Cystatin C

Application Note for the Gentian Cystatin C Immunoassay on Beckman Coulter the IMMAGE 800 System[1]

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 IFU available on www.gentian.com.

Assay kit components

Products available	
Gentian Cystatin C Reagent Kit • R1 Assay Buffer (100 mL) • R2 Immunoparticles (2 x 10 mL)	REF A52761
Gentian Cystatin C Calibrator Kit (6 levels x 1 mL)	REF A52763
Gentian Cystatin C Control Kit (2 levels x 1 mL), or Gentian Cystatin C Control Kit (2 levels x 5 mL)	REF 1019 REF 1026

All products are ready for use.

Reagent stability

The in-use stability of the Gentian Cystatin C Reagent Kit on Immage Systems was found to be 5 weeks performed as an open vial study (at 2-8 °C). For the in-use stability of Gentian Cystatin C Calibrator kit and Gentian Cystatin C Control kit , refer to their respective Instructions for Use (IFU) available on www.gentian.com.

Calibration stability

For calibration curve stability, please see the IFU for the Gentian Cystatin C Calibrator Kit 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 0.36-6.79 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 0.36 mg/L.

Linearity

The linearity range of the Gentian Cystatin C Immunoassay was found to be 0.35-6.79 mg/L in a linearity study with 9 samples based on the CLSI guideline EP06 [2].

Security zone

No antigen excess effect in samples below 43 mg/L was observed for the Gentian Cystatin C Immunoassay in a study based on the CLSI guideline EP34 [3]. Samples with a cystatin C concentration above the highest calibrator and up to 43 mg/L return a value above the highest calibrator and are flagged for rerun with automatic dilution.

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 6 times with 2 replicates (n=12).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Between day CV [%]	Total CV [%]
P1	0.72	1.71	3.46	0.00	3.86
P2	0.62	2.35	2.18	4.58	5.59
P3	0.67	3.74	0.00	0.43	3.76
P4	0.96	1.63	0.00	2.64	3.10
CL	0.82	2.14	0.00	6.43	6.78
CH	2.54	0.67	0.20	3.77	3.84

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 101-110 %.

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
Intralipid	16 g/L
Bilirubin	0.8 g/L

Instrument variation

Results obtained with the Gentian Cystatin C Immunoassay were compared using Passing-Bablok regression with results from the Hitachi 917 instrument (Roche) in a study based on the CLSI guideline EP09 [8].

n	Range of samples [mg/L]	Term	Coefficient	95 % CI
24	0.58-6.97	Intercept	0.08	[0.05, 0.11]
		Slope	1.01	[0.99, 1.03]

[1]Registered trademark of Beckman Coulter®

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References

1. CLSI. *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition.* CLSI document EP17-A2. Wayne, PA: Clinical and Laboratory Standards Institute ;2012.
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 Laboratory Standards Institute; 2018.

Modifications from previous version

- Added number of the Notified Body to CE mark.
- Minor editorial changes and corrections throughout the document.

Date of issue

2023-07-12

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Instrument settings for the Gentian Cystatin C Immunoassay on the Beckman Coulter® IMMAGE 800 System[1]

Page 1

Test name: CYSX
Unit: mg/L
Reagent lot number: *
Protocol: Non-competitive NIPIA
Cartridge number: **
Reagent expiry date: *
Reagent series number: **
Tests per lot: 40
AGXS Limit:
AGXS Enabled:

Page 2
Buffer: BUF10
Diluent: DIL10
Sample volume: 5 µl
Calibrator dilution: 1:1
Reaction buffer volume: 0 µl
Sample dilution: 1:1
Reagent A volume: 30 µl
Reaction time: 5 minutes
Reagent B volume: 195 µl

Page 3:
Calibrator Level
Levels: 6
Level 1: *
Replicates: 2
Level 2: *
Level update: 3
Level 3: *
Replicates: 2
Level 4: *
Calibration Type: 3.order polynom
Level 5: *
Level 6: *

Slope and Offset (under 'Reagent and Calibration')

Factor a (a·x + b) : 1.10

Transfer Gentian Cystatin C Assay Buffer into compartment B and Gentian Cystatin C immunoparticles in compartment A. The maximum volume of compartment "A" and "B" of the UDR cartridge is 8.5 mL. Hence the maximum number of tests loaded into the cartridge is approximately 40 tests.

* Lot specific. See analytical value sheet available on www.gentian.com.
** Instrument dependent

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