Superior biomarker of renal function¹

CYSTATIN C

Recommended for assessment of Glomerular Filtration Rate (GFR) and kidney function²

An open channel turbidimetric immunoassay

CE-marked 🛑 FDA510(k) cleared 🍎 ERM-DA471/IFCC standardised

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A better estimated Glomerular Filtration Rate (eGFR)

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 can receive more accurate eGFRs with cystatin C, since cystatin C is less susceptible to factors that affect muscle mass, like age, diet, sex, race, physical activity, etc.^{3,4}.

Clinical use of cystatin C is recommended in guidelines published by KDIGO⁵. The National Kidney Foundation (NKF) in the US and the American Society of Nephrology (ASN) have also recently, in a joint taskforce, recommended to increase the use of cystatin C combined with serum (blood) creatinine as a confirmatory assessment of GFR or kidney function⁶.

Removing the race factor from creatinine equations

The NKF-ASN task force also suggests removing the race factor from the creatinine equations³. The removal of the race factor introduces systematic misclassification that cannot be eliminated even when numerous non-GFR determinants of the serum creatinine level are accounted for⁷. Cystatin C based eGFR equations are without a race factor and cystatin C can be used together with creatinine, or on its own, to calculate the eGFR without the race factor. The most accurate results will be with the combination of cystatin C and creatinine⁸.



"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 2020

Cystatin C in drug dosing

Precise eGFR determination is 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 for example Digoxin, Carboplatin and Vancomycin can lead to better patient outcomes, decreased length of stay and lower treatment cost⁹.





The ideal combination with creatinine

Serum creatinine levels are only elevated after about 50% of renal function is lost¹⁰. This insensitivity to mild renal insufficiency within what is known as the creatinine blind area (30-70 ml/min/1.73 m2) could give a false sense of security that in-tern leads to under diagnosis of chronic kidney disease (CKD) stages 1 and 2. Depending on creatinine alone to assess kidney function may therefore prevent detection of a variety of renal diseases for which early treatment is critical¹¹.

GFR estimating equations that incorporate both creatinine and cystatin C values together are more accurate than equations that use either marker alone^{7,12}. Using cystatin C in conjunction with creatinine to risk stratify CKD patients can allow for better allocation resources such as nephrology referrals, medication dosage adjustments and more invasive kidney function tests¹³. Use of cystatin C in combination with creatinine has also been shown to strengthen the association between eGFR and risk of cardiovascular disease, progression into end-stage renal disease and death¹⁴.

Cystatin C with stronger correlation with mGFR:



Correlation between cystatin C and iohexol clearance in 160 patient samples



The graphs to the left 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 care¹⁵.

Correlation between creatinine and iohexol clearance in 160 patient samples

The Gentian Cystatin C Immunoassay - Advantages



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References: 1. Dharnidharka, VR et al. Am J Kidney Dis, 2002. 40(2): p. 221-6. 2. Ebert, N and MG Shlipak. Curr Opin Nephrol Hypertens, 2020. 29(6): p. 591-598. 3. Tangri, N et al. Kidney International, 2011. 79(4): p. 471-477. 4. Grubb, A. Ejifcc, 2017. 28(4): p. 268-276. 5. KDIGO Guidelines 2012 published in Kidney International Supplements Vol3 Issue 1, Jan 2013. 6. Miller, WG et al. National Kidney Foundation Laboratory Engagement Working Group Recommendations for Implementing the (KD-EPI 2021 Race-Free Equations for Estimated Glomerular Filtration Rate: Practical Guidance for Clinical Laboratories. Clinical Chemistry, 2021. 7 Hsu, C-Y et al. New England Journal of Medicine, 2021. 8. Delgado, C et al. Am J Kidney Dis, 2017. 69(5): p. 658-666. 10. Gounden V, BH, Jialal, StatPearls. 2021, https://www.ncbi.nlm.nih.gov/books/NBKS07821/: StatPearls Publishing. 11. Schaeffner, ES et al. Ann Intern Med, 2012. 157(7): p. 471-81. 12. Inker, LA et al. New England Journal of Medicine, 2021. 13. Murty, MS et al. Indian J Nephrol, 2013. 23(3): p. 180-3. 14. Shlipak, MG et al. New England Journal of Medicine, 2013. 369(10): p. 932-943. 15. Flodin, M et al. Scand J Clin Lab Invest, 2007. 67(5): p. 560-7.

Immunoassay performance

Gentian Cystatin C Immunoassay performance		
Sample type	Plasma and serum	
Assay type	PETIA	
Format	Two reagents ready to use	
Precision*	Total CV $<$ 2.0 % within the measuring range	
LoQ*	0.4 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 DxC 700 AU® application validation.

Compatible with selected clinical chemistry instruments from:

Abbott Laboratories, Beckman Coulter, Mindray, Ortho Clinical Diagnostics, Roche and Siemens Healthcare

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



** Only available in the US.

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

Gentian HQ

Bjørnåsveien 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

