

TRINA



CONTROLS & CALIBRATORS

CLINICAL CHEMISTRY

Clinical Chemistry Controls & Lipids

Clinical Chemistry and lipid quality controls have been manufactured from true human serum to ensure they perform the same manner as a patient sample with minimal lot to lot variety. The multi-analyte controls enable test menu consolidation which, along with the three year shelf life from the date of manufacture, ensures minimal waste and helps to reduce costs.

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OEM Manufacturing

TRINA Manufactures customized bulked and vialled controls, calibrators and panels. Through our scalable and lean production design, we ensure low cost and consistency in many IVD supply chains worldwide. Our strength lies in the customization and adaption of each product, while having an unrivaled access to raw materials, antigens, plasmas and components.

1. Human Plasma / Serum

- Characteristics: Matrix, Population, Regulatory
- Titer: Assay, Subtyping, IgG, IgM / Viral load / Antigen load

2. Processed Plasma

- Filter Method
- Buffer
- Antimicrobial / Antifungal Agents
- Proprietary Stabilization
- Heat treatments
- Processing Method
- Defibrination
- Delipidation
- Dialyse
- Level adjustment

3. Controls / Calibration / Proficiency testing / Panels

- Natural Enzyme immobilization
- Protease Inhibitors
- Stability Data
- Vial Selection
- Additives / Antioxidants
- Additives for Lyophilization / Liquid Stability
- Cryoprotectants

controler level process

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1.1 Multi Analyte Immunology, liquid / lyophilized

Analytes	units	Level 1	Level 2	Level 3
25-OH Vitamin D	ng/mL	15	40.00	100
Acetaminophen	ug/mL	10	30	120
ACTH	pg/mL	30	130	400
Aldosterone	pg/mL	125	350	650
Alpha Fetoprotein	ng/mL	30	120	240
Amikacin	ug/mL	4.5	12.5	25
Amitripyline	ng/mL	40	90	120
Androstenedione	ng/mL	0.8	2.5	8.0
Angiotensin I	ng/L	20	100	200
Angiotensin II	ng/L	20	40	80
b-HCG	mIU/mL	5	25	300
BMG	mg/L	1	2.5	5
CA 125	U/mL	10	25	60
CA 15-3	U/mL	10.00	25.0	100
CA19-9	U/mL	10	50	350
Caffeine	ug/mL	1.50	8.0	13
Calcitonin	ng/L	10	30	100
Carbamezapine	ug/mL	3.00	8.0	13
CEA	ng/mL	3	14	40
CK-MB	ng/mL	2.5	10	40
Cortisol	ug/dL	5	20	40
C-Peptide	ng/mL	1	5	18
Cyclosporine	ng/mL	80	175	350
DHEA Sulfate	ug/dL	60	200	500
Digoxin	ng/mL	0.6	1.6	2.8
Disopyramide	ug/mL	1.0	3.5	6.0
Estradiol	pg/mL	100	400	800
Ethosuximide	ug/mL	30	75	120
Ferritin	ng/mL	40	100	300
Folate	ng/mL	4.0	7.0	15
Follicloe Stimulating Hormone	mIU/mL	6.5	15	45
Gentamicin	ug/mL	2.5	5.0	9.0
Human Chorionic Gonadotropin	mIU/mL	5	25	300
Human Growth Hormone	mIU/mL	5	10	20
IgE	IU/mL	70	100	350
IGF-1	ng/mL	50	200	500

Analytes	units	Level 1	Level 2	Level 3
IGF-BP3	ug/mL	0.1	1.0	10
Insulin	uU/mL	25	100	200
Leutinizing Hormone	mIU/mL	2	20	60
Lidocaine	ug/mL	1.5	4.0	7.0
Lithium	mmol/L	0.5	1.0	2.25
Myoglobin	ng/mL	30	100	300
NAPA	ug/mL	2.0	4.5	10
Phenobarbital	ug/mL	10	30	50
Phenytoin	ug/mL	7.0	15	25
Primidone	ug/mL	3.0	7.0	13
Progesterone	ng/mL	1.5	10	24
Prolactin	ng/mL	8	20	40
Prostate Specific Antigen, Free	ng/mL	0.4	2.3	18
Prostate Specific Antigen, Total	ng/mL	0.5	2.9	22
PTH	pg/mL	30	300	1000
Quinidine	ug/mL	7.0	15	25
Salicylate	mg/dL	3.0	14	40
SHBG	ug/mL	AF	AF	AF
T3, Free	pg/mL	2	10	20
T3, Total	ng/mL	0.8	1.8	3
T4, Free	ng/dL	0.55	1.83	3.85
T4, Total	ug/dL	3.5	8.5	15
TBG	ug/mL	AF	AF	AF
Testosterone	ng/dL	80	700	1350
Theophylline	ug/mL	5.0	15	30
Thyroid Stimulating Hormone	uIU/mL	0.5	5.00	22.5
Tobramycin	ug/mL	1.5	5.0	9.0
Troponin, I	ng/mL	1	15	50
Valproic Acid	ug/mL	30	75	125
Vancomycin	ug/mL	4	17	30
Vitamin B12	pg/mL	250	650	900

1.2 Lipid chemistry and lipid control, with human lipids

High quality human based lipid control.

Analyte, Units	Mean	Range	Mean	Range
Albumin g/dL	2.8	2.2 – 3.4	4.5	3.4 – 5.5
Alkaline Phosphatase (ALP) U/L	98	73 – 122	394	296 – 493
ALT/SGPT U/L	49	38 – 61	186	143 – 229
Amylase, Pancreatic U/L	76	56 – 96	303	263 – 343
Asp. Aminotransferase (AST/SGOT) U/L	87	67 – 107	299	230 – 368
Bilirubin – Direct mg/dL	0.6	0.2 – 1.0	1.8	1.3 – 2.2
Bilirubin – Total mg/dL	1.4	1.0 – 1.8	4.2	3.1 – 5.3
BUN (Urea Nitrogen) mg/dL	22	17 – 27	53	48 – 58
Calcium Total mg/dL	7.9	6.9 – 8.9	11.8	10.5 – 13.1
Carbon Dioxide (CO ₂) mmole/L	12	7 – 17	28	22 – 34
Chloride mmole/L	101	92 – 111	118	107 – 128
HDL Cholesterol mg/dL	41	33 – 49	64	51 – 77
Total Cholesterol mg/dL	151	130 – 172	267	229 – 304
Creatine Kinase (CK) U/L	195	156 – 234	731	585 – 878
Creatinine mg/dL	1.6	1.0 – 2.2	5.4	4.2 – 6.6
GGT U/L	46	36 – 56	200	156 – 244
Glucose mg/dL	76	64 – 88	290	243 – 336
Lactate mmol/L	1.79	1.51 – 2.08	4.14	3.47 – 4.80
Lactate Dehydrogenase (LDH) U/L	130	107 – 154	484	397 – 571
Magnesium mg/dL	1.6	1.3 – 1.9	4.6	3.9 – 5.4
Phosphorus mg/dL	2.8	2.3 – 3.3	6.3	5.2 – 7.4
Potassium mmole/L	3.3	2.8 – 3.8	6.6	6.0 – 7.2
Protein, Total g/dL	5.0	4.5 – 5.5	7.6	6.9 – 8.4
Sodium mmole/L	133	125 – 141	161	152 – 171
Triglycerides mg/dL	144	118 – 170	290	238 – 342
Uric Acid mg/dL	3.8	3.2 – 4.3	10.6	9.1 – 12.1
CRP mg/L	40	34 – 45	128	110 – 146

1.3 Lyophilized chemistry control

Very stable clinical chemistry control to cover most laboratory QC requirements. Any given analytes can be added to customize your control.

No	Analytes	Unit	L1 Target	L2 Target
1	a-HBDH	U/L	140	400
2	ALB	g/L	42	30
3	ALP	U/L	120	300
4	ALT	U/L	25	250
5	AMY	U/L	50	250
6	AST	U/L	25	250
7	Ca	mmol/L	1.5	2.8
8	CHE	U/L	6000-8000	2000-3000
9	CHOL	mg/dL	220	110
10	CK	U/L	100	300
11	Cl	mmol/L	120	95
12	CO2	mmol/L	30	15
13	Copper	umol/L	20	10
14	Crea	mg/dL	1	5
15	DBIL	mg/dL	0.5	2
16	GGT	U/L	40	200
17	GLU	mg/dL	60	300
18	HDL	mg/dL	70	30
19	Iron	ug/dL	190-290	50-70
20	K	mmol/L	2.5	5.5
21	Lactate	mg/dL	50	15
22	LDH	U/L	130	300
23	LDL	mg/dL	110	50
24	Lipase	U/L	50	300
25	Lithium	mmol/L	0.5	2
26	Mg	mmol/L	0.6	2
27	Na	mmol/L	150	120
28	P	mmol/L	1	3
29	TBA	umol/L	15	120
30	TBIL	mg/dL	0.8	5

1.4 Chemistry & Lipid linearity Calibration / Verification

Analyte	Unit	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6	Level 7
ALT	U/L	2	185.0	368.0	551.0	734.0	917.0	1100
ALB	g/L	15	24.2	33.3	42.5	51.7	60.8	70
ALP	U/L	10	191.7	373.3	555.0	736.7	918.3	1100
Tbil	umol/L	2	51.7	101.3	151.0	200.7	250.3	300
Dbil	umol/L	1	25.8	50.7	75.5	100.3	125.2	150
Ca	mmol/L	1	1.7	2.3	3.0	3.7	4.3	5
Cl	mmol/L	50	71.7	93.3	115.0	136.7	158.3	180
CK	U/L	2	185.0	368.0	551.0	734.0	917.0	1100
Crea	umol/L	10	175.0	340.0	505.0	670.0	835.0	1000
GGT	U/L	2	185.0	368.0	551.0	734.0	917.0	1100
GLU	mmol/L	1	5.8	10.7	15.5	20.3	25.2	30
LDH	U/L	2	185.0	368.0	551.0	734.0	917.0	1100
Mg	mmol/L	0.3	0.8	1.2	1.7	2.1	2.6	3
P	mmol/L	0.4	1.0	1.6	2.2	2.8	3.4	4
K	mmol/L	2	3.0	4.0	5.0	6.0	7.0	8
TP	g/L	40	50.0	60.0	70.0	80.0	90.0	100
Na	mmol/L	110	123.3	136.7	150.0	163.3	176.7	190
Urea	mmol/L	1	5.8	10.7	15.5	20.3	25.2	30
UA	umol/L	10	175.0	340.0	505.0	670.0	835.0	1000
Chol	mmol/L	2	4.2	6.3	8.5	10.7	12.8	15
TG	mmol/L	0.5	1.8	3.0	4.3	5.5	6.8	8
HDL	mmol/L	0.5	1.8	3.0	4.3	5.5	6.8	8
LDL	mmol/L	0.5	1.8	3.0	4.3	5.5	6.8	8
AMY	U/L	5	187.5	370.0	552.5	735.0	917.5	1100
AST	U/L	2	185.0	368.0	551.0	734.0	917.0	1100
CO2	mmol/L	5	11.7	18.3	25.0	31.7	38.3	45
LAC	mmol/L	0.2	1.8	3.5	5.1	6.7	8.4	10

1.5 Lipid profile controls

The lipid profile control includes assayed method specific target values and ranges for 8 analytes covering the complete lipid profile.

Value	Level 1	Level 2
HDL-Cholesterol	32 mg/dL	68 mg/dL
LDL-Cholesterol	80 mg/dL	180 mg/dL
Total Cholesterol	130 mg/dL	300 mg/dL
Triglyceride	100 mg/dL	380 mg/dL
Apolipoprotein A	90 mg/dL	200 mg/dL
Apolipoprotein B	75 mg/dL	150 mg/dL
Apolipoprotein E	4 mg/dL	8 mg/dL
Lp (a)	12 mg/dL	20 mg/dL

- Very low turbidity
- Lyophilised or liquid enhanced stability
- 100% human serum
- Assayed target values provided for 8 parameters
- Stable to expiry date at 2°C – 8°C
- Reconstituted stability of 7 days at 2°C – 8°C or 4 weeks at -20°C

1.6 Lipids

A wide range of lipoprotein calibrators and standard controls are made upon customer request. All items are available in different specifications and concentration levels.

Code	Specificity	Source	Form
CD1130	Cholesterol TC / TG / HDL / LDL Ctrl.	human plasma	frozen / lyophil.
CD1112	HDL Concentrate, 1000 mg/dl	human plasma	frozen / lyophil.
CD1111	LDL Concentrate, 1000 mg/dl	human plasma	frozen / lyophil.
CD1113	VLDL Concentrate	human plasma	frozen / lyophil.
CT1120	BCC Concentrate, 2000 mg/dl	bovine plasma	frozen

- The listed items are only a small selection of available materials.

1.7 Lipid Control CD 1130

Item	Low level	High level
HDL-C	40 ~ 80 mg/dl	80 – 100 mg/dl
LDL-C	110 ~ 150 mg/dl	250 – 350 mg/dl
Total Cholesterol	180 ~ 250 mg/dl	400 – 500 mg/dl
Triglyceride	90 ~ 160 mg/dl	420 – 520 mg/dl

- 0.2 ml - 10 ml vials or 10L - 100L bulk
- frozen or lyophilized, 2 Years stability
- for manual / or automated platforms
- customized levels, aliquots, OEM labels, OEM boxes

Notes



Your Swiss reference partner
for IVD and Pharma customized
bulk materials.

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