respons®910

# Creatinine PAP FS*

**Diagnostic reagent for quantitative in vitro determination of creatinine in serum, plasma or urine on DiaSys respons®910**

## Order Information

**Cat. No. 1 1759 99 10 920**
4 twin containers for 180 tests each

## Method

Enzymatic colorimetric test

## Principle

Creatinine is determined by the following reaction:

$$\text{Creatinine} + H_2O \xleftrightarrow{\text{Creatininase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xleftrightarrow{\text{Creatinase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xleftrightarrow{\text{Sarcosine oxidase}} \text{Glycine} + HCHO + H_2O_2$$

$$H_2O_2 + \text{HTIB} + \text{4-AA} \xleftrightarrow{\text{Peroxidase}} \text{Quinone dye}$$

The absorbance of the produced red dye at 545 nm is proportional to the creatinine concentration in the sample.

## Reagents

### Components and Concentrations

| | | | |
|---|---|---|---|
| **R1:** | Goods buffer | pH 8.1 | 25 mmol/L |
| | Creatinase | | ≥ 30 kU/L |
| | Sarcosine oxidase | | ≥ 10 kU/L |
| | Ascorbate oxidase | | ≥ 2.5 kU/L |
| | Catalase | | ≥ 350 kU/L |
| | HTIB (3-Hydroxy 2,4,6-triiodo benzoic acid) | | 2.3 mmol/L |
| **R2:** | Goods buffer | pH 8.1 | 25 mmol/L |
| | Creatininase | | ≥ 150 kU/L |
| | Peroxidase | | ≥ 50 kU/L |
| | 4-Aminoantipyrine (4-AA) | | 2 mmol/L |
| | Potassium hexacyanoferrate | | 0.18 mmol/L |

### Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 - 8°C, protected from light and contamination is avoided. DiaSys respons containers provide protection from light. Do not freeze the reagents!

### Warnings and Precautions

1. Reagent 2 contains sodium azide (0.95 g/L) as preservative. Do not swallow! Avoid contact with skin and mucous membranes.
2. High homogentisic acid concentrations in urine samples lead to false results.
3. In very rare cases, samples of patients with gammopathy might give falsified results [9].
4. N-acetylcysteine (NAC), acetaminophe, metamizole and phenindione medication leads to falsely low, eltrombopag medication to falsely low or high results in patient samples.
5. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient`s medical history, clinical examinations and other findings.
6. For professional use only!

### Waste Management

Please refer to local legal requirements.

### Reagent Preparation

The reagents are ready to use. The bottles are placed directly into the reagent rotor.

## Specimen

Serum, heparin plasma or urine

Stability [1]:

**Serum/plasma**

| | | |
|---|---|---|
| 7 days | at | 4 - 25°C |
| 3 months | at | -20°C |

**Urine**

| | | |
|---|---|---|
| 2 days | at | 20 - 25°C |
| 6 days | at | 4 - 8°C |
| 6 months | at | -20°C |

Discard contaminated specimens. Freeze only once.

## Calibrators and Controls

For calibration, the DiaSys TruCal U calibrator is recommended. The calibrator values have been made traceable to NIST (National Institute for Standardization) Standard Reference Material SRM 967 using level 1 and 2 and, therefore, to GC-IDMS (gas chromatography-isotope dilution mass spectrometry). For internal quality control DiaSys TruLab N and P or TruLab Urine controls should be assayed. Each laboratory should establish corrective action in case of deviations in control recovery.

| | Cat. No. | Kit size |
|---|---|---|
| TruCal U | 5 9100 99 10 063 | 20 x 3 mL |
| | 5 9100 99 10 064 | 6 x 3 mL |
| TruLab N | 5 9000 99 10 062 | 20 x 5 mL |
| | 5 9000 99 10 061 | 6 x 5 mL |
| TruLab P | 5 9050 99 10 062 | 20 x 5 mL |
| | 5 9050 99 10 061 | 6 x 5 mL |
| TruLab Urine Level 1 | 5 9170 99 10 062 | 20 x 5 mL |
| | 5 9170 99 10 061 | 6 x 5 mL |
| TruLab Urine Level 2 | 5 9180 99 10 062 | 20 x 5 mL |
| | 5 9180 99 10 061 | 6 x 5 mL |

## Performance Characteristics

| | |
|---|---|
| Measuring range up to 160 mg/dL creatinine in serum and 440 mg/dL in urine (in case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function). | |
| Limit of detection** | 0.1 mg/dL creatinine |
| On-board stability | 3 weeks |
| Calibration stability | 3 weeks |

| **Interfering substance** | **Interferences (serum) < 10%** | **Creatinine [mg/dL]** |
|---|---|---|
| **Ascorbate** | up to 30 mg/dL | 1.16 |
| **Hemoglobin** | up to 400 mg/dL | 1.55 |
| | up to 550 mg/dL | 5.08 |
| **Bilirubin, conjugated** | up to 30 mg/dL | 1.81 |
| | up to 35 mg/dL | 16.2 |
| **Bilirubin, unconjugated** | up to 20 mg/dL | 1.75 |
| | up to 30 mg/dL | 16.2 |
| **Lipemia** (triglycerides) | up to 1000 mg/dL | 1.66 |
| | up to 2000 mg/dL | 15.4 |
| **Creatine** | up to 40 mg/dL | 1.52 |
| | up to 60 mg/dL | 15.0 |
| **Proline** | up to 12 mg/dL | 1.10 |
| For further information on interfering substances refer to Young DS [8]. | | |

| **Precision in serum** | | | |
|---|---|---|---|
| **Within run (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 0.79 | 1.31 | 8.04 |
| Coefficient of variation [%] | 2.09 | 1.77 | 1.46 |
| **Between run (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 0.57 | 1.07 | 6.54 |
| Coefficient of variation [%] | 3.20 | 2.62 | 1.88 |

| **Method comparison in serum (n=149)** | |
|---|---|
| Test x | DiaSys Creatinine PAP FS (Hitachi 917) |
| Test y | DiaSys Creatinine PAP FS (respons®910) |
| Slope | 1.01 |
| Intercept | 0.033 mg/dL |
| Coefficient of correlation | 0.99996 |

| **Precision in urine** | | | |
|---|---|---|---|
| **Within run (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 60.0 | 167 | 261 |
| Coefficient of variation [%] | 2.77 | 2.40 | 2.18 |
| **Between run (n=20)** | **Sample 1** | **Sample 2** | **Sample 3** |
| Mean [mg/dL] | 36.4 | 164 | 255 |
| Coefficient of variation [%] | 4.00 | 3.45 | 5.09 |

| **Method comparison in urine (n=110)** | |
|---|---|
| Test x | DiaSys Creatinine PAP FS (BioMajesty 6010) |
| Test y | DiaSys Creatinine PAP FS (respons®910) |
| Slope | 0.992 |
| Intercept | -0.171 mg/dL |
| Coefficient of correlation | 0.9995 |

** according to NCCLS document EP17-A, vol. 24, no. 34

# respons®910

## Calculation of Creatinine-Clearance [mL/min/1.73 $m^2$] [2]

$$= \frac{\text{mg Creatinine} / 100\ \text{mL Urine} \times \text{mL Urine}}{\text{mg Creatinine} / 100\ \text{mL Serum} \times \text{min Urine collection time}}$$

The calculated creatinine clearance refers to the average body surface of an adult (1.73 $m^2$).

## Conversion factor

Creatinine [mg/dL] x 88.4 = Creatinine [µmol/L]

## Reference Range

**Serum/Plasma**

| | mg/dL | µmol/L |
|---|---|---|
| **Adults** [4] | | |
| Women | 0.51 – 0.95 | 45 – 84 |
| Men | 0.67 – 1.17 | 59 – 104 |
| **Children** [5] | | |
| 0 – 7 days | 0.6 - 1.1 | 53 - 97 |
| 1 week – 1 month | 0.3 – 0.7 | 27 - 62 |
| 1 – 6 month(s) | 0.2 – 0.4 | 18 - 35 |
| 7 – 12 months | 0.2 – 0.4 | 18 - 35 |
| 1 – 18 year(s) | 0.2 – 0.7 | 18 - 62 |

**1st Morning urine** [4]

| | | |
|---|---|---|
| Women | 29 – 226 mg/dL | 2.55 – 20.0 mmol/L |
| Men | 40 – 278 mg/dL | 3.54 – 24.6 mmol/L |

**24h urine** [2]

| | | |
|---|---|---|
| Women | 720 – 1510 mg/24h | 6 – 13 mmol/24h |
| Men | 980 – 2200 mg/24h | 9 – 19 mmol/24h |

**Creatinine clearance** [2]

66.3 - 143 mL/min/1.73 $m^2$

**Albumin/creatinine ratio (early morning urine)** [10]:

< 30 mg Albumin/g Creatinine

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

## Literature


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## Manufacturer

IVD CE


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respons®910

# Creatinine PAP FS

## Application for serum, plasma or urine samples

This application was set up and evaluated by DiaSys. It is based on the standard equipment at that time and does not apply to any equipment modifications undertaken by unqualified personnel.

| Identification | |
|---|---|
| This method is usable for analysis: | Yes |
| Twin reaction: | No |
| Name: | CREAP |
| Shortcut: | |
| Reagent barcode reference: | 031 |
| Host reference: | |

| Technic | |
|---|---|
| Type: | End point |
| First reagent:[µL] | 160 |
| Blank reagent | Yes |
| Sensitive to light | |
| Second reagent:[µL] | 80 |
| Blank reagent | Yes |
| Sensitive to light | |
| Main wavelength:[nm] | 546 |
| Secondary wavelength:[nm] | 700 |
| Polychromatic factor: | 1.000 |
| 1 st reading time [min:sec] | (04:24) |
| Last reading time [min:sec] | 10:00 |
| Reaction way: | Increasing |
| Linear Kinetics<br>Substrate depletion: Absorbance li | |
| Linearity: Maximum deviation [%] | |
| Fixed Time Kinetics<br>Substrate depletion: Absorbance limit | |
| Endpoint<br>Stability: Largest remaining slope | |
| Prozone Limit [%] | |

| Reagents | |
|---|---|
| Decimals | |
| Units | |

| Sample | |
|---|---|
| Diluent | DIL A (NaCl) |
| Hemolysis: | |
| Agent [µL] | 0 (no hemolysis) |
| Cleaner | |
| Sample [µL] | 0 |
| Technical limits | |
| Concentration technical limits-Lower | 0.1 |
| Concentration technical limits-Upper | 160 |
| SERUM | |
| Normal volume [µL] | 4 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | 8 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 4 |
| Above normal dilution (factor) | 6 |
| URIN | |
| Normal volume [µL] | 4 |
| Normal dilution (factor) | 10 |
| Below normal volume [µL] | 8 |
| Below normal dilution (factor) | 10 |
| Above normal volume [µL] | 4 |
| Above normal dilution (factor) | 16 |
| PLASMA | |
| Normal volume [µL] | 4 |
| Normal dilution (factor) | 1 |
| Below normal volume [µL] | 8 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 4 |
| Above normal dilution (factor) | 6 |
| CSF | |
| Normal volume [µL] | 4 |
| Normal dilution (factor) | 1 |
| Below normal volume[ µL] | 8 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 4 |
| Above normal dilution (factor) | 6 |
| Whole blood | |
| Normal volume [µL] | 4 |
| Normal dilution (factor) | 1 |
| Below normal volume[ µL] | 8 |
| Below normal dilution (factor) | 1 |
| Above normal volume [µL] | 4 |
| Above normal dilution (factor) | 6 |

| Results | |
|---|---|
| Decimals | 2 |
| Units | mg/dL |
| Correlation factor-Offset | 0.000 |
| Correlation factor-Slope | 1.000 |

| Range | |
|---|---|
| Gender | Male |
| Age | |
| SERUM | >=0.7<=1.2 |
| URINE | >=980 <=2200 mg/24h |
| PLASMA | >=0.7<=1.2 |
| CSF | |
| Whole blood | |
| Gender | Female |
| Age | |
| SERUM | >=0.5<=1.0 |
| URINE | >=720 <=1510 mg/24h |
| PLASMA | >=0.5<=1.0 |
| CSF | |
| Whole blood | |

| Contaminants |
|---|
| Please refer to r910 Carryover Pair Table |

| Calibrators details | |
|---|---|
| **Calibrator list** | **Concentration** |
| Cal. 1/Blank | 0 |
| Cal. 2 | * |
| Cal. 3 | |
| Cal. 4 | |
| Cal. 5 | |
| Cal. 6 | |
| | **Max delta abs.** |
| Cal. 1 | 0.003 |
| Cal. 2 | 0.010 |
| Cal. 3 | |
| Cal. 4 | |
| Cal. 5 | |
| Cal. 6 | |
| Drift limit [%] | 0.8 |

| Calculations | |
|---|---|
| Model | X |
| Degree | 1 |

* Enter calibrator value