

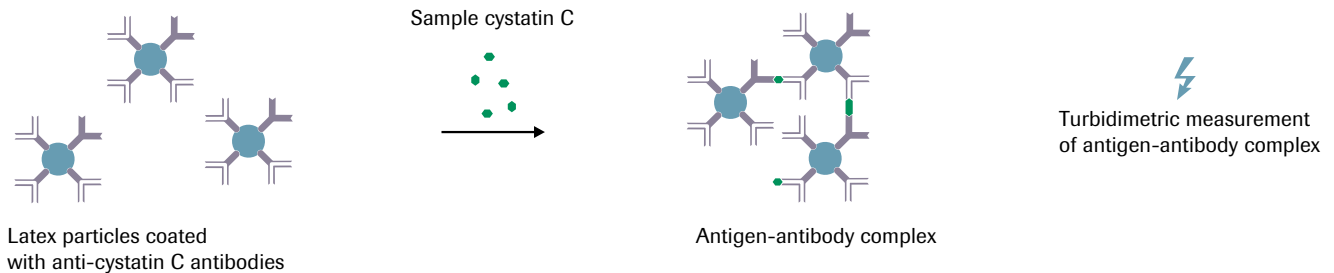
# Tina-quant<sup>®</sup> Cystatin C

## *Particle-enhanced turbidimetric immunoassay (PETIA) for the quantitative determination of cystatin C in human serum and plasma*

### Indication

Cystatin C is a non-glycosylated, single chain protein of 13.3 kDa molecular weight. It is produced by all nucleated cells at a constant rate over the entire lifetime. Due to the fact that the elimination of cystatin C from the circulation is almost entirely via glomerular filtration, the cystatin C plasma concentration is independent from muscle mass, gender and age. Thus any changes, however small, in the glomerular filtration rate (GFR) are reflected by a change in the serum cystatin C level. Patient groups which benefit most are those with mild to moderate kidney disease, patients with acute renal failure, elderly people (> 50 years), children, pregnant women with suspicion of pre-eclampsia, people with diabetes or skeletal muscle diseases as well as renal transplant recipients. Additionally, cystatin C has been discussed in recent literature as a prognostic marker for acute heart failure.

### Test principle: Particle-enhanced turbidimetric immunoassay (PETIA)



### Mixing & incubating of antibody reagent and sample

The latex enhanced particles coated with anti-cystatin C antibodies (rabbit) in the reagent agglutinate with the human cystatin C in the sample. During the incubation phase an antigen-antibody complex is formed.

### Measurement of the antigen-antibody complex

The degree of the turbidity caused by the aggregate can be determined turbidimetrically at 546 nm and is proportional to the amount of cystatin C in the sample: the higher the cystatin C concentration, the higher the turbidity.

### Turbidimetry technology

Turbidimetry is Roche's technology for homogeneous immunoassay detection. Continuous development of turbidimetric technology over the past years – both in detection methods as well as in assay design – have made turbidimetry a highly precise and sensitive detection method. The use of bichromatic wavelengths in spectrophotometry in conjunction with the measurement of a sample blank minimizes interference effects.



Life needs answers

### Tina-quant® Cystatin C test characteristics

	<b>cobas c 311 analyzer/ cobas c 501/c 502 module COBAS INTEGRA® 400 plus/800</b>	<b>cobas c 701/c 702 module</b>	Roche/Hitachi MODULAR analyzer
Analyzer compatibility	<b>cobas c 311 analyzer/ cobas c 501/c 502 module COBAS INTEGRA® 400 plus/800</b>	<b>cobas c 701/c 702 module</b>	Roche/Hitachi MODULAR analyzer
Reaction time	10 min	10 min	10 min
Calibration	6 point spline	6 point spline	6 point spline
Sample material	Serum, Li-heparin plasma	Serum, Li-heparin plasma	Serum, Li-heparin plasma
Repeatability	0.52 mg/L = 2.7% 6.30 mg/L = 0.6%	0.499 mg/L = 3.6% 0.857 mg/L = 1.2% 7.37 mg/L = 0.7%	0.75 mg/L = 1.7% 5.14 mg/L = 0.7%
Intermediate precision	0.65 mg/L = 3.8% 7.16 mg/L = 2.6%	0.65 mg/L = 3.8% 7.16 mg/L = 2.6%	0.73 mg/L = 2.8% 4.98 mg/L = 2.1%
Expected values	For individuals 20-70 years: 0.47 - 1.09 mg/L	For individuals 20-70 years: 0.47 - 1.09 mg/L	For individuals 20-70 years: 0.47 - 1.09 mg/L
Measuring range	0.4 - 8 mg/L	0.4 - 8 mg/L	0.4 - 8 mg/L
On-board stability	8 weeks	8 weeks	8 weeks
Calibration frequency	Each reagent lot and after 90 days	Each reagent lot and after 90 days	Each reagent lot and after 90 days

### Estimated glomerular filtration rate (eGFR)

Current guidelines define chronic kidney disease as kidney damage or glomerular filtration rate (GFR) less than 60 mL/min per 1.73 m<sup>2</sup> for 3 months or more, regardless of cause. GFR is the most frequently used criteria in the assessment of renal function. For calculation of eGFR from cystatin C values measured with the Roche Tina-quant® Cystatin C assay the following prediction equation is recommended using only concentration in mg/L and a prepubertal factor:

$$\text{eGFR [mL/min/1.73 m}^2\text{]} = \frac{84.69}{\text{cystatin C [mg/L]}^{1.680}} \times 1.384^*$$

\* for children < 14 years

### Order information

Tina-quant® Cystatin C <b>cobas c 311 analyzer/ cobas c 501/c 502 modules COBAS INTEGRA® 400 plus/800</b>	225 tests	04975723 190
Tina-quant® Cystatin C <b>cobas c 701/c 702 modules</b>	200 tests	05950716 190
Tina-quant® Cystatin C Hitachi MODULAR analyzer	R1: 1 x 21 mL R2: 1 x 5 mL	04975774 190
C.f.a.s. Cystatin C	4 x 1 mL	04975901 190
Cystatin C Control Set	2 x 4 x 1 mL	04975936 190

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