

Cystatin C

A highly sensitive and specific biomarker for early kidney damage

A far superior biomarker than creatinine in the assessment of GFR (Glomerular Filtration Rate)



Normal values are independent of age, race, gender, weight, height or muscle mass

Early detection of kidney damage due to adverse side effects of cancer therapeutics or antibiotics



Easy to use in paediatric patients, just one single blood sample



Fast measurements can be made from single serum or plasma samples, which may help clinicians in diagnosing, treating and monitoring patients with early kidney damage



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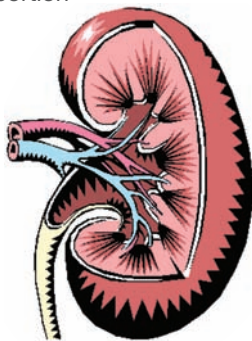
Cystatin C

Introduction

Cystatin C is a low molecular weight (13.4 kDa) cytoplasmic protein, functioning as an inhibitor of various cysteine proteases in the bloodstream. Cystatin C has a stable production rate and is removed from the blood circulation by glomerular filtration. In healthy individuals Cystatin C is completely reabsorbed and degraded in the tubules. Depending on the type of analytical method, normal values for Cystatin C in serum are between 0.8 and 1.2 mg/L and in patients with renal tubular disorders may be raised as high as 2 to 5 times normal values. Normal Cystatin C serum levels are the same for men, women and children, unlike creatinine, which has varying normal levels for these groups.

Clinical relevance

In clinical practice Cystatin C is becoming more frequently known as the biomarker of choice for detecting renal failure and unlike creatinine is not dependent of age, sex, race, lean muscle mass or any inflammatory processes. Creatinine-based determinations of estimated glomerular filtration rates (eGFR) are sensitive to these factors and some must be taken into consideration. A substantial proportion of patients with reduced GFR display normal serum creatinine levels and even a 50% reduction of GFR is not always associated with an abnormal concentration of creatinine ⁽¹⁾. At the same time Cystatin C has also been described more frequently as a



marker for elevated risk of death from cardiovascular diseases, myocardial infarction and stroke, especially in elderly people ⁽²⁾.

Cancer therapeutics unfortunately have the potential to inflict severe damage to the kidneys, hence an early indication of renal dysfunction would allow the oncologist to adjust the drug dosage before irreversible kidney damage has occurred ⁽³⁾.

Cystatin C is also a better predictor of GFR than creatinine for renal transplant, cancer, liver disease patients and for easier monitoring of GFR changes in the paediatric population.

Summary

Cystatin C may help clinicians in diagnosing early kidney damage more effectively than by measuring creatinine levels alone. Early intervention in the development of this kind of disease may consequently reduce the number of patients developing chronic renal failure and further progression into ESRD, a disease with both devastating social and financial consequences.

Detection method

Denka Seiken Co., Ltd. has developed an easy to use latex based Turbidimetric Immuno Assay (TIA) test for the accurate measurement in blood of Cystatin C, which can be used on various automated clinical chemistry analysers. This test uses latex particles coated with anti-human Cystatin C, which form a complex with Cystatin C present in a blood sample (serum or plasma). This complex formation results in a change in turbidity, which can be measured in automated clinical chemistry analysers. Direct comparison with known concentrations of standardised materials allows the

accurate determination of the Cystatin C value in the tested samples.

Accurate measurement range is from 0.1 – 10 mg/L hence normal and abnormal values can be measured without any additional dilutions. When tested on Hitachi 917 the prozone tolerance was at least up to 30 mg/L and recovery rates were more than 99% at Cystatin C values in excess of 0.5 mg/L. Little or no interference was detectable in blood samples containing high concentrations of Haemoglobin, Bilirubine (conjugated and free) or fats. Intra run precision was 1.82% and 1.09% (at mean value of 0.545 and 1.162 mg/L respectively). For more detailed information please read the Denka Seiken Cystatin C Product Insert.

References

- 1) *Journal of Internal Medicine* 2004; 256; 510-518, A.G.Christensson et al.
- 2) *Clinical Chemistry* 51:2, 321-327 (2005) Wolfgang Koenig et al.
- 3) *Clinical Chemistry* 46:2, 193-197 (2000) Boru Štabuc et al.

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