

TRINA



CONTROLS & CALIBRATORS

IMMUNOASSAY

TUMOR

CARDIAC

## Immunoassay / Cardiac / Tumor Marker

Controls designed to monitor the precision of Tumor and Cardiac Markers tested at clinically relevant levels. All products are liquid or lyophilized, human based multianalyte controls, any given additional analyte can be added. Specialty products our strength.

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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 Immunoassay, liquid / lyophilized

All-in-one immunoassay control, with proteins, hormones, cardiac and tumor markers with assigned values for 67 analytes from the most frequently used instruments on the market.

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
Amitrypyline	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

<b>Analytes</b>	<b>units</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Human Growth Hormone	mIU/mL	5	10	20
IgE	IU/mL	70	100	350
IGF-1	ng/mL	50	200	500
IGF-BP3	ng/mL	AF	AF	AF
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
Theophyline	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 Cardiac Marker Controls & Calibrators

Designed to monitor the precise cardiac levels.

Product Name	Cat. No.
<b>Troponin I Calibrator</b>	
Level 1: 0 ng/ml Level 2: 10 ng/ml	CD1963
<b>CKMB Calibrator</b>	
Level 1: 0 ng/ml Level 2: 200 ng/ml	CD0350
<b>Myoglobin Calibrator</b>	
Level 1: 0 ng/ml Level 2: 1500 ng/ml	CD1270
<b>BNP Calibrator</b>	
Level 1: 0 pg/ml Level 2: 2500 pg/ml	CD0212
<b>NSE Calibrator</b>	
Level 1: 0 ng/ml Level 2: 125 ng/ml	CD1340
<b>ACTH Calibrator</b>	
Level 1: 0 pg/ml Level 2: 1000 pg/ml	CD0171

## 1.3 Multiple Cardiac Markers

Cardiac Marker Control, level 1		Cat. No.
Product Name		CD3250
Troponin I:	0.5 ng/ml	
CKMB:	6 ng/ml	
Myoglobin:	60 ng/ml	
BNP:	90 pg/ml	
Cardiac Marker Control, level 2		Cat. No.
Product Name		CD3251
Troponin I:	35 ng/ml	
CKMB:	70 ng/ml	
Myoglobin:	800 ng/ml	
BNP:	3500 pg/ml	

- Lyophilized
- Packaging: 2ml per vial in dark-brown glass vials
- Stability: 2 years at -20°C

## 1.4 Specialty Bone Immunoassay I, lyophilized

Priority	Analyte	Unit	Level 1	Level 2
1	Carbon Dioxide (CO2)	mmol/L	9	11
2	Alpha-L-Fucosidase (AFU)	U/L	5	11
3	Beta Hydroxybutyrate (β-HB)	mmol/L	0.2	0.82
4	Fructosamine (Fruc, GSP)	umol/L	180	450
5	Adenosine Deaminase (ADA)	U/L	20	150
6	5'Nucleotidase (5'-NT)	U/L	15	40
7	Anti-Cyclic Citrullinated Peptide (Anti-CCP)	IU/ml	15	50
8	Cystatin C	mg/L	0.45	1.5
9	CH50	U/mL	25	60

- Form: Lyophilized
- Packaging: 3ml per vial in dark-brown glass vials



## 1.5 Specialty Immunoassay II Hypertension, lyophilized

Name	Focused analyzer	Unit	Level 1	Level 2
ACTH	Roche Elecsys	pg/ml	10-50	350-500
TRAb	Roche Elecsys	IU/L	0-2	4-6
Anti-TG	Roche Elecsys	IU/ml	40-100	300-500
Anti-TPO	Roche Elecsys	IU/ml	30-80	300-500
TG	Roche Elecsys	ng/ml	0-10	100-160
Renin	Roche Elecsys	pg/ml	10-30	60-100
Angiotensin I	Roche Elecsys	ng/L	10-30	150-250
Angiotensin II	Roche Elecsys	ng/L	10-30	60-100
Aldosterone	Roche Elecsys	pg/ml	40-10	300-500
Calcitonin	Roche Elecsys	ng/L	5-15	70-130
ProGRP	Roche Elecsys	pg/mL	20-60	1000-2000
Procalcitonin	Roche Elecsys	ng/mL	0.4-0.8	10-13

- 3ml per vial in dark-brown glass vials
- Stability:
  - open vial: > 5 days at +2 ~ +8°C
  - closed vial: 3 years at +2 ~ +8°C
- Discrepancy between vial: < 0.5%

Notes

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Your Swiss reference partner  
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bulk materials.

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