



# Cystatin C

## Procedure

## KK-CYC

### Pre-Analytics

Samples required: Serum  
EDTA/Heparinized Plasma

Volume required in reaction: 3 µl

Sample storage: RT 14 days  
2-8°C 21 days  
-20°C 3 months

### Procedural Notes

- It is recommended to analyse fresh samples
- Mix samples well before analysing

### Literature

1. Abrahamson M et al: Biochem J 1990; 268:287-94.
2. Laterza OF et al: Clin Chem 2002; 48:63-99.
3. Grubb AO. Adv Clin Chem 2000; 35: 63-99.
4. Filler G et al: Clin Biochem 2005; 38:1-8.
5. Sonntag O, Scholer A: Ann Clin Biochem 2001; 38:376-85.

### General Settings

The following reaction mode is recommended:

1. Mixing of (diluted) sample and reaction buffer.
2. Incubation (until stable readings are obtained).
3. Addition of the immunoparticle reagent.
4. Blanking (first reading) immediately after mixing all reagents.
5. Measuring signals during reaction until an end-point is obtained.

Parameters	Suggestion
Incubation time before adding Immunoparticles	120 sec
Sample dilution	1
Sample Volumes	3 µl
Assay Buffer Volume	220 µl
Immunoparticle Volume	45 µl
Total volume	268 µl
Reaction Time	300 sec
Total analysis Time	420 sec

Calibrator Standards	Rel. dilution factor
Calibrator A (lowest)	0.0313
Calibrator B	0.0625
Calibrator C	0.125
Calibrator D	0.25
Calibrator E	0.5
Calibrator F (highest)	1.0

Spline regression is the preferred math model.

### Automated Procedure

Cystatin C immunoassay can be performed on any open clinical chemistry analyzer. Applications are available upon request for the following analyzers

### Validated Applications

Analyser	Theoretical number of tests per 10 ml particles
Roche Hitachi 911	250 Tests
Roche Hitachi 917	250 Tests
Roche Modular P	250 Tests
Roche Cobas c501	312 Tests
Siemens Advia 1650	625 Tests
Siemens Advia 1200/1800/2400	625 Tests
Olympus AU*	333 Tests
Ortho Vitros 5,1*	250 Tests
Abbott Architect	222 Tests
Horiba Pentra 200/ 400	250 Tests

\*Application on Olympus AU and Ortho Vitros 5,1 require pre-diluted calibrators which will be provided by BÜHLMANN with the Cystatin C kit.

Ordering code KK-CYC-6





# Cystatin C

## Characteristics

## KK-CYC

### Intended Use

The Cystatin C Immunoassay is an in-vitro diagnostic test for quantitative determination of cystatin C in human serum and plasma. The assay can be applied on any clinical analyzer according to a specific protocol. The measurement of cystatin C is used in the diagnosis and treatment of renal diseases.

### Summary and Explanation

The non-glycosylated basic protein, cystatin C (molecular weight 13.2 kDa), is produced at a constant rate in nearly every nucleated cell in the human body [1]. It is freely filtered through a normal glomerular membrane, and is then reabsorbed and almost entirely catabolized in the proximal tubules. Hence, the cystatin C concentration in human blood is closely related to glomerular filtration rate (GFR) [2]. A reduction in the GFR causes a rise in the concentration of cystatin C. Cystatin C concentration has not been shown to be significantly influenced by other factors such as muscular mass, inflammatory diseases, sex, age or diet [2, 3, 4].

### Assay Principle

Serum or plasma sample from human is mixed with cystatin C immunoparticles. Cystatin C from the sample and anti cystatin C from the immunoparticles aggregate. The complex particles created absorb light, and by turbidimetry the absorption is related to cystatin C concentration via interpolation on an established standard calibration curve.

### Assay Performance Data

All results refer to the validation of BÜHLMANN Cystatin C Immunoassay on Abbott Architect® ci8200

**Limit of Detection** 0.031 mg/L

**Limit of Quantification** 0.33 mg/L

#### Precision

5 day precision in accordance with NCCLS protocol EP5-A 4 serum pools, 2 control levels; range 0.69-5.71 mg/L

Within-Run CV(%) 1.3 %

Total CV(%) 3.1 %

**Linearity** 0.3 - 8.8 mg/L

**Analytical Recovery** 100 - 107 %

#### Interference

No interference is detected with:

Triglycerides 12.5 mmol/mL  
Haemoglobin 8.0 g/L  
Intralipid 11.0 g/L  
Bilirubin 420 mg/L

No interference detected with drugs tested on recommendation from Sonntag and Scholer [5].

There is no rheumatoid factor (RF) interference because the use of avian antibody.

### Normal Values

The CLSI Guideline, C28-A2; *How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline Second edition* was followed to determine the transferability of the reference interval.

For Architect® ci8200 the reference interval is **0.53-1.01 mg/L**.

For any other instrument the reference interval should be in accordance with the interval obtained on the Architect® ci8200.

It is recommended that every laboratory determines a local reference interval since values may vary depending on the populations tested.

#### Ordering codes:

KK-CYC  
KK-CYC-6\*

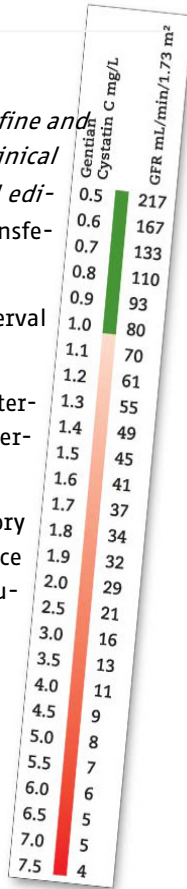
\*\*Kit contains pre-diluted Calibrators for the use in Olympus AU and Ortho Vitros 5.1

Cystatin C kits (KK-CYC, KK-CYC-6) are IVD products.

Canada: Cystatin C kits are available for Research Use Only. Not for use in diagnostic procedures.

#### Ordering codes:

KK-CYC-U  
KK-CYC-6-U



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