

## Creatinine PAP FS\*

### Order Information

#### Cat. No.

1 1759 99 10 920

#### Kit size



720 (4 x 180)

### Intended Use

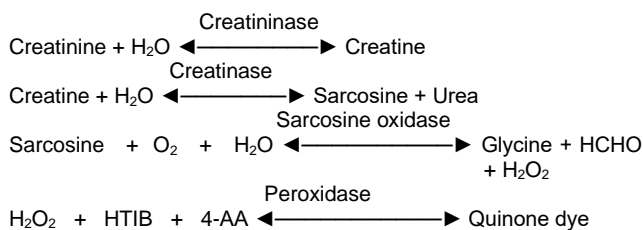
Diagnostic reagent for quantitative in vitro determination of creatinine in human serum, heparin plasma or urine on automated respons<sup>®</sup>940.

### Summary

Creatinine, a molecule produced by muscle cells, is a byproduct of creatine metabolism and is excreted in urine [1]. Since healthy kidneys consistently filter creatinine through the glomeruli, its blood concentration serves as a marker of kidney function [2]. Creatinine determination is used to evaluate kidney function and detect general kidney damage but is not intended for early-stage detection. Elevated plasma or serum levels indicate impaired kidney function, although age, gender, and muscle mass can influence results [1]. The glomerular filtration rate (GFR) is a more accurate kidney function measure, with a reduced GFR indicating decreased filtration ability [3]. Calculating creatinine clearance, based on plasma, serum, and a 24-hour urine sample, provides a direct kidney filtration assessment, but complex handling may lead to errors [1]. The currently recommended strategy for GFR estimation is based on specific formulas using plasma or serum creatinine values. The latest KDIGO guideline recommends the use of the 2021 CKD-EPI or EKFC formula [4]. This approach is used to screen, diagnose, and classify kidney disease and monitor patients with kidney damage [1,3,4]. Chronic kidney disease (CKD) is one of the most common causes of impaired kidney function. As outlined in the KDIGO guideline CKD is diagnosed when the estimated GFR remains below 60 mL/min/1.73 m<sup>2</sup> for over three months [4].

### Method

Enzymatic, colorimetric test in which creatinine is converted by the use of several enzymes (creatininase, creatinase, and sarcosine oxidase) to produce hydrogen peroxide. In a final reaction in the presence of 4-aminophenazone, the enzyme peroxidase catalyzes the hydrogen peroxide and generates a red quinone dye. The amount of produced red dye measured by the change of absorption at 545 nm is proportional to the amount of creatinine present in the sample. [5, 6]



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

### Reagents

#### Components and Concentrations

<b>R1:</b>	Good's buffer	pH 8.1	25 mmol/L
	Creatininase		≥ 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
<b>R2:</b>	Good's 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 and Stability

Reagents are stable up to the date of expiry indicated on the kit, if stored at 2 – 8°C and contamination is avoided. Do not freeze and protect from light.

The open-vial stability of the reagent is 9 months until expiry date.

### 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. The reagents contain material of biological origin. Handle the product as potentially infectious according to universal precautions and good clinical laboratory practice.
3. Some clinical chemistry reagents may cause interferences. Please take care to avoid contamination and carry-over. Special caution is needed when using reagents for the measurement of HDL-C and LDL-C. Consumables have to be cleaned thoroughly after use with other tests. In case of automated measurements please refer to the system manual for special programs.
4. High homogentisic acid concentrations in urine samples lead to false results.
5. In very rare cases, samples of patients with gammopathy might give falsified results [7].
6. N-acetylcysteine (NAC), acetaminophen, metamizole and phenindione medication leads to falsely low, eltrombopag medication to falsely low or high results in patient samples.
7. In case of product malfunction or altered appearance that could affect the performance, contact the manufacturer.
8. Any serious incident related to the product must be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is located.
9. Please refer to the safety data sheets (SDS) 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.
10. For professional use only.

### Waste Management

Refer to local legal requirements for chemical disposal regulations as stated in the relevant SDS to determine the safe disposal.

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

### Reagent Preparation

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

### Materials Required

General laboratory equipment

### Specimen

Human serum, heparin plasma or urine

Only use suitable tubes or collection containers for specimen collection and preparation.

When using primary tubes, follow the manufacturer's instructions.

Stability in serum/plasma [8]:

7 days	at	4 – 25°C
3 months	at	-20°C

Stability in urine [8]:

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

Dilute TruLab Urine controls 1 + 9 with dist. water and multiply results by 10.

Only freeze once. Discard contaminated specimens.

### Calculation

**Creatinine Clearance** [mL/min/1.73 m<sup>2</sup>] [9]

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

The calculated creatinine clearance refers to the average body surface of an adult (1.73 m<sup>2</sup>).

## Calibrators and Controls

DiaSys TruCal U is recommended for calibration. Calibrator values have been made traceable to the 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). Use DiaSys TruLab N and P or TruLab Urine Level 1 and Level 2 for internal quality control. All target values of the controls are traceable to DiaSys reagent/calibrator system. Quality control must be performed after calibration. Control intervals and limits have to be adapted to the individual requirements of each laboratory. Results must be within the defined ranges. Follow the relevant legal requirements and guidelines. 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

### Serum/Plasma

Measuring range from 0.1 mg/dL up to 68 mg/dL. Linearity < 0.5 mg/dL is given with  $\pm 0.06$  mg/dL, between 0.5 mg/dL to 1.0 mg/dL within  $\pm 10\%$ , at > 1.0 mg/dL within  $\pm 5\%$ . 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
Limit of quantitation**	0.1 mg/dL
Onboard stability	11 weeks
Calibration stability	11 weeks

Interference by	Interferences $\leq 10\%$ up to	Analyte concentration [mg/dL]
<b>Ascorbic acid</b>	18 mg/dL	0.670
	30 mg/dL	1.78
<b>Bilirubin (conjugated)</b>	15 mg/dL	0.644
	17 mg/dL	1.98
<b>Bilirubin (unconjugated)</b>	24 mg/dL	0.634
	25 mg/dL	2.05
<b>Creatine</b>	50 mg/dL	0.638
	72 mg/dL	2.06
<b>Hemolysis</b>	711 mg/dL	0.650
	1300 mg/dL	1.70
<b>Levodopa</b>	2.25 mg/dL	0.652
	2.70 mg/dL	2.02
<b>Lipemia (triglycerides)</b>	1000 mg/dL	0.618
	2000 mg/dL	1.88
<b>N-acetylcysteine (NAC)</b>	18 mg/dL	0.628
	18 mg/dL	2.06
<b>Proline</b>	12 mg/dL	0.634
	24 mg/dL	2.06

For further information on interfering substances, refer to the literature [11-13].

Precision			
Repeatability (n=80)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.676	1.46	7.10
CV [%]	1.57	1.20	0.893
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	0.676	1.46	7.10
CV [%]	2.59	2.04	2.07

Method comparison (n=215)	
Test x	Competitor Creatinine PAP (cobas c 501)
Test y	DiaSys Creatinine PAP FS (respons <sup>®</sup> 940)
Slope	1.01
Intercept	0.011 mg/dL
Coefficient of correlation	0.999

### Urine

Measuring range from 1 mg/dL up to 680 mg/dL. Linearity < 5 mg/dL is given with  $\pm 0.6$  mg/dL, between 5 mg/dL to 10 mg/dL within  $\pm 10\%$ , at > 10 mg/dL within  $\pm 5\%$ . In case of higher concentrations re-measure samples after manual dilution with NaCl solution (9 g/L) or use rerun function.

Limit of detection**	1 mg/dL
Limit of quantitation**	1 mg/dL
Onboard stability	11 weeks
Calibration stability	11 weeks

Interference by	Interferences $\leq 10\%$ up to	Analyte concentration [mg/dL]
<b>Ascorbic acid</b>	300 mg/dL	54.3
	300 mg/dL	333
<b>Boric acid</b>	301 mg/dL	52.4
	301 mg/dL	373
<b>Glucose</b>	2400 mg/dL	57.1
	2400 mg/dL	390
<b>Hydrochloric acid</b>	6 mL/dL	57.7
	6 mL/dL	368
<b>Protein</b>	321 mg/dL	52.0
	321 mg/dL	381
<b>Sodium oxalate</b>	71 mg/dL	52.7
	71 mg/dL	379
<b>Urea</b>	13000 mg/dL	59.0
	15000 mg/dL	377
<b>Uric acid</b>	24 mg/dL	55.5
	24 mg/dL	370
<b>Urobilinogen</b>	48 mg/dL	52.8
	48 mg/dL	379
<b>Vitamin B12</b>	6.2 mg/L	52.0
	6.2 mg/L	377

For further information on interfering substances, refer to the literature [11-13].

Precision			
Repeatability (n=80)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	25.9	65.0	253
CV [%]	3.01	2.92	2.92
Within-laboratory (n=80)	Sample 1	Sample 2	Sample 3
Mean [mg/dL]	25.9	65.0	253
CV [%]	3.40	3.55	3.62

Method comparison (n=55)	
Test x	DiaSys Creatinine PAP FS (BioMajesty <sup>®</sup> JCA-BM6010/C)
Test y	DiaSys Creatinine PAP FS (respons <sup>®</sup> 940)
Slope	1.05
Intercept	-1.81 mg/dL
Coefficient of correlation	0.998

\*\* according to CLSI document EP17-A2, Vol. 32, No. 8

## Conversion Factor

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

Creatinine [mg/dL] x 0.0884 = Creatinine [mmol/L]

## Reference Range

### Serum/Plasma

	mg/dL	µmol/L
<b>Adults [13]</b>		
Women	0.51 – 0.95	45 – 84
Men	0.67 – 1.17	59 – 104
<b>Children [14]</b>		
0 – 21 days	0.26 – 1.01	22 – 90
2 months – < 3 years	0.15 – 0.39	11 – 34
3 – < 7 years	0.24 – 0.48	21 – 42
7 – < 11 years	0.32 – 0.64	28 – 57
11 – < 15 years	0.42 – 0.81	37 – 72

### Urine

#### 1<sup>st</sup> Morning urine [13]

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

#### 24h urine [9]

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

#### Albumin/creatinine ratio (early morning urine) [15]:

< 30 mg/g Creatinine

#### Creatinine clearance [9]

66.3 – 143 mL/min/1.73 m<sup>2</sup>

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

## Literature

1. Thomas L. Clinical Laboratory Diagnostics [Internet]. Prof. Lothar Thomas; 2024 [cited 2024 November 05]. [https://www.clinical-laboratory-diagnostics.com/k12.html#\\_idTextAnchor4288](https://www.clinical-laboratory-diagnostics.com/k12.html#_idTextAnchor4288) and [https://www.clinical-laboratory-diagnostics.com/k12.html#\\_idTextAnchor4328](https://www.clinical-laboratory-diagnostics.com/k12.html#_idTextAnchor4328).
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Additions and/or changes in the document are highlighted in grey. For deletions, please refer to the customer information for the corresponding edition number of the package inserts.



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\* Fluid Stable

# Creatinine PAP FS

Application for serum, plasma and urine

Test Details		Test Volumes		Reference Ranges	
Test	: CREAP			Auto Rerun	<input type="checkbox"/>
Report Name	: Creatinine PAP			Online Calibration	<input type="checkbox"/>
Unit	: mg/dL	Decimal Places	: 2	Cuvette Wash	<input type="checkbox"/>
Wavelength-Primary	: 546	Secondary	: 700	Special Diluent	<input type="checkbox"/>
Assay Type	: 2-Point	Curve Type	: Linear	Warn after	: 20
M1 Start	: 23	M1 End	: 23	Reagents Used	: 2
M2 Start	: 57	M2 End	: 57	Reagent R1	CREAP R1
Sample Replicates	: 1	Standard Replicates	: 2	Reagent R2	CREAP R2
Control Replicates	: 1	Control Interval	: 0	<b>Consumables/Calibrators:</b>	
Reaction Direction	: Increasing	React. Abs. Limit	: 0.0000	Blank /Level 0	0
Prozone Limit %	: 0	Prozone Check	: Lower	Calibrator 1	*
Linearity Limit %	: 0	Delta Abs./Min.	: 0.0000	Calibrator 2	
Technical Minimum	: 0.1000	Technical Maximum	: 68.0000	Calibrator 3	
Y = aX + b a=	: 1.0000	b=	: 0.0000	Calibrator 4	
Reagent Abs Min	: 0.0000	Reagent Abs Max	: 0.0000	Calibrator 5	

Test Details		Test Volumes		Reference Ranges	
Test	: CREAP				
Sample Type	: Serum				
<b>Sample Volumes</b>				<b>Sample Types</b>	
Normal	: 5.00 $\mu$ L	Dilution Ratio	: 1 X	<input checked="" type="checkbox"/> Serum	
Increase	: 8.00 $\mu$ L	Dilution Ratio	: 1 X	<input type="checkbox"/> Urine	
Decrease	: 2.00 $\mu$ L	Dilution Ratio	: 1 X	<input type="checkbox"/> CSF	
				<input checked="" type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	
Standard Volume	: 5.00 $\mu$ L				
<b>Reagent Volumes and Stirrer Speed</b>					
RGT-1 Volume	: 180.00 $\mu$ L	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 90.00 $\mu$ L	R2 Stirrer Speed	: High		

Test Details		Test Volumes		Reference Ranges	
Test	: CREAP				
Sample Type	: Urine				
<b>Sample Volumes</b>				<b>Sample Types</b>	
Normal	: 5.00 $\mu$ L	Dilution Ratio	: 10 X	<input type="checkbox"/> Serum	
Increase	: 8.00 $\mu$ L	Dilution Ratio	: 10 X	<input checked="" type="checkbox"/> Urine	
Decrease	: 2.00 $\mu$ L	Dilution Ratio	: 10 X	<input type="checkbox"/> CSF	
				<input type="checkbox"/> Plasma	
				<input type="checkbox"/> Whole Blood	
				<input type="checkbox"/> Other	
Standard Volume	: 5.00 $\mu$ L				
<b>Reagent Volumes and Stirrer Speed</b>					
RGT-1 Volume	: 180.00 $\mu$ L	R1 Stirrer Speed	: Medium		
RGT-2 Volume	: 90.00 $\mu$ L	R2 Stirrer Speed	: High		

Test Details	Test Volumes	Reference Ranges															
Test : <input type="text" value="CREAP"/>																	
Sample Type : <input type="text" value="Serum**"/> <input type="text" value="Urine**"/>																	
Reference Range : <input type="text" value="DEFAULT"/>																	
Category : <input type="text" value="Male"/>																	
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">Reference Range</th> </tr> <tr> <th style="width: 50%;">Lower Limit (mg/dL)</th> <th style="width: 50%;">Upper Limit (mg/dL)</th> </tr> </thead> <tbody> <tr> <td>Normal : <input type="text" value="#"/></td> <td><input type="text" value="#"/></td> </tr> <tr> <td>Panic : <input type="text" value="#"/></td> <td><input type="text" value="#"/></td> </tr> </tbody> </table>		Reference Range		Lower Limit (mg/dL)	Upper Limit (mg/dL)	Normal : <input type="text" value="#"/>	<input type="text" value="#"/>	Panic : <input type="text" value="#"/>	<input type="text" value="#"/>	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Sample Types</th> </tr> </thead> <tbody> <tr><td><input checked="" type="checkbox"/> Serum</td></tr> <tr><td><input checked="" type="checkbox"/> Urine</td></tr> <tr><td><input type="checkbox"/> CSF</td></tr> <tr><td><input checked="" type="checkbox"/> Plasma</td></tr> <tr><td><input type="checkbox"/> Whole Blood</td></tr> <tr><td><input type="checkbox"/> Other</td></tr> </tbody> </table>	Sample Types	<input checked="" type="checkbox"/> Serum	<input checked="" type="checkbox"/> Urine	<input type="checkbox"/> CSF	<input checked="" type="checkbox"/> Plasma	<input type="checkbox"/> Whole Blood	<input type="checkbox"/> Other
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\* Enter calibrator value  
 \*\* Specimen selected by user  
 # Editable by user