CK-MB

UV-Method
RX SERIES

INTENDED USE

A CK-MB test system is a device intended for the quantitative *in vitro* determination of CK-MB concentration in serum and plasma. This product is suitable for use on RX **series** instruments, which includes the RX **daytona** and the RX **imola**.

Cat. No.

CK 3813	R1a. Buffer/Glucose	2 x 70 ml
	R1b. Enzyme/Coenzyme/Antibody	4 x 20 ml
	R2. Substrate	4 x 6 ml

GTIN: 05055273201499

CLINICAL SIGNIFICANCE [1]

Creatine Kinase (CK) is internationally accepted as a sensitive and specific indicator of acute myocardial infarction (AMI). There are 3 iso-enzymes of CK, CK-MM, CK-MB and CK-BB. CK-BB is produced by the brain in very small insignificant amounts. CK-MM is produced by the skeletal and heart tissue and CK-MB is produced by the heart muscle. In the vast majority of cases the CK activity rises within 6 hours of an acute infarction. After about 20 hours maximum values are observed. The CK activity generally returns to normal between the fourth and fifth day post- infarction.

PRINCIPLE [2]

Immunoinhibition Assay: An antibody is incorporated into the CK reagent. This antibody will bind to and inhibit the activity of the M subunit of CK-MB. This means that only the activity of the B subunit in serum is measured. If the activity is multiplied by a factor of 2, it will give the activity of CK-MB in serum.

SPECIMEN COLLECTION AND PREPARATION [2, 3]

Serum : May be used.
Plasma : EDTA or heparinized plasma may be used.

Serum samples not processed within 12hrs can be stored in tightly closed containers, protected from light, for 3 days at +4 to +8°C and 4 weeks at –20°C.

REAGENT COMPOSITION

Contents		Concentrations in the Test
R1a.	**Buffer/Glucose**	
	Imidazole Buffer	0.10 mol/l, pH 6.7
	Glucose	20 mmol/l
	Mg-Acetate	10 mmol/l
	EDTA	2.0 mmol/l
	Sodium Azide	0.02% w/v
R1b.	**Enzyme/Coenzyme/Antibody**	
	ADP	2.0 mmol/l
	AMP	5.0 mmol/l
	Diadenosine Pentaphosphate	10 ≥mol/l
	NADP	2.0 mmol/l
	HK	≥ 2.5 U/ml
	G-6-PDH	≥ 1.5 U/ml
	N-Acetylcysteine	20 mmol/l
	Polyclonal Antibody to CK-MM.	
R2.	**Substrate**	
	Creatine Phosphate	30 mmol/l

SAFETY PRECAUTIONS AND WARNINGS

For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents.

Solution R1a is classified as hazardous according to Regulation (EC) No. 1272/2008 (CLP).

Danger

H360D: May damage the unborn child

Solution R1a contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.

Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.

Safety Data Sheets are available on request.

The reagents must be used only for the purpose intended by suitably qualified laboratory personnel, under appropriate laboratory conditions.

STABILITY AND PREPARATION OF REAGENTS

All reagents are stable up to expiry when stored unopened at +2 to +8°C.

R1. Buffer/Glucose/Enzyme/ Coenzyme/Antibody
Reconstitute one vial of Enzyme/Coenzyme/Antibody R1b with **20 ml** of Buffer/Glucose R1a.

R2. Substrate
Reconstitute one vial of Substrate R2 with **6 ml** of Buffer/Glucose R1a.

MATERIALS PROVIDED

Buffer/Glucose
Enzyme/Coenzyme/Antibody
Substrate

MATERIALS REQUIRED BUT NOT PROVIDED

Randox CK-MB Control (Cat. No. CK 1212)
Randox Tri-Level Cardiac Control (Cat. No. CQ 3100 - Level 2 and Level 3 only)
Randox CK-MB Calibrator (Cat. No. CK 2393)

PROCEDURE NOTES

To avoid the potential for reagent carryover, it is recommended that the testing order of the reagents is confirmed. Please consult the reagent carryover document available on www.randox.com under support and documentation - Reagent product inserts or by contacting Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

The Chemistry Parameters for Randox Dedicated RX **series** Assays are predefined on the hard drive of the analyser PC. The required programs should be downloaded to the analyser software. Please note that the predefined chemistry parameters use SI units. If alternative units are required, these can be edited by the user. In this case, the technical range should be edited in accordance with the users selected units. All necessary instructions are encoded on the barcode. If the barcode cannot be read by the analyser, enter manually the series of numbers given beneath the barcode. If problems continue, contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 94451070.

CALIBRATION

Randox CK-MB Calibrator is recommended for calibration.

QUALITY CONTROL

Randox CK-MB Control or Tri-level Cardiac Control are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water. Contaminants i.e. bacterial growth may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 94451070.

Quality control requirements should be determined in conformance with government regulations or accreditation requirements.

SPECIFICITY/LIMITATIONS

Haemolysis may interfere with the assay. [7, 8]
High levels of CK-BB and atypical forms of CK such as Macro-CK (Type 1) and mitochondrial CK (Type 2) may cause elevated results in CK-MB immunoinhibition not associated with myocardial infarction. [5, 9, 10]
Erroneous results may be reported for patients undergoing treatment with Sulfasalazine or Sulfapyridine. It is important to consider other factors as detailed in the Normal Values section when making a diagnosis. [6]
In very rare cases, gammopathy, especially monoclonal IgM (Waldenström's macroglobulinemia), may cause unreliable results. [11]

INTERFERENCE

The analytes below were tested up to the following levels and were found not to interfere up to ± 10% of the target concentration:

Haemoglobin	Interferes
Free Bilirubin	25 mg/dl
Conjugate Bilirubin	25 mg/dl
Triglycerides	1000 mg/dl
Intralipid	200 mg/dl

Physiological changes in serum or plasma analyte concentrations can be caused by a number of substances. Comprehensive discussion of possible interfering substances, their serum or plasma concentrations, and their possible physiological involvements is beyond the scope of this document. The listed reference contains specific details on known potential interfering substances [12]. The user must remain vigilant to the possible effect on results of unknown interferences from medications or endogenous substances. All patient results must be evaluated in light of the total clinical status of the patient.

NORMAL VALUES IN SERUM [1, 4]

Myocardial infarction (MI)
The likelihood of myocardial damage is high when the following 3 factors are present: -

		Temperature		
		25°C	30°C	37°C
1	CK_{men}	>80 U/l[1]	>130 U/l[4]	>195 U/l*
	CK_{women}	>70 U/l[1]	>110 U/l[4]	>170 U/l*
2	CK-MB	>10 U/l[1]	> 16 U/l[4]	> 25 U/l*
3	a CK-MB activity between 6 and 25% of the total CK activity			

*Calculated values

MI could be suspected but the values obtained may be below the specified limits. To confirm if a recent infarct has occurred, the test should be repeated after 4 hours.

Diagnosis of MI should not be made on CK-MB results, but used in conjunction with the patient's history, ECG and other laboratory tests.

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

The following performance data was obtained using an RX **daytona** analyser at 37°C.

LINEARITY

The CK-MB assay is linear up to a concentration of 1182 U/l.

SENSITIVITY

The minimum detectable activity of CKMB with an acceptable level of precision was determined as 8.30 U/l.

PRECISION

Intra assay

	Level 1	Level 2	Level 3
Mean (U/l)	32.1	62.6	171
SD	1.99	1.98	3.84
CV (%)	6.20	3.17	2.24
n	20	20	20

Inter assay

	Level 1	Level 2	Level 3
Mean (U/l)	32.9	62.0	174
SD	2.25	2.27	2.76
CV (%)	6.86	3.66	1.58
n	20	20	20

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:

Y = 1.04 X - 1.93
and a correlation coefficient of r = 1.00

34 patient samples were analysed spanning the range 11 to 962 U/l.

REFERENCES

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The presence of a vertical bar in the margin indicates a technical update from the previous revision.

EC REP

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