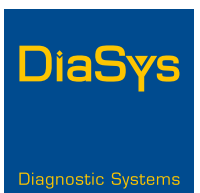


# Cystatin C FS

## High Performance in Renal Diagnostics



Early. Ageless. Powerful.  
Overcoming diagnostic uncertainty.



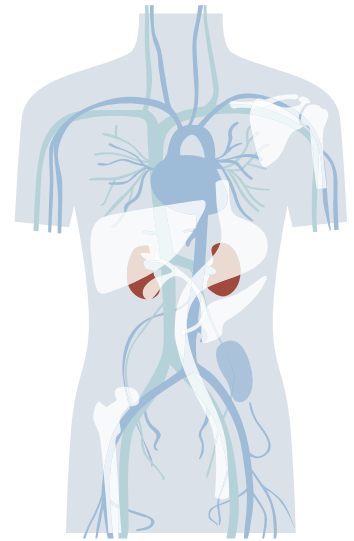
CHOOSING QUALITY.



# Clinical Relevance

Cystatin C is a non-glycosylated protein, endogenously expressed at a constant rate by all nucleated cells. Cystatin C represents an excellent biomarker for moderate impairment of kidney function, since increased Cystatin C levels indicate an even slightly impaired glomerular filtration rate (GFR).

Although the occurrence of kidney diseases is very common and disease progression is harmful, nephropathies are well treatable, if detected early. Since kidney diseases develop slowly and at least in the beginning painless, the majority of individuals with early stages of chronic kidney disease (CKD) remain undiagnosed. Therefore, early detection of renal insufficiency by a sensitive marker as Cystatin C is of increasing importance to avoid the irreversible condition of renal failure and to subsequently initiate intervention strategies.



## Benefits of Cystatin C over Creatinine

Cystatin C blood levels are, in contrast to creatinine, independent from factors as gender, muscle mass, diet, most inflammatory processes or age. Thereby, Cystatin C is especially suitable for children and elderly people, but also for individuals with decompensated liver cirrhosis, cancer, diabetes, hypertension and renal transplant recipients.

Increased creatinine serum levels do not occur until kidney function is reduced to ~ 50%. Therefore, Cystatin C determination is especially useful in the “creatinine blind-range“ defined by a GFR of 40–80 mL/min/1.73 m<sup>2</sup>.

Cystatin C represents a superior marker for detection of reduced GFR compared to creatinine, especially for the identification of mild to moderate impaired kidney function.

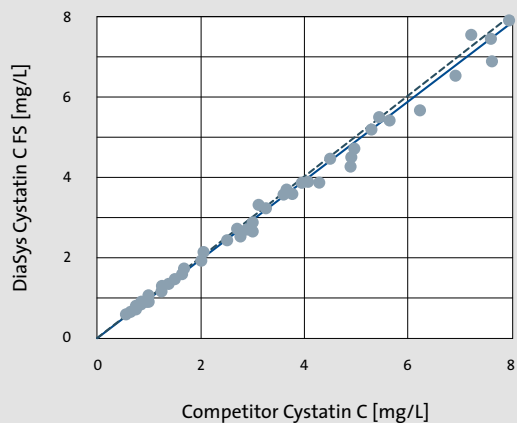
## Strong Arguments for Cystatin C FS

### Test Characteristics

- Particle-enhanced immunoturbidimetric test
- Suitable for serum and plasma samples
- Perfectly matched liquid-stable reagents, calibrators and controls
- Wide measuring range from 0.1 to 8.0 mg/L
- High prozone security up to 30 mg/L
- Outstanding analytical sensitivity
- Excellent on-board (up to 12 weeks) and calibration stability (up to 6 weeks)
- Application on a broad range of clinical chemistry analyzers
- Standardized against ERM<sup>®</sup>-DA471/IFCC reference material

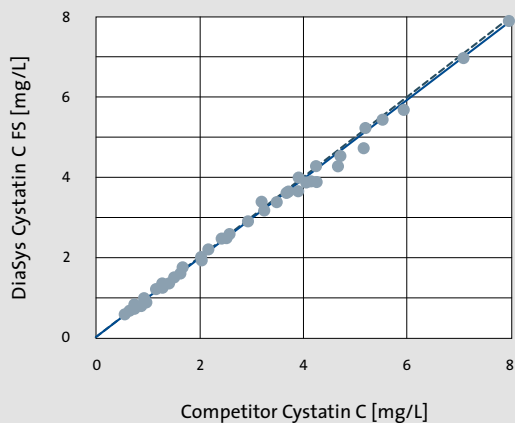
# Performance Data

## Method comparison vs nephelometric method



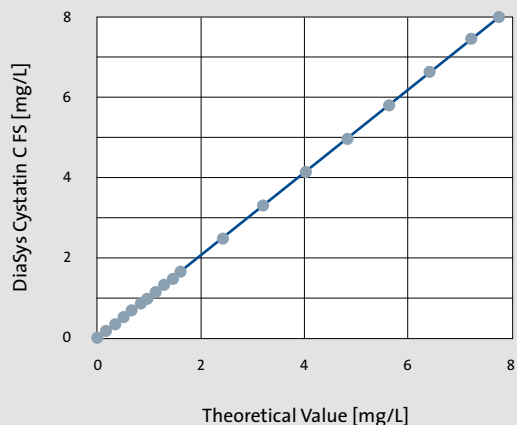
n = 109; Passing/Bablok Regression:  
 $Y = 0.974 \cdot X + 0.017 \text{ mg/L}; r = 0.9970$

## Method comparison vs immunoturbidimetric method



n = 105; Passing/Bablok Regression:  
 $Y = 0.984 \cdot X + 0.032 \text{ mg/L}; r = 0.9975$

## Linearity according to CLSI



Source: CLSI guideline EP06-A section 5.1

## Imprecision

Intra-assay N = 20	Mean (mg/L)	SD (mg/L)	CV (%)
Sample 1	0.62	0.01	2.00
Sample 2	0.89	0.01	1.52
Sample 3	3.19	0.02	0.63

## Leading Technology in Fluid-stable Reagents from DiaSys

- Over 20 years of experience in development and production of clinical chemistry tests
- Premium service supply in technics, applications and after sales
- Quality products made in Germany
- High performance, ready-to-use reagents with minimized interferences, long shelf life, on-board stability and traceability to international references
- Perfectly matched fluid-stable reagents, calibrators and controls
- High grade raw materials from traceable origin
- Processes and resources certified according to ISO 13485, ISO 9001, fulfilling highest quality standards
- Sustainable processes and products preserve the environment

## CHOOSING QUALITY.

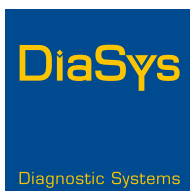
DiaSys offers reagent kits for manual and automated use plus the appropriate calibrators and controls. Detailed information about the Cystatin C test is available on our website [www.diasys-diagnostics.com/products/reagents](http://www.diasys-diagnostics.com/products/reagents) and in our product catalogue.

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