

CYSTATIN C

Superior biomarker of renal function¹
recommended by KDIGO² and NICE³



CE-marked ● FDA510(k) cleared ● ERM-DA471/IFCC standardised ● Clinical chemistry ● Platform agnostic

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Cystatin C in diagnosis and therapeutic assessment of renal function

Cystatin C is an established marker for estimating glomerular filtration rate (GFR). GFR calculations performed using cystatin C are independent of protein intake, ethnicity and muscle mass²⁻⁵. Equations that include cystatin C predict GFR more accurately than serum creatinine in children^{*6}, adults⁷, and older adults⁸. Clinical use of cystatin C is recommended in guidelines published by KDIGO² and NICE³.



"Hospital laboratories must make cystatin C available for clinical care to improve the safety and efficacy of medications that have narrow therapeutic windows"

Dr. N. Ebert and Dr. M. Shlipak

- Current Opinion in Nephrology and Hypertension nr 6 2020⁹

The Gentian Cystatin C Immunoassay

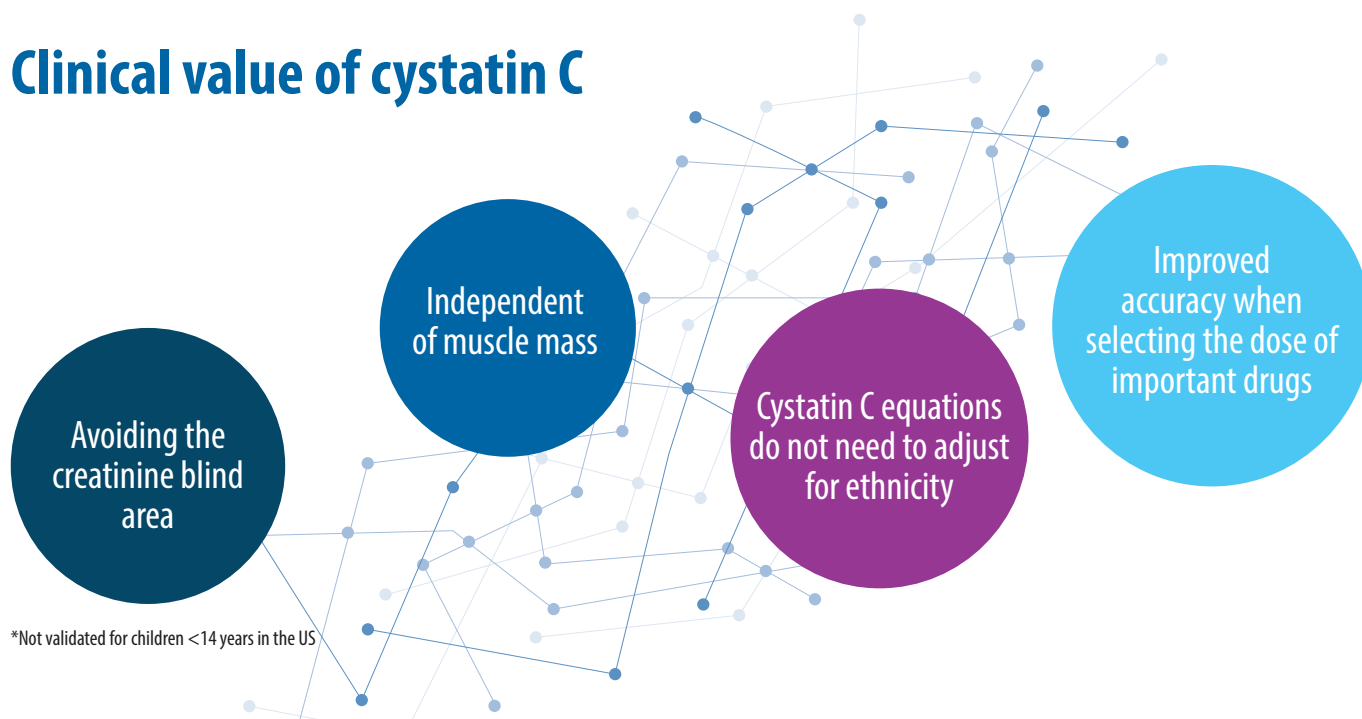
The Gentian Cystatin C Immunoassay (ERM-DA471/IFCC standardised) is an in vitro diagnostic test for quantitative determination of cystatin C in human serum and plasma. The FDA510(k) cleared, CE-marked, Particle-Enhanced Turbidimetric Immunoassay (PETIA) can be used on most clinical chemistry analysers that are currently on the market.

Cystatin C in clinical settings

While the clinical use of cystatin C can have far-reaching benefits across all patient groups, certain vulnerable patient populations may experience a greater benefit. Specifically, children, amputees and the elderly would receive more accurate eGFRs with cystatin C because its concentrations are independent of muscle mass and show less age and gender-related variation relative to creatinine²⁻⁸.

Precise eGFR determination is also important in patients who are prescribed medications that are renally excreted. Drugs with a narrow therapeutic index or toxic range can be more accurately dosed when cystatin C is included in the evaluation of the patients' kidney function. Cystatin C based dosing of pharmaceuticals such as Digoxin, Carboplatin and Vancomycin can lead to better patient outcomes, decreased length of stay and lower treatment cost¹⁰.

Clinical value of cystatin C



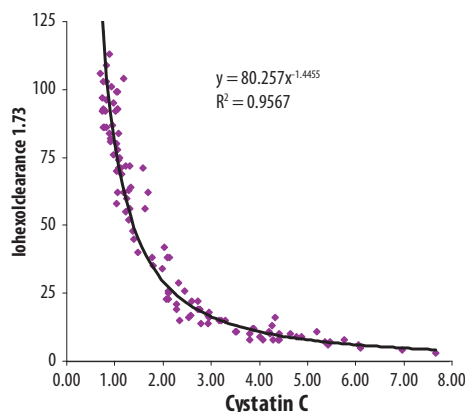
*Not validated for children <14 years in the US

Cystatin C in addition to creatinine

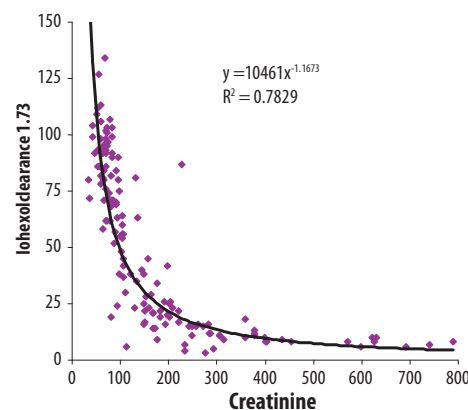
GFR can be estimated with greater accuracy if both cystatin C and creatinine are used. Cystatin C based GFR-estimating equations are superior to creatinine-based equations in predicting end-stage renal disease, cardiovascular manifestations, hospitalisation and death⁵.

Serum creatinine does not increase until the GFR has moderately decreased about 40 ml/min/1.73 m². This insensitivity for small to moderate decreases in GFR in creatinine blind GFR area (30-70 ml/min/1.73 m²) gives a false sense of security and leads to late detection of kidney damage⁸. All this makes serum creatinine less reliable for making therapeutic decisions in critically ill patients, such as decision to change nephrotoxic drugs or measures to increase renal perfusion¹¹.

Cystatin C with stronger correlation with mGFR:



Correlation between cystatin C and iohexol clearance in 160 patient samples



Correlation between creatinine and iohexol clearance in 160 patient samples

The graphs above illustrate the stronger correlation observed between cystatin C serum concentrations and iohexol clearance rates relative to that which is seen with creatinine. This improved correlation can be of clinical significance and lead to improved patient care¹².

The Gentian Cystatin C Immunoassay - Advantages



**Turbidimetric
test
Faster
throughput**



**Can be applied
on most
automated
platforms**



**Process time
normally less
than 10 minutes**



**Avian
antibodies**

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References: 1. Dharnidharka VR, et al. Am. J. Kidney Dis. 2002;40:221–226. 2. KDIGO Guidelines 2012 published in Kidney International Supplements Vol3 Issue 1, Jan 2013. 3. NCIC Clinical guideline (CG182) updated jan 2015 section 2.1 <https://www.nice.org.uk/guidance/cg182/chapter/2-Implementation-getting-started>. 4. Tangri N, et al. Kidney Int 2011;79:471–7. 5. Grubb A, et al. eJIFCC 2017 Vol 28 NO4 pp 268–276. 6. Björk J et al. Pediatr Nephrol. 2019;34:1087–1098. 7. Lesly A et al. N Engl J Med 2012;367:20–29. 8. Schaeffner ES et al. Ann Intern Med 2012;157:471–481. 9. Ebert N et al. Curr Opin Nephrol Hy. 2020;29(6):592–598 10. Frazee E et al- Am J Kidney Dis 2017;69:658–666. 11. Murty MS et al. Indian J Nephrol. 2013;23(3):180–183. 12. Flodin M. et al. Scand J Clin Lab Invest. 2007;67(5):560–7.

Compatible with

ADVIA®, Siemens Healthcare • ARCHITECT®, Abbott Laboratories • AU®, Beckman Coulter • VITROS®, Ortho Clinical Diagnostics • BS®, Mindray • COBAS®, Roche

Gentian Cystatin C Immunoassay Performance	
Sample type	Serum and plasma
Assay type	PETIA
Format	Two reagents ready to use
Precision*	Total CV < 2.0 % within the measuring range
LoQ*	0.40 mg/L
Security zone*	10.3 mg/L
Measuring range	~ 0.4 - 8.0 mg/L
Assay Time	~ 10 minutes
Standardisation	Calibrated against reference material ERM-DA471/IFCC

*Instrument specific, results from the Dx C 700 AU® application validation.

Calibrator standardisation

The calibrator for the Gentian Cystatin C Immunoassay is available in two versions, one-level calibrator for auto-dilution or a 6-point pre-diluted calibrator kit. Both types of calibrators are standardised against the international calibrator standard ERM-DA471/IFCC.

Product range

Product no.	Product	Content
1101	Gentian Cystatin C Immunoassay Reagent Kit	58 mL + 10 mL
1019	Gentian Cystatin C Control Kit	2 x 1 mL
1026	Gentian Cystatin C Control Kit	2 x 5 mL
1029	Gentian Cystatin C Single Use Control Low	100 x 150 µL
1030	Gentian Cystatin C Single Use Control High	100 x 150 µL
1051	Gentian Cystatin C Calibrator Kit	6 x 1 mL
1012	Gentian Cystatin C Calibrator	1 mL



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Contact information: marketing@gentian.com • www.gentian.com

Gentian HQ

Bjørnåseveien 5, PO Box 733
1509 Moss
Norway

Gentian Diagnostics AB

Kungsgatan 8
11143 Stockholm
Sweden

Gentian USA Inc

215 N Eola Dr
Orlando
Florida USA

Beijing Rep. Office

Zhongren Building Rm. 4076
Chaowai St Jia No.10
Chaoyang District, Beijing, China

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