

ARCHITECT Cystatin C Product Information

Method	Particle Enhanced Turbidimetric ImmunoAssay (PETIA)		
Systems	ARCHITECT c4000*, c8000, c16000, ci4100*, ci8200, ci16200 and AEROSET		
Throughput	ARCHITECT c8000: photometric assays up to 800 tests per hour AEROSET and ARCHITECT c16000: photometric assays up to 1600 tests per hour		
Time to first result	ARCHITECT c8000, ARCHITECT c16000, AEROSET: 4–10 Minutes		
Automatic dilution	1:5		
Sample type	Serum, Plasma (lithium heparin [with or without gel barrier], sodium heparin, and EDTA)		
Standardization	Internal standard obtained from highly purified material		
Sample volume	2 µL		
Sample stability	7 days at 2–8 °C		
Calibration curve stability	45 days/reagent lot		
Reagent stability	45 days at 2–8 °C		
Reagents, Calibrators, Controls	Liquid ready to use		
Sensitivity** (LOD)	0.05 mg/L		
Imprecision** (total %CV)	Serum and Plasma: < 5.0%CV		
Dynamic range**	0.05 mg/L up to highest Calibrator (7–9 mg/L)		
Expected values***	Gender	Age < 50	Age > 50
	Female	0.44–0.76 mg/L	0.47 – 0.88 mg/L
	Male	0.45 – 0.74 mg/L	0.44 – 0.93 mg/L

* in development

Abbott data on file

** Representative data; results in individual laboratories may vary from data shown.

*** It is recommended that each laboratory establish its own expected range.

Ordering Information

Product	Packaging size	L/N
ARCHITECT c Systems and AEROSET Cystatin C Reagent	500 T (2x250 T) (R1: 2x46 mL, R2: 2x13 mL)	1P93-01
ARCHITECT c Systems and AEROSET Cystatin C Reagent	2000 T (8x250 T) (R1: 8x46 mL, R2: 8x13 mL)	1P93-02
Cystatin C Calibrator (7–9 mg/L)	2 x 1 mL	1P93-10
Cystatin C Controls	Low Control at 0.50–0.90 mg/L High Control at 2.50–4.00 mg/L	2 x 1 mL 1P93-20
ARCHITECT Special Chemistry Assay Disc	1 CD-ROM	2P10-01 (conv. units) 2P11-01 (SI units)



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ARCHITECT Cardiac
and Renal Assays

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Detect the invisible disease

ARCHITECT Cystatin C



ARCHITECT Cystatin C

Synthesis and Catabolism

- All nucleated cells express and constantly secrete Cystatin C
- Cystatin C is almost completely cleared by glomerular filtration and degraded upon reabsorption by tubular cells

Very small changes in the glomerular filtration rate (GFR) may significantly influence serum Cystatin C concentration indicating that Cystatin C is a very sensitive marker of kidney function.

Clinical Benefits

Clinically, Cystatin C measurement can be used as a measure of GFR. Its sensitivity to changes in GFR was found to be superior to serum Creatinine because its circulating concentration is largely unaffected by various extra-renal factors like weight, height, muscle mass and gender.

Cystatin C shows advantages over Creatinine for estimating glomerular filtration rate especially in:

- Children
- High risk patients (e.g. diabetes)
- Elderly patients
- Intensive care unit patients (reduced muscle mass, increased body water)

Cystatin C is also a reliable marker for eGFR in patients with mild kidney dysfunction and increased risk for cardiovascular disease.

Cystatin C helps to detect already mild decrease in kidney function which cannot be identified with creatinine.

G. Filler et al., Clinical Biochemistry 38, 1–8 (2005)
 V. Menon et al., Ann Intern Med. 147, 19–27 (2007)
 R. Hojs et al., Nephrol Dial Transplant 21, 1855–1862 (2006)
 A. S. Go et al., NEJM, 351; 1296–305 (2004)
 M. G. Shlipak et al., NEJM, 352; 2049–60 (2005)

Calculation of the GFR

Cystatin C concentration inversely correlates with the glomerular filtration rate. The glomerular filtration rate can be easily calculated with the following formula which was developed for the Abbott Cystatin C assay using the ARCHITECT c systems or AEROSET, with n= 522 (n= 445 adults, n=77 children).

$$\text{eGFR (mL/min/1.73 m}^2\text{)} = \frac{71}{\text{Cystatin C [mg/L]}^{1.28}}$$

The formula needs to be multiplied with a juvenile factor of 1.332 for children below the age of 14.

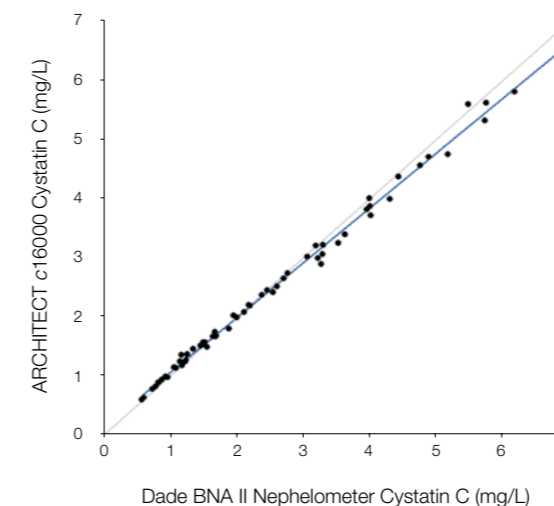
Using this formula stages of chronic kidney disease can be determined easily

Stage	Description	eGFR [mL/min/1.73 m ²]	Cystatin C value [mg/L]
1	Slight kidney damage with normal or increased filtration	≥90	<0.83
2	Mild decrease in kidney function Stage 2 is known as the creatinine blind area but can be correctly detected with Cystatin C measurement.	60–89	1.14–0.84
3	Moderate decrease in kidney function	30–59	1.96–1.16
4	Severe decrease in kidney function	15–29	3.37–2.01
5	Kidney failure requiring dialysis or transplantation	< 15 or dialysis	>3.37

J. Björk, V. Lindström, L.-O. Hansson, A. Grubb, Poster submitted for presentation at the EuroMedlab congress, Innsbruck, Austria, June 2009
 J. Roos et al., Clinical Biochemistry 40, 383–391 (2007)
 M. Chen et al., Am J Kidney Dis 42: 4, 623–625 (2003)

Method Comparison

ARCHITECT c16000 vs Nephelometer
 $y = 0.929x + 0.126$, $r = 0.998$, $n = 61$



ARCHITECT c8000 vs AEROSET
 $y = 1.020x - 0.029$, $r = 0.998$, $n = 80$

