

# 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).<sup>1</sup> Studies also suggest that Cystatin C may help facilitate kidney disease screening in the elderly, and those with diabetes, hypertension, or cardiovascular disease.<sup>2-7</sup>

## **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:  

Health Canada Registered

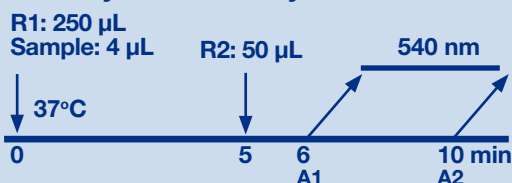
# CYSTATIN C ASSAY

Dual Vial  
Liquid Stable

## ASSAY SPECIFICATIONS

|                                   |                                                                                                                                                             |
|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Method</b>                     | Latex Enhanced Immunoturbidometric (Avian IGY antibodies quantification at 540 nm)                                                                          |
| <b>Sample Type &amp; Volume</b>   | <ul style="list-style-type: none"><li>Serum</li><li>Plasma<ul style="list-style-type: none"><li>Heparin</li><li>EDTA</li></ul></li></ul> Sample Volume 4 µL |
| <b>Method Correlation</b>         | N = 45<br>y-intercept = 0.0715<br>Slope = 0.9999<br>R <sup>2</sup> = 0.9922                                                                                 |
| <b>Linearity</b>                  | 0.2 to 8.0 mg/L                                                                                                                                             |
| <b>LOB</b>                        | 0.04 mg/L                                                                                                                                                   |
| <b>LOD</b>                        | 0.068 mg/L                                                                                                                                                  |
| <b>LOQ</b>                        | 0.19 mg/L                                                                                                                                                   |
| <b>Calibration Levels</b>         | 5-Point Calibration                                                                                                                                         |
| <b>Traceability</b>               | Standard traceable to ERM-DA471/IFCC primary reference material                                                                                             |
| <b>Reagent On-Board Stability</b> | 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](mailto:support@diazyme.com)

## 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 <sub>i</sub> ) | Level 1<br>0.9 mg/L | Level 2<br>2.5 mg/L | Level 3<br>5.4 mg/L |
|----------------------------------------|---------------------|---------------------|---------------------|
| <b>N</b>                               | 80                  | 80                  | 80                  |
| <b>Mean (mg/L)</b>                     | 0.91                | 2.51                | 5.40                |
| <b>SD (mg/L)</b>                       | 0.03                | 0.06                | 0.11                |
| <b>CV (%)</b>                          | 3.5                 | 2.5                 | 2.0                 |

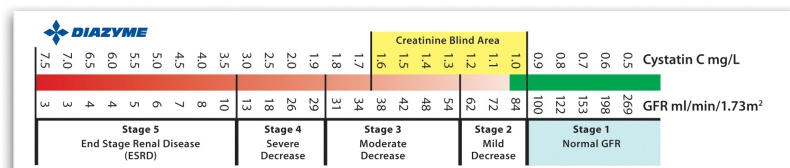
| Within-Laboratory Precision (S <sub>T</sub> ) | Level 1<br>0.9 mg/L | Level 2<br>2.5 mg/L | Level 3<br>5.4 mg/L |
|-----------------------------------------------|---------------------|---------------------|---------------------|
| <b>N</b>                                      | 80                  | 80                  | 80                  |
| <b>Mean (mg/L)</b>                            | 0.91                | 2.51                | 5.40                |
| <b>SD (mg/L)</b>                              | 0.04                | 0.08                | 0.25                |
| <b>CV (%)</b>                                 | 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.<sup>8-9</sup>



$$(n = 451) \text{ Population GFR} = 83.93 \times \text{Cystatin C [mg/L]}^{\wedge} - (1.68)$$

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