CYSTATIN C ASSAY

Renal and Pancreatic Marker

The Diazyme Cystatin C assay is a cost effective dual vial liquid stable system which is directly traceable to ERM-DA471/IFCC, the international standard reference material. The test utilizes Avian IGY antibodies to virtually eliminate some of the most common causes for interference in immunoassay's.

In published literature, studies show that Cystatin C is an effective renal biomarker for eGFR and, per KDIGO 2012 guideline, is recommended for the early confirmation and diagnosis of Chronic Kidney Disease (CKD).[1] Studies also suggest that Cystatin C may help facilitate kidney disease screening in the elderly, and those with diabetes, hypertension, or cardiovascular disease.[2-7]

DIAZYME CYSTATIN C ASSAY ADVANTAGES

- Accurate Cystatin C immunoassay measurement with Avian IgY antibodies
- No interference from rheumatoid and HAMA factors
- Assay is traceable to the international standard reference, (ERM-DA471/IFCC)
- Linearity: 0.2-8.0 mg/L
- Liquid stable reagent, calibrator and controls requires no additional preparation
- Wide range of instrument parameters available for simplifying implementation

REGULATORY STATUS

510(k) Cleared; EU: CE IVD

DIAZYME
Innovations in Clinical Diagnostics

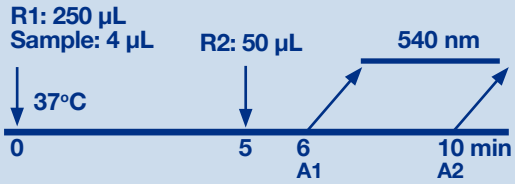
CYSTATIN C ASSAY

Dual Vial
Liquid Stable

ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidometric (Avian IGY antibodies quantification at 540 nm)
Sample Type & Volume	• Serum • Plasma - Heparin - EDTA Sample Volume 4 µL
Method Correlation	N = 45 y-intercept = 0.0715 Slope = 0.9999 R^2 = 0.9922
Linearity	0.2 to 8.0 mg/L
LOB **LOD** **LOQ**	0.04 mg/L 0.068 mg/L 0.19 mg/L
Calibration Levels	5-Point Calibration
Traceability	Standard traceable to ERM-DA471/IFCC primary reference material
Reagent On-Board Stability	Opened: 4 weeks when kept stored at 2-8°C

Cystatin C Assay Procedure*



***Analyzer Dependent**

Parameter questions for Cystatin C Assay should be addressed to Diazyme Technical Support. Please call 858.455.4768 or email support@diazyme.com

1. Kidney International Supplements (2013) 3, 136–150; doi:10.1038/kisup.2012.72; 5-8.
2. Filler G, Bökenkamp A, Hofmann W, Le Bricon T, Martinéz-Brú C, Grubb A. Cystatin C as a marker of GFR - history, indications, and future re-search. Clin Biochem 2005; 38: 1-8.
3. Dharnidharka VR, Kwon C, Stevens G. Serum cystatin C is superior to serum creatinine as a marker of kidney function: a meta-analysis. Am J Kidney Dis 2002; 40: 221-226.
4. Grubb A, Björk J, Bondesson P, Lindström V, Sterner G, Nyman U. Cystatin C estimates glomerular filtration rate better than creatinine clear-ance using the Cockgroft-Gault formula. Scand J Clin Lab Invest 2005; 65: 1-10.
5. Thomassen SA, Johannesen IL, Erlandsen EJ, Abrahamsen J, Randers E. Serum cystatin C as a marker of the renal function in patients with spinal cord injury. Spinal Cord 2002; 40: 524-528.
6. Christensson AG, Grubb AO, Nilsson JA, Norrgren K, Sterner G, Sundkvist G. Serum Cystatin C advantageous compared with serum creatinine in the detection of mild but not severe diabetic nephropathy. J Intern Med 2004; 256: 510-518.
7. Alan H.B. Wu. Tietz Clinical Guide to Laboratory Tests. Fourth Ed. Saunders Elsevier, 11830 Westline Industrial Drive, St. Louis, Missouri 63146. 2006; 328-329.
8. Grubb A, Nyman U, Bjork J, et al. Simple Cystatin C-based prediction equations for glomerular filtration rate compared with the modification of diet in renal disease prediction equation for adults and the Schwartz and the Counahan-Barratt prediction equations for children. Clin Chem 2005; 51:1420-31.
9. Inker, L.; Brad, A.; Chester, F.; et al. "KDOQI US Commentary on the 2012 KDIGO Clinical Practice Guideline for the Evaluation and Management of CKD." Am J Kidney Dis. 2014; 63(5):713-735.

ASSAY PRECISION

The precision of the Diazyme Cystatin C Assay was evaluated according to Clinical Laboratory Standards Institute (formerly NCCLS) EP5-A guideline. In the study, three samples containing Cystatin C were tested on Hitachi 917 2 runs per day in duplicates over 20 working days.

Within-Run Precision (S_r)	Level 1 0.9 mg/L	Level 2 2.5 mg/L	Level 3 5.4 mg/L
N	80	80	80
Mean (mg/L)	0.91	2.51	5.40
SD (mg/L)	0.03	0.06	0.11
CV (%)	3.5	2.5	2.0

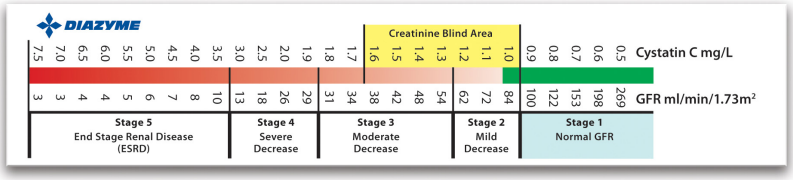
Within-Laboratory Precision (S_r)	Level 1 0.9 mg/L	Level 2 2.5 mg/L	Level 3 5.4 mg/L
N	80	80	80
Mean (mg/L)	0.91	2.51	5.40
SD (mg/L)	0.04	0.08	0.25
CV (%)	4.6	3.0	4.6

ASSAY INTERFERENCE

The following substances do not interfere with this assay at the levels tested (less than 10% bias):

Hemoglobin:	*up to 1000 mg/dL*
Bilirubin:	*up to 40 mg/dL*
Bilirubin Conjugated:	*up to 40 mg/dL*
Triglycerides:	*up to 1000 mg/dL*
Ascorbic Acid:	*up to 176 mg/dL*
Rheumatoid Factor:	*up to 1000 IU/mL*

The reference interval is 0.5 - 1.03 mg/L. However, each laboratory is recommended to establish a range of normal values for the population in their region.[8-9]



(n = 451) Population GFR = 83.93 × Cystatin C [mg/L]^ – (1.68)

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