

Survey for cardiac marker CM4/18

Survey directors:

Prof. Dr. med. C. Knabbe, Prof. Dr. Dr. K. P. Kohse, Prof. Dr. M. Neumaier

Organization:

Dr. W.-J. Geilenkeuser, Ms. Dr. A. Kessler

Comments on the evaluation

Registered online-users can find their individual pdf-evaluations on our website.

(If you are interested please register free of charge for future surveys under www.rfb.bio)

Validity of certificates

According to the guideline for the external quality control in Germany certificates will have a validity of six months, beginning from the date of issue. This date corresponds to the return date of the survey and is printed on the certificate.

Our printing and mailing date is independent from this date of issue.

Individual evaluation

Your certificate lists all quantities for which the requirements of the survey are fulfilled. These requirements correspond to the guideline of the German Medical Association (Lit.: Dt. Ärzteblatt, Jg. 111, Heft 38, 19.09.2014).

An additional participation certificate is only printed if at least for one analytes the requirements are not fulfilled ($-$ or \pm).

Target values

For the quantities albumin, IgA, IgG, IgM, coeruloplasmin and haptoglobin the reference method values are used, determined by the corresponding reference methods. For all other quantities, the medians of the results of all participants in a subcollective using the same method-kit-combination were used as target values (systemspecific target values). These medians were only used if the corresponding subcollective contained at least 4 results, otherwise the medians of the corresponding method (same method) or the total median were used. In the case of large system specific differences between results this can lead to a not appropriate, negative evaluation ($-$) in some cases. In these cases the results up to the collective number $n < 8$ were not evaluated (\pm in the list of results) and a participation certificate was issued. To give you the possibility to

compare your results with the target values, these data are printed in the list of results nevertheless (grey).

For the quantities and their concentrations in this survey the following maximum allowable deviations are applied:

quantity	MZA
CK-MB _M (concentration)	$\pm 40 \%$
CK-MB _A (activity)	$\pm 40 \%$
Myoglobin	$\pm 40 \%$
Troponin I	$\pm 33 \%$
Troponin T	$\pm 33 \%$
NT-proBNP ≥ 30 pg/ml	$\pm 40 \%$
NT-proBNP < 30 pg/ml	± 12 pg/ml
BNP	$\pm 40 \%$

Notes / Comments

Troponin I (Siemens, 3-40, 3-328;

Beckman Coulter, 3-13)

The results of the participants form separate collectives, which were evaluated separately. The reasons of the differences are currently unknown (3-40/3-Siem2; 3-328/3-Siem3; 3-13/3Beckm2).

Troponin T

The values determined in our control samples by Cardiac Reader (7-30) and Cobas h 232 (8-30) from Roche differ significantly from those measured by Elecsys. The reason might be the matrix of the control samples (serum) which is different from whole blood the instruments normally use. Therefore, the diagnosis depending on these values does not reflect the investigation of patient samples.

Youden diagrams and kit evaluations

For every quantity that you have measured you will get a Youden diagram showing the results of all the participants (grey points). All the points belonging to your method-kit-combination are printed in black. The position of your results is marked by broken lines.

In coloured evaluations your collective is printed in dark blue dots and your result is indicated by a marked circle. Light blue dots represent your collective independent of the used reagent.

Summary of results

A summary of all results you can find on our website (www.rfb.bio) and can also be sent to you on demand.

The tables next to the Youden diagrams contain the following informations for each of the two samples:

The code of the method (M), the code of the used kit, the number of results (N), minimum and maximum value (Min, Max), 16th percentile, median, 84th percentile (16.P, 50.P, 84.P). In addition, the position of the acceptance range (| |) (for coloured evaluations: green range), the median including the range between the 16.P and the 84.P (—|—) as well as your individual results (□) are shown graphically. The position of your values in the Youden diagram is marked by lines. For small collectives at "other kits" by > < marked is your kit. Depending on the number of resulting method-kit-combinations for a quantity below a certain number of participants working with the same method and kit, the calculation of percentiles is omitted, and the method-kit-combination is listed under "other kits". The number of participants using this combination is shown in brackets.

Dr. W.-J. Geilenkeuser
Dr. A. Kessler

Please notice that we will offer separate samples for the determination of BNP (Set 2).

code	methods
1	enzyme immunoassay (ELISA, EIA etc.)
2	fluorescence immunoassay, fluorescence polarisation immunoassay (IMx, AxSYM: FPIA + MEIA, Stratus, AxSym)
3	luminescence IA (LOCI, Architect, Access et al.)
4	nephelometry, turbidimetry
5	electrophoresis
6	electro-chemiluminescence IA (ECLIA)
7	test strip (Cardiac Reader et al.), cassettes (i-STAT), Triage System
8	test strip (Roche cobas h 232)
9	enzymatical testing after inhibition
10	other methods

II code numbers for test strip results

test strip results	code
analytes 8 - 10	1 negative
	2 borderline
	3 positive

If you use a read-out system (e. g. Cardiac Reader) and you get semi-quantitative results, please enter the results at analyte 1 - 7 (method 7 for test strip).

Reagenzien und Geräteschlüssel / Reagent and instrument key				Ringversuch / survey CM184	
Hersteller / manufacturer	Chiffre	Hersteller / manufacturer	Chiffre	Hersteller / manufacturer	Chiffre
Abbott	4	EKF Diagnostik	112	Omega Diagnostics GmbH	182
Acade Diag. Syst.	6	ELIAS	82	OPH Medical Systems	185
Advanced Instruments	240	Elitech Group Chemistry (vorm. Vital Scientific)	163	Organon Teknika NML	24
AESKU.Diagnostics	139	Eppendorf	22	ORGENTEC Diagnostika	141
Agilent	134	Euro-Diagnostika	29	Orion Diagn.	3
Alere GmbH (vorm. Biosite)	121	Euroimmun	5	Ortho Clinical Diagnostics	8
Alere GmbH (vormals Inverness Medical)	130	Fresenius Medical Care	340	PerkinElmer Auto DELFIA	245
Allergopharma	94	Fujifilm	89	PerkinElmer DELFIA manuell	246
ANALYTICON	37	Fujirebio Diagn.	74	PerkinElmer Diagnostics	91
ARK Diagnostics (Cobas)	167	GA-Generic Assays	133	PerkinElmer GSP	247
ARK Diagnostics(andere Geräte)	157	Gabmed	230	Pfaff	115
Arkray	164	Gentian	295	Protzek GmbH	129
AVL	136	Helena Diagnostika	46	R-Biopharm	148
Axis-Shield (vorm. Nycomed / Progen)	175	HemoCue	152	Radim	92
Axonlab	33	Hico	113	Radim (vorm. Adaltis)	76
Bayer Vital	17	Hitachi Chemical Diagn.	80	Radiometer	61
BDL Labordiagnostik	144	Hitado / Nobis	34	Randox-Laboratories	105
Beckman Coulter	13	Horiba ABX / Axon Lab	7	Recipe	75
Beckman Coulter / AU-serie	38	Human	25	Roche Diagn.	30
Beckman Coulter manuell (Nr. IM1664, A21854, IM0729)	211	Human BID-Diagnostic	18	Roxall	88
Beckman Coulter manuell (vorm. DSL and Immunotech)	111	Hybritech	86	Sarstedt	110
Becton Dickinson	10	Hycor	93	Sebia	101
Bio-Rad	2	HYPHEN BioMed (Coachrom)	174	Securetec Detektion-Systeme AG	150
Biomar Diagn.	56	IASON GmbH	155	Sentinel Diagnostics	45
Biomed	16	IBL	41	SERAMUN Diagnostica GmbH	60
bioMerieux	21	IDS S.A.	23	Serva	153
Biosite	70	IME-DC GmbH	63	Shimadzu	135
Biosource	53	Immualysis	158	Siemens Healthcare (Gerät Dimension EXL)	328
Biotec-Fischer	50	Immundiagnostik	69	Siemens Healthcare (Immulite)	44
BLW Diagnostics	280	IMMUNO	11	Siemens Healthcare (vorm. DB, Dimension RxL)	128
Boditech	159	Innovacon	78	Siemens Healthcare (vorm. DB, Vista)	228
Bruker Corporation	162	invicon	138	Siemens Healthineers	
BST Bio Sensor Tech. GmbH	67	IRIS GmbH	146	(ehem. Bayer, Atellica Solution)	40
CARE-Diagnostica	31	Kabe	1	Siemens Healthineers (vorm.Dade Behring)	28
Centronic GmbH	84	Knauer	165	Snibe	335
Chromsystems	47	Labo Bio-medical Products (LBP)	149	Sorin Clin. Assays	79
Cisbio Bioassays	143	Labor + Technik	108	Stago / Tcoag	117
Dako	14	Labor Diagnostika Nord (LDN)	355	Stago, STA-Geräte	217
Demeditec	49	Labsystems Diagnostics Oy	350	Stago, STA-Geräte	217
Determine	180	Lange	26	Systemex	145
DiAgam	156	Leica	260	Technicon	85
Diaglobal	83	lfrn DIAGNOSTIKA	170	Technoclon	87
Diagnostics Biochem Canada	270	Macherey-Nagel	127	TECOmedical	285
Diagnostik Nord	173	Mahsan	122	The Binding Site	140
Dialab Deutschland	160	Mediagnost	66	ThermoFisherScientific (vorm.Phadia)	72
Dialab Österreich	161	Medichem	15	ThermoFisherScientific, B.R.A.H.M.S	48
DiaSorin	77	Medipan Diagnostica	71	ThermoFisherScientific/Konelab	126
DiaSys	12	MENARINI diagnostics	64	Tosoh Bioscience	54
DiaSys Deutschland	20	Merck	27	ulti med	102
Diazyme	147	Meso Scale Discovery	250	Virotech Diagnostics (vorm. Sekisui Virotech)	90
Doverton Ltd	131	Mikrogen	181	Wako	103
Dr. Fooke	73	Milenia Biotec	142	Werfen (ehem. Biokit)	154
Dr. Müller Gerätebau	57	Millipore	190	Werfen (ehem. IL)	32
DRG-eigene/andere Prod.	35	MöLab	125	Willi Fox	195
DRG-Immchem. Corp.	42	Molter	114	YSI Life Sciences	345
DRG-RSL	68	MP Biomedicals	52	Zentech	9
DRG: Hybrid.XL	36	nal von minden GmbH	151	Anderer Hersteller, other producer	99
Dynabio	255	Nichols Institute	62		
Eiken/Meccenti	51	Nodia	59		
		Nycomed / Progen	97		
		oekonomed	109		

Note: Some parts of the surveys (packing, data transfer / sample preparation, manufacturing) can from time to time be subcontracted. When subcontracting occurs, it is placed with a competent subcontractor and the proficiency testing provider is responsible for this work.