2	17.8	Hexokinase
	mg/dl	279	238	320	
	mmol/l	15.9	13.5	18.3	Glucose oxidase
	mg/dl	287	243	331	
Iron	µmol/l	36.6	30.0	43.2	Colorimetric without ppt.
	µg/dl	205	168	242	
Lactate	mmol/l	4.47	3.67	5.27	Colorimetric Lactate Oxidase
	mg/dl	40.3	33.1	47.5	
LD (LDH)	U/l	716	609	823	P->L German methods 37°C
	U/l	358	304	412	L->P IFCC 37°C
Lipase	U/l	76	61	91	Randox Colorimetric 37°C
Lithium	mmol/l	1.87	1.65	2.09	Colorimetric
	mg/dl	1.30	1.15	1.45	
Magnesium	mmol/l	1.38	1.21	1.55	Xylidyl Blue
	mg/dl	3.35	2.94	3.76	
Phosphate Inorganic	mmol/l	2.28	1.94	2.62	Phosphomolybdate UV
	mg/dl	7.07	6.01	8.13	

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

RX SERIES®

Range

Analyte	unit	Target	low	high	methods
Potassium	mmol/l	6.23	5.73	6.73	ISE direct
	mmol/l	5.91	5.44	6.38	Enzymatic
Protein Total	g/l	76.4	61.1	91.7	Biuret reaction end point
	g/dl	7.64	6.11	9.17	
Sodium	mmol/l	151	143	159	ISE direct
	mmol/l	148	141	155	Enzymatic
TIBC	µmol/l	45.7	36.1	55.3	Direct Colorimetric
	µg/dl	255	202	308	
Triglycerides	mmol/l	2.52	2.12	2.92	Lipase/GPO-PAP no correction
	mg/dl	223	188	258	
Urea	mmol/l	21.2	18.0	24.4	Urease kinetic
	mg/dl	127	108	146	
	mmol/l	21.2	18.0	24.4	BUN
	mg/dl	59.5	50.6	68.4	
Uric Acid (Urate)	mmol/l	0.527	0.460	0.600	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	8.85	7.73	10.1	
	mmol/l	0.511	0.440	0.580	Uricase peroxidase no ascorbate oxidase
	mg/dl	8.58	7.39	9.74	

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

Cat. No. AE1032 Lot No. 342SE Size: 20 x 5 ml Expiry: 2018-04

SIEMENS ADVIA 1200/1650/2400®

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	300	255	345	p-Nitrophenylphosphate AMP 37°C
	U/l	449	382	516	Diethanolamine buffer DEA 37°C
ALT (GPT)	U/l	123	98	148	Tris buffer without P5P 37°C
Amylase Total	U/l	496	422	570	pNP Maltotrioxide substrates 37°C
AST (GOT)	U/l	185	148	222	Tris buffer without P5P 37°C
Bilirubin Direct	µmol/l	20.7	16.4	25.0	Vanadate Oxidation
	mg/dl	1.21	0.960	1.46	
Bilirubin Total	µmol/l	83.2	65.7	101	Vanadate Oxidation
	mg/dl	4.87	3.84	5.91	
Calcium	mmol/l	3.26	2.93	3.59	Cresolphthalein complexone
	mg/dl	13.1	11.7	14.5	
	mmol/l	3.11	2.80	3.42	Arsenazo III
	mg/dl	12.5	11.2	13.7	
Cholesterol	mmol/l	6.05	5.26	6.84	Cholesterol Oxidase
	mg/dl	234	203	265	
CK Total	U/l	457	375	539	CK-NAC (IFCC) 37°C
Creatinine	µmol/l	512	410	614	Jaffe rate blanked comp. (-26 µmol/l)
	mg/dl	5.79	4.63	6.94	
Gamma-GT	U/l	116	99	133	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C
Glucose	mmol/l	16.1	13.7	18.5	Glucose oxidase
	mg/dl	290	247	333	
	mmol/l	15.8	13.4	18.2	Hexokinase
	mg/dl	285	241	328	
Iron	µmol/l	38.3	31.4	45.2	Colorimetric without ppt.
	µg/dl	214	176	252	
LD (LDH)	U/l	334	284	384	L->P 37°C
	U/l	701	596	806	P->L German methods 37°C
Magnesium	mmol/l	1.49	1.31	1.67	Xylidyl Blue
	mg/dl	3.62	3.18	4.06	
Phosphate Inorganic	mmol/l	2.28	1.94	2.62	Phosphomolybdate UV
	mg/dl	7.07	6.01	8.13	
Protein Total	g/l	72.5	58.0	87.0	Biuret reaction end point
	g/dl	7.25	5.80	8.70	
Triglycerides	mmol/l	2.64	2.22	3.06	Lipase/GPO-PAP no correction
	mg/dl	234	196	272	
Urea	mmol/l	22.2	18.9	25.5	Urease kinetic
	mg/dl	133	114	152	
	mmol/l	22.2	18.9	25.5	BUN
	mg/dl	62.3	53.0	71.6	
Uric Acid (Urate)	mmol/l	0.545	0.474	0.616	Uricase Peroxidase with ascorbate oxidase @ 546nm
	mg/dl	9.16	7.96	10.4	