DIAZYME LABORATORIES

RENAL & PANCREATIC MARKER

CYSTATIN C ASSAY

Dual Vial Liquid Stable

Cystatin C is an emerging renal Biomarker for eGFR and is recommended as part of the KDIGO 2012 guidelines for the early confirmation and diagnosis of Chronic Kidney Disease (CKD).[1] In addition to confirming CKD at earlier stages than is possible with serum Creatinine, studies suggest that Cystatin C may help facilitate kidney disease screening efforts in the elderly, and those with diabetes, hypertension, or cardiovascular disease.[2-7] 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.

DIAZYME CYSTATIN C ASSAY ADVANTAGES

- Diazyme's Cystatin C Assay uses Avian IGY antibodies which are not interfered with by rheumatoid and HAMA factors for increased reliability
- The assay is traceable to (ERM/DA471/IFCC) the international standard reference material providing increased accuracy and performance
- Liquid stable reagent, calibrator and controls are offered separately for added convenience
- A wide range of instrument parameters are offered for facilitating and simplifying implementation

REGULATORY STATUS

510(k) Cleared CE

AVAILABLE INSTRUMENT SPECIFIC PACKAGING

- **Roche**
  - Hitachi
- **Beckman**
  - Synchron
  - AU Series
- **Siemens**
  - Dimension

CYSTATIN C ASSAY

Dual Vial Liquid Stable

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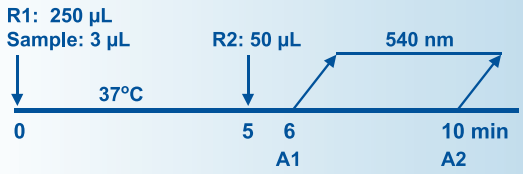
ASSAY SPECIFICATIONS

Method	Latex Enhanced Immunoturbidometric (Avian IGY antibodies quantification at 540 nm)
Sample Type & Volume	• Serum • Plasma - Heparin - EDTA Sample Volume 3 µL
Method Correlation	N = 45 y-intercept = 0.0715 Slope = 0.999 R^2 = 0.992
Linear Range	0.2 to 8.0 mg/L
LOB LOQ LOD	0.04 mg/L Cystatin C 0.19 mg/L Cystatin C 0.068 mg/L Cystatin C
Calibration Levels	5-Point Calibration
Traceability	Standard traceable to ERM-DA471/IFCC primary reference material
Reagent On-Board Stability	Unopened: 24 months when stored at 2-8°C Opened: 4 weeks when kept stored at 2-8°C on-board Hitachi 917

*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 Cystatin C	**Level 2** 2.5 mg/L Cystatin C	**Level 3** 5.4 mg/L Cystatin C
No. of Data Points	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_T)	**Level 1** 0.9 mg/L Cystatin C	**Level 2** 2.5 mg/L Cystatin C	**Level 3** 5.4 mg/L Cystatin C
No. of Data Points	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%

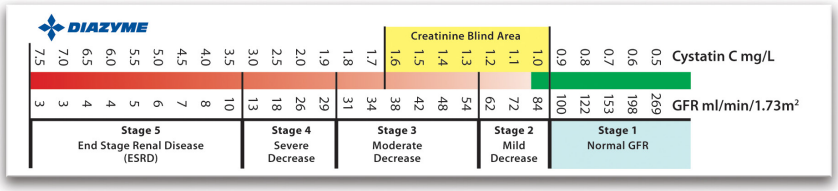
ASSAY INTERFERENCE

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

Hemoglobin:	up to 1000 mg/d
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

ASSAY REFERENCE RANGE

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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