

## Product information

|              |                 |                 |
|--------------|-----------------|-----------------|
| 24CKNAC01-UN | Meditest CK-NAC | 4x40 mL 2x20 mL |
| 24CKNAC01-AU | Meditest CK-NAC | 4x40 mL 2x20 mL |
| 24CKNAC01-AB | Meditest CK-NAC | 4x40 mL 2x20 mL |
| 24CKNAC01-ER | Meditest CK-NAC | 4x40 mL 2x20 mL |
| 24CKNAC01-AR | Meditest CK-NAC | 4x40 mL 2x20 mL |

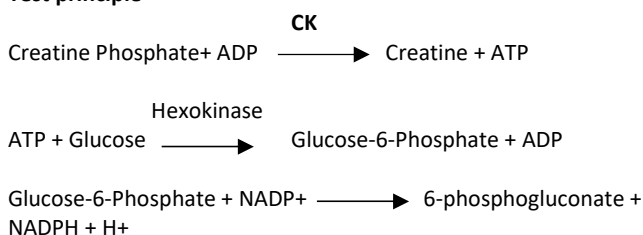
## Purpose

In vitro assay for the quantitative determination of creatinine kinase in human serum and plasma.

## Summary

CK is a dimeric enzyme that occurs in 4 different forms, a mitochondrial iso-enzyme and 3 Cytoplasmic iso-enzymes. CK MM is a muscle enzyme, CK BB is a brain enzyme and CK MB is a heart enzyme. CK activity is elevated in many diseases, including skeletal muscle, heart, central nervous system, and thyroid. Most CK determinations performed in the clinical laboratory are used for the early detection of Myocardial Infarction, in which the enzyme is elevated within 3 to 8 hours of the attack.

## Test principle



## Reagents - working solutions

|     |                            |             |
|-----|----------------------------|-------------|
| R 1 | Imidazole Buffer pH 6.7    | <100 mmol/L |
|     | Glucose                    | <20 mmol/L  |
|     | Magnesium Acetate          | >10 mmol/L  |
|     | EDTA                       | <2.0 mmol/L |
|     | ADP                        | <2.0 mmol/L |
|     | AMP                        | <5.0 mmol/L |
|     | NADP                       | <2.0 mmol/L |
|     | HK                         | >2.5 U/ml   |
|     | N-acetylcysteine           | >20 mmol/L  |
| R 2 | Creatinin Phosphate        | 30 mmol/L   |
|     | G6P-DH                     | >1.5 u/mL   |
|     | Diadenosine pentaphosphate | 10 mmol/L   |

## Precautions warnings

It is intended for in vitro diagnostic use by healthcare professionals. Follow the normal precautions necessary in handling all laboratory reagents.

Infectious or microbial waste:

Warning: handle waste as potentially biohazardous. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards: Follow all relevant local disposal regulations to determine that it has been disposed of safely. If requested, a safety data sheet can be provided to professional users.

Inhibit foam formation in all reagents and sample types (sample, calibrator and control).

If there is any damage on the package, do not use it. Read the user manual carefully before use, do not use the expired assay kit. Do not mix different lot reagents.

All samples should be considered epidemic material, please dispose of them in accordance with the laboratory working standard of infectious diseases.

Take the necessary protective measures to prevent users from becoming infected during operation.

## Use of reagents

Ready to use.

## Storage and stability

All components of the kit are stable until the expiration date on the label when stored tightly closed at 2-8°C, protected from light and contamination is avoided during their use.

Do not use reagents after the expiration date. Signs of reactive deterioration: Presence of particles and turbidity.

## Sample collection and preparation

Hemolysis-free serum is the sample of choice, as plasma can produce unpredictable reaction rates. It is recommended to follow NCCLS procedures (or similar standardized conditions) in relation to sample handling. Once the serum has been collected, it should be separated from the cells as quickly as possible.

Stability: up to 7 days if stored in a light-proof, tightly sealed tube and stored at 4°C.

## Required Materials (not included in the kit)

1. Cat# 24BIO01-DC Meditest Diachem Calibrator
2. Cat# 24BIO01-DQ Meditest Diachem Control L1
3. Cat# 24BIO02-DQ Meditest Diachem Control L2
4. General laboratory equipment
5. Distilled or deionized water

## Working Procedure

If you are using a spectrophotometer to perform this test, work with the following procedure. Ask your representative for the application data for fully automatic devices.

### 1. Test Conditions:

Wavelength: . 340 nm

Cuvette: . . . . . 1 cm light path

Temperature: . 30°C/25 or 37°C

2. Set the appliance to zero with distilled water.

3. Place the pipettes in a cuvette.

|                 | Blank | Calibrator | Sample |
|-----------------|-------|------------|--------|
| R1 (μL)         | 800   | 800        | 800    |
| Sample (μL)     | -     |            | 40     |
| Calibrator (μL) | -     | 40         | -      |

4. Mix slowly and incubate at 37°C for 5 minutes.

5. Add

|        |     |     |     |
|--------|-----|-----|-----|
| R2(μL) | 200 | 200 | 200 |
|--------|-----|-----|-----|

6. Mix slowly and incubate at 37°C for 2 min, then measure the change in Optical Density (ΔOD/min) per minute for the next 4 minutes.

### Calculation

$\frac{\Delta OD \text{ Sample} - \Delta OD \text{ Blank}}{\Delta OD \text{ Calibrator} - \Delta OD \text{ Blank}} \times \text{Concentration of Calibrator} = \text{CK MB}$

Activity

$\Delta OD \text{ Calibrator} - \Delta OD \text{ Blank}$

Conversion factor: mg/dL x 88.4 = μmol/L

### Expected values

When the following 3 conditions are met, there is a high probability of myocardial injury.

|    |                                                              | U/L at 25°C | μkat/l at 25°C | U/L at 30°C | μkat/l at 30°C | U/L at 37°C | μkat/l at 37°C |
|----|--------------------------------------------------------------|-------------|----------------|-------------|----------------|-------------|----------------|
| 1. | CK                                                           | Men         | > 80           | > 1.33      | > 130          | > 2.17      | 190>           |
|    |                                                              | Women       | > 70           | > 1.17      | > 110          | > 1.83      | > 167          |
| 2. | CK-MB                                                        |             | > 10           | > 0.17      | > 15           | > 0.25      | > 24           |
| 3. | CK-MB activity accounts for 6 – 25% of the total CK activity |             |                |             |                |             |                |

These values are for orientation purposes; Each laboratory should establish its own reference range

### Limitations

Bilirubin (mixed isomers): Less than 10% interference up to 400 μmol/l Bilirubin

Hemolysis: Less than 10% interference up to 1.25 g/l Hemoglobin

Lipemia: Less than 10% interference Intralipid up to 5 g/l.

### Performance characteristics

Measuring range: 0-1806 U/L

If the results obtained are greater than the linearity limit, dilute the sample by 1/2 with 9 g/L NaCl and multiply the result by 2.

### Precision

| N=20    | Intra-assay   |       |      | Inter-assay   |       |      |
|---------|---------------|-------|------|---------------|-------|------|
|         | Mean (μmol/L) | SD    | %CV  | Mean (μmol/L) | SD    | %CV  |
| Level 1 | 177           | 2.5   | 1.41 | 169           | 1.50  | 0.89 |
| Level 2 | 408           | 3.43  | 0.84 | 383           | 1.29  | 0.34 |
| N=20    | Intra-assay   |       |      | Inter-assay   |       |      |
|         | Mean (U/L)    | SD    | %CV  | Mean (U/L)    | SD    | %CV  |
| Level 1 | 172.1         | 4.88  | 2.83 | 165.4         | 5.58  | 3.37 |
| Level 2 | 776.4         | 13.46 | 1.73 | 740.2         | 15.26 | 2.06 |

**Accuracy:** Results obtained using Meditest reagents (y) showed no systematic differences when compared to other commercial reagents (x). The results obtained using 50 samples are as follows:

**Correlation coefficient (r)<sup>2</sup>:** 0.986

**Regression equation** y= 0.997x + 5.765

The results of the performance characteristics depend on the analyzer used.

### References

1. Ann. Biol. Clin.40 (1982) 99. & Stein W. Med Weit. 1985, 36:572.
2. Stein W. Med Weit. 1985, 36:572 & Burtis CA, Ashwood ER. Tietz Fund. Of Clin. Chem. 5th ed. 30-54, 352-390 and 974-97
3. Szasz G, Busch EW. Third European Congress of Clinical Chemistry, Brighton, England, 3-8 June 1979 (abstract)



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