Cystatin C Assay Kit (Cys C)

Method: Latex Enhanced IT

Cat . No.	Size	Instrument
GB350S	R1: 1×45 ml R2: 1×15 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS351S	R1: 1×45 ml R2: 1×15 ml	For Hitachi917 & OlympusAU640/400/600
GS351S/B	R1: 3×45 ml R2: 1×45 ml	For Hitachi 7170/7080 & Olympus AU640/400/600
GX351S	R1: 1×45 ml R2: 1×15 ml	For SYNCHRON CX5/7/9/LX20
GT351S	R1: 1×45 ml R2: 1×15 ml	For TOSHIBA
GD351S	R1: 8×3.8 ml R2: 4×2.6 ml	For DATE DEMENSION

INTENDED USE

The Cystatin C test system is a device intended for the *in vitro* quantitative determination of Cys C in serum or plasma.

CLINICAL SIGNIFICANCE[1,2,3,4,5]

Glomerular Filtration Rate (GFR) is a direct marker of renal functions, which starts to decline early in the course of renal diseases. Accurate determination of GFR is required for monitoring the progress of renal diseases when deciding on therapy to avoid impairing the organ function. GFR is determined by measuring the clearance of exogenous substances such as inulin, iohexol and so on, which can freely filter through the glomerular membrane and re-enter the circulation. However, their routine measurement is limited for technical, economical and organizational reasons. Determination of creatinine clearance is the most widely used method for non-invasive estimation of GFR in current practice. Serum creatinine is usually considered moderately specific but of poor sensitivity, as significant increases are only observed if GFR is reduced to 50% or less (creatinine blind range). Creatinine evaluation is influenced by a muscle mass, body surface and flood intake, so it must consider about the age, gender, height and body composition. Creatinine clearance leads to significant overestimation on GFR in case of patients with highly decreased GFR due to tubular secretion. The collection of 24 hr urine is time-consuming and creates additional sources of errors.

Cystatin C is a base proteinase inhibitor with a low molecular mass of 13Kd, and it is produced at a constant rate in all nucleated cells and appears in human plasma and serum. Cystatin C is freely filtered through the glomerulus, is not secreted by the tubule or eliminated via any extra-renal route, and is almost completely absorbed and catabolized by proximal tubular cells.

Cystatin C is not influenced by acute phase reaction (vs. Beta2-microgloblin), and not influenced by endogenous or analytical factor (vs. creatinine or creatinine clearance). These advantages makes Cystatin C an excellent non-invasive indicator for GFR.

Clinical applications of Cystatin C are for monitoring GFR in children and elderly patients, for assessment of renal transplantation status, for monitoring GFR in nephrotoxic drug therapy, for monitoring GFR in acute and chronic kidney diseases including a diabetic nephropathy.

ASSAY PRINCIPLE

Sample is reacted with a buffer and anti-Cys C coated latex. The formation of the antibody-antigen complex during the reaction results in an increase in turbidity, the extent of which is measured as the amount of light absorbed at 570 nm. By constructing a standard curve from the absorbance of the standards, Cystatin C concentration of sample can be determined.

SAMPLE COLLECTION AND PREPARATION

Use fresh patient serum or plasma samples(EDTA or Heparin plasma).
Samples are stable for 12 days at 4℃.

REAGENT COMPOSITION

Contents	Concentration of Solutions
Reagent 1	Tris-buffer solution
Reagent 2	Suspension of latex particles coated with rabbit anti-human Cystatin C polyclonal antibody

STABILITY AND PREPARATION OF REAGENTS

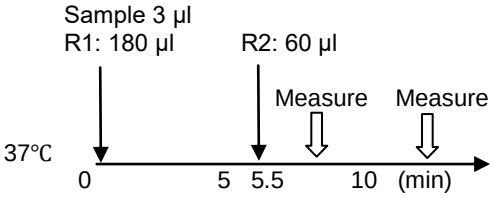
All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.
Once opened the reagent is stable for 1 month on-board the analyser at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 917)

Assay Mode: 2 Point Rate 19-34

Wave length (main/sub): 570 nm/800 nm



1. Mix 3 µl sample with 180 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 60 µl R2 into cuvette, mix and incubate for 30 seconds at 37℃.
3. Read initial absorbance A_1 and incubate for another 4.5 minutes, read final absorbance A_2.
4. Calculate the absorbance change $\Delta A=A_2-A_1$.

MATERIALS REQUIRED BUT NOT PROVIDED

Gcell Cys C Calibrator (Cat .No. GC-CysC-L).
Gcell Cys C Control (Cat .No. GQ-CysC-L).

CALIBRATION

Beijing Strong Biotechnologies, Inc.
Add: 5/F Kuang Yi Building, No. 15 Hua Yuan Dong Lu, Haidian District, Beijing 100191 P. R. China
Tel: +86 10 8201 2486 Fax: +86 10 8201 2812
Web: www.bsbe.com.cn Email:jq.tech@bsbe.com.cn

Recommend that this assay should be calibrated using Gcell calibrator (Cat .No. GC-CysC-L).

CALCULATION

By constructing a standard curve from the absorbance of the standards, Cys C concentration of sample can be determined. Do not attempt to extrapolate above or below the range of the calibrators.

QUALITY CONTROL

For quality control, use GQ-Cys C as daily quality control sera and can be purchased separately. Values should fall within a specific range. If these values fall outside the range and repetition excludes error, the following steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.

NORMAL VALUE

Serum or Plasma:

Aged 1-60：<1.03mg/L；

Aged >60：<1.26mg/L.

It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

The method is linear up to 8.0 mg/L. Sample above this concentration should be diluted with 0.9% NaCl and repeat assay. Multiply the result by dilution fator.

PRECISION

the CV of the test should be ≤ 5%

Intra assay precision		
N=20	Level 1	Level 2
Mean (mg/L)	0.84	1.71
SD	0.02	0.03
CV	2.7%	1.8%
Inter assay precision		
N=5	Level 1	Level 2
Mean (mg/L)	0.86	1.72
SD	0.03	0.03
CV	3.9%	1.6%

SENSITIVITY

The minimum detectable level of Cys C with an acceptable level of precision has been determined as 0.1 mg/L.

INTERFERENCE

The following analytes concentrations were not found to affect the assay:

Hemoglobin:	up to 500 mg/dl
Bilirubin:	up to 20 mg/dl
Intralipid:	up to 2500 mg/dl
RF:	up to 500 mg/dl

CORRELATION

This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=0.9021X+0.1464, R^2=0.9983; 80 patient samples were analyzed.

PROZONE

Antigen excess effects are not noted until levels approach 44 mg/L.

SAFETY PRECAUTIONS AND WARNINGS

1. For *in vitro* diagnostic use.
2. Aviod ingesting and contact with skin and eyes.
3. Do not use after expiration date printed on label.
4. Both reagents contains sodium azide. Disposal of this reagent into sinks with copper or lead plumbing should be followed with copious amounts of water to prevent formation of potentially explosive metallic azides.
5. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES

1. Barrett AJ, Davies ME, Grubb A. The place of human gamma-trace (Cystatin C) among the cysteine proteinase inhibitors. Biochem Biophys Res Commun 1984; l20: 631-6.
2. Grubb A. Diagnostic value of analysis of cystatin C and protein HC in biological fluids. Clin Nephrol 1992; 38: S20-7.
3. Randers E, Erlandsen EJ. Serum Cystatin C as an endogenous marker of the renal function-a review. Clin Chem Lab Med, 1999, 37: 389-395.
4. Newman DJ, Thakkar H, Edwards RG et al. Serum Cystatin C measured by automated immunoassay: a more sensitive marker of changes in GFR than serum creatinine. Kidney International, 1995, 47: 312-318.
5. Jung K, Jung M. Cystatin C: a promising marker of glomerular filtration rate to replace creatinine[J] Nephron, 1995, 70: 370-1.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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Web: www.bsbe.com.cn Email:jq.tech@bsbe.com.cn