Cystatin C

Application Note for the Gentian Cystatin C Immunoassay on Architect[1] Module c8000

For *in vitro* diagnostic use by laboratory professionals.

This document describes the instrument specific settings and performance of the product on the instrument above. For assay information, please refer to the Package Insert available on www.gentian.com.

Assay kit components

Products available	
Gentian Cystatin C Reagent Kit • R1 Assay Buffer (58 mL) • R2 Immunoparticles (10 mL)	REF 1101
Gentian Cystatin C Calibrator (1 level x 1 mL)	REF 1012
Gentian Cystatin C Control Kit (2 levels x 1 mL), or	REF 1019
Gentian Cystatin C Control Kit (2 levels x 5 mL)	REF 1026

All products are ready for use.

Reagent stability

For the in-use stability of Gentian Cystatin C Reagent Kit, Gentian Cystatin C Control Kit and Gentian Cystatin C Calibrator refer to their respective Package Insert available on www.gentian.com.

Calibration stability

For calibration curve stability, see the Package Insert for the Gentian Cystatin C Calibrator available on www.gentian.com.

Performance characteristics

All results refer to validation of the Gentian Cystatin C Immunoassay on one instrument site with one lot of reagents, unless otherwise stated.

Measuring range

The measuring range of the Gentian Cystatin C Immunoassay was found to be 0.40-8.8 mg/L. The exact measuring range is specific to the calibrator lot, please refer to the analytical value sheet available on www.gentian.com.

Analytical sensitivity

The analytical sensitivity of the Gentian Cystatin C Immunoassay was tested in a study based on the CLSI guideline EP17 [1]. The Limit of Quantification (LoQ) is defined as the lowest concentration of an analyte that can be reliably detected and at which the total error meets the requirements for accuracy. The LoQ of the Gentian Cystatin C Immunoassay was found to be 0.40 mg/L.

Linearity

The linearity range of the Gentian Cystatin C Immunoassay was found to be 0.27-8.8 mg/L in a linearity study based on the CLSI guideline EP06 [2].

Security zone

No antigen excess effect in samples below 16 mg/L was observed for the Gentian Cystatin C Immunoassay in a study based on the CLSI guideline EP34 [3] performed on Roche Modular P. Samples with a cystatin C concentration above the highest calibrator and up to 16 mg/L return a value above the highest calibrator and are flagged for rerun.

Precision

Precision of the Gentian Cystatin C Immunoassay was tested in a study based on the CLSI guideline EP05 [4]. Four serum pools and 2 controls were measured in 2 replicates 2 times a day, for 5 days (n=20).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Between day CV [%]	Total CV [%]
P1	0.69	1.51	2.11	1.07	2.81
P2	5.71	1.12	3.35	2.23	4.18
P3	3.38	1.93	2.77	1.62	3.75
P4	1.35	0.97	2.12	1.30	2.67
Cl	0.88	1.42	3.09	1.51	3.72
CH	3.58	0.71	1.21	0.10	1.41

Recovery

Recovery was analysed by spiking a low analyte sample with a high analyte sample according to Westgard [5]. The Gentian Cystatin C Immunoassay had a recovery of 103-108 %.

Analytical specificity and limitations

Interference was tested in a study based on the CLSI guideline EP07 [6]. As the antibodies in the Gentian Cystatin C Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [7]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	8 g/L
Triglycerides	15 mmol/L
Intralipid	11 g/L
Bilirubin	0.42 g/L

Method comparison

Results obtained with the Gentian Cystatin C Immunoassay were compared using Passing-Bablok regression with a commercially available nephelometric assay on BN ProSpec, in a study based on CLSI guideline EP09 [8]:

n	Range of samples [mg/L]	Term	Coefficient	95% CI
87	0.52-7.91	Intercept	-0.06	[-0.10, 0.02]
		Slope	0.98	[0.96, 1.01]

[1] Registered trademark of Abbott Laboratories

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Bibliography

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2. CLSI. *Evaluation of the Linearity of Quantitative Measurement Procedures*. 2nd ed. CLSI guideline EP06. Clinical Laboratory Standards Institut;2020.
3. CLSI. *Establishing and Verifying and Extended Measuring Interval Through Specimen Dilution and Spiking*; 1st Edition. CLSI guideline EP34. Wayne, PA: Clinical and Laboratory Institute; 2018.
4. CLSI. *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition.* CLSI document EP05-A3. Wayne, PA: Clinical Laboratory Standards Institute; 2014.
5. Westgard JO. Basic Method Validation, 3rd Edition. 2008; ISBN13: 9781886958258.
6. CLSI. *Interference Testing in Clinical Chemistry*. 3rd ed. CLSI guideline EP07. Wayne, PA: Clinical Laboratory Standards Institute; 2018.
7. Larsson A et al: Poultry Science 1993 ;72 :1807-1812.
8. CLSI. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 3rd ed. CLSI guideline EP09c. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

Modifications from the previous version

- Corrected application settings.

Date of issue

14 OCT. 2025

Instrument settings for the Gentian Cystatin C Immunoassay on Architect[1] Module c8000

Assay Parameters for Architect

General Parameters

Name: Gent Cys C*
Assay number: *
Assay version: *

* User defined

Assay type: Photometric
Assay availability: Enabled
Cal version:

Reaction Definition:

Reaction mode: End up
Primary wavelength: 548
Secondary wavelength: 700
Last read required: 33
Absorbance range: 0.000 – 0.000

Sample blank type: Self
Blank Assay:

Main read time: 31 - 33
Flex read time:
Color correction read time: 0-0
Blank read time: 18 - 18

Reagent/Sample:

Reagent 1: ****
R1 reagent volume: 220
R1 water volume: 0
R1 dispense mode: Type 0
Diluent name: 02201

R2 reagent volume: 45
R2 water volume: 0
R2 dispense mode: Type 0
Diluent dispense mode: Type 0

Dilution name	Sample volume	Diluted sample volume	Diluent volume	Water volume	Dilution factor
Normal	3.0				1:1.00
1:10	10.0	3.0	90		1:10.00

**** User defined

Validity checks:

Reaction check type: None
Read time A range:
Calculation limit:

Read time B range:
Minimum absorbance:
Rate linearity:

Maximum absorbance variation: 0.00

Calibration parameters:

Calibration method: Spline
Use cal factor from:
Full interval hours: 0
Adjustment type: None
Expected cal factor: 0.00
Expected cal factor tolerance %: 0

Factor:
Adjustment interval hours: 0
Adjustment level:
Default ordering type: Full
Blank absorbance range: 0.000 – 0.000

Span absorbance range: 0.00 – 0.00

Span:
Max curve fit: 0.00
Calibrator set name: ****

Replicates: 2

Cal Level	Concentration	Sample volume	Diluted sample volume	diluent volume	Water volume
Water	0.00	3.0			
1	CV	8.0	3.0	190	
1	CV	16.0	3.0	190	
1	CV	22.0	3.0	130	
1	CV	35.0	5.0	130	
1	CV	35.0	6.0	80	
1	CV	3.0			

*** user defined
CV See Analytical Value Sheet for Calibrator Value

Smart wash

Results parameters

Linearity range: 0.27 – 8.8
Flag range specifications:

Interpretation parameters

Result units

Result concentration units: mg/L
Result decimal places: 2

Correlation Factor: 1.0000
Intercept: 0

Disclaimer: The specific settings above is what used to validate the application on the specific instrument. For any instrument specific settings, please refer to the instrument manual. Please be aware that illustrations or settings might be affected in case of an instrument software update.