Cystatin C

Gentian Cystatin C Immunoassay on Beckman Coulter® AU Systems (AU5800, AU680, AU480, DxC 500 AU, DxC 700 AU)

REF B08179

For *in vitro* diagnostic use by laboratory professionals.

This document describes the general use and the instrument specific settings of the product above.

Intended purpose

The Gentian Cystatin C Immunoassay is an immunoturbidimetric assay intended for the *in vitro* quantitative determination of cystatin C in human serum and plasma on automated clinical analysers by laboratory professional users. The measurement of cystatin C is used in the diagnosis and treatment of renal diseases.

Summary and explanation of test

The non-glycosylated basic protein, cystatin C (molecular weight 13.2 kD), 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. The cystatin C concentration has not been shown to be significantly influenced by other factors such as muscular mass, inflammatory diseases, gender, age or diet [2, 3, 4].

Calibrator standardisation

The Gentian Cystatin C Calibrator is standardised against the international calibrator standard ERM-DA471/IFCC.

Relevant calculations

GFR prediction calculation

Several cystatin C based prediction equations for calculation of GFR for adults and children have been published. It should be noted that these formulas were evaluated with different cystatin C assays (Particle-Enhanced Nephelometric Immunoassay PENIA or Particle-Enhanced Turbidimetric Immunoassay PETIA) and may reveal inaccurate GFR results if an inappropriate combination of formula and assay is used. For calculation of GFR from cystatin C values measured with the Gentian assay the following prediction equation is recommended using mg/L as the unit factor [5]. The equation is valid for persons above 14 years.

$$\text{GFR [mL/min/1.73 m}^2\text{]} = \frac{79.901}{\text{Cystatin C (mg/L)}^{1.4389}}$$

Assay principle

The Gentian Cystatin C Immunoassay is a Particle-Enhanced Turbidimetric Immunoassay (PETIA). The plasma or serum sample is mixed with cystatin C immunoparticles. Cystatin C from the sample and the anti-cystatin c antibodies from the immunoparticle solution bind to form aggregates that increase the turbidity of the solution. The degree of turbidity is proportional to the concentration of cystatin C, which can be quantified via an established standard calibration curve.

Assay kit components

Products provided	BCI REF	Gentian REF
Gentian Cystatin C Reagent Kit for Beckman Coulter® AU Systems • R1 Assay Buffer (58 mL) • R2 Immunoparticles (10 mL)	B08179	1103
Products required but not provided		
Gentian Cystatin C Calibrator Kit (6 levels x 1 mL)	A52763	1051
Gentian Cystatin C Control Kit (2 levels x 1 mL)	A52765	1019

All products are ready for use.

Composition

Reaction Buffer 1 (R1, 58 mL inactive ingredient): Gentian Cystatin C Assay Buffer. R1 is a MOPS [3-(N-Morpholino)-propane sulfonic acid] buffered saline, containing avian proteins and preserved with sodium azides (0.09 % (w/v)).

Reaction Buffer 2 (R2, 10 mL active ingredient): Gentian Cystatin C Immunoparticles. R2 contains a purified immunoglobulin fraction directed against human cystatin C, which is covalently attached to polystyrene nanoparticles. The solution is preserved with 0.09 % (w/v) sodium azide and antibiotics.

Warnings and precautions

1. Contains substances from human or animal origin and should be considered as potentially infectious material. Handle with caution and discard following local regulations.
2. The sodium azide concentration of the assay is not characterised as hazardous. Although, accumulated NaN_3 in lead and copper pipes may cause generation of explosive metal azides. To prevent this, rinse thoroughly if discarded into the drain.
3. Contains a sensitizing substance below concentration limit. May produce an allergic reaction in some people and may cause respiratory irritation if inhaled.
4. Contains antibiotics and must be handled with due caution.
5. Exposure may result in irritation of skin and eyes.
6. Avoid contact with incompatible materials.
7. Avoid exposure to heat and direct sunlight.

For additional safety information, please refer to the SDS (Safety Data Sheet) available on www.gentian.com.

Additional handling instructions

1. This test is for *in vitro* use only and must be handled by laboratory professionals.
2. Use only validated and approved instrument applications.
3. Do not use products after the expiration date has passed.
4. Do not mix reagents of different lots or interchange caps of reagents, controls, calibrators, and lots.
5. Tighten caps carefully back on after use of reagents, calibrators, and controls to avoid evaporation.

Cystatin C

Reagent storage and stability

All products provided for the Gentian Cystatin C Immunoassay must be stored at 2-8 °C. The expiry date is printed on the labels. The in-use stability of the Gentian Cystatin C Reagent Kit was found to be at least 9 weeks on an AU400 instrument performed as an on board study.

Specimen collection and handling

Required sample material is human serum or plasma. It is recommended to analyse the samples as fresh as possible. Sample stability testing showed that cystatin C in serum and plasma samples are stable for 14 days at room temperature (8-25 °C) and 21 days if stored at 2-8 °C. If stored below -70 °C the samples are stables for at least 5 years [6]. Mix samples well before analysing. The samples can be shipped without special cooling and must then be analysed within 14 days after shipment.

Performance characteristics

Performance characteristics AU5800

All results refer to validation of the Gentian Cystatin C Immunoassay on an AU5800 instrument at one site with one lot of reagents, unless otherwise stated.

Measuring range

The measuring range of the Gentian Cystatin C Immunoassay was found to be 0.49-7.07 mg/L. The exact measuring range is specific to the calibrator, please refer to the analytical value sheet for the lot specific calibrator values available on www.gentian.com.

Analytical sensitivity

The analytical sensitivity of the Gentian Cystatin C Immunoassay was tested based on the CLSI guideline EP17 [7]. 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 0.23 mg/L.

Linearity

The linearity range of the Gentian Cystatin C Immunoassay was found to be 0.49–7.07 mg/L in a linearity study based on the CLSI guideline EP06 [8].

Security zone

No antigen excess effect in samples below 32 mg/L was observed for the Gentian Cystatin C Immunoassay in a study based on the CLSI guideline EP34 [9]. Samples with a cystatin C concentration above the highest calibrator and up to 32 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 [10]. 3 serum pools and 2 controls were measured 2 times with 2 replicates (n=20).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
P1	0.90	0.82	1.78	1.96
P2	5.29	0.49	2.05	2.10
P3	2.08	0.43	1.56	1.62
CL	0.86	1.10	3.24	3.42
CH	2.91	0.81	2.26	2.40

Recovery

Recovery was analysed by spiking a low analyte sample with a high analyte sample according to Westgard [11]. The Gentian Cystatin C Immunoassay had a recovery of 96-100 %.

Analytical specificity and limitations

There is no interference detected with the drugs tested on the recommendations from Sonntag and Scholer [12]. As the antibodies in the Gentian Cystatin C Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [13]. Interference was tested in a study based on the CLSI guideline EP07[14]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	6 g/L
Intralipid	10 g/L
Bilirubin	0.4 g/L

Instrument variation

Results obtained with the Gentian Cystatin C Immunoassay on the AU5800 instrument were compared using Passing-Bablok regression with results from AU400 instrument (Beckman Coulter) in a study based on the CLSI guideline EP09 [15].

n	Range of samples [mg/L]	Term	Co-efficient	95% CI
32	0.75-4.06	Intercept	-0.05	[-0.08, -0.02]
		Slope	1.02	[1.00, 1.06]

Performance characteristics AU680

All results refer to validation of the Gentian Cystatin C Immunoassay on an AU680 instrument at one site with one lot of reagents, unless otherwise stated.

Measuring range

The measuring range of the Gentian Cystatin C Immunoassay was found to be 0.44–7.30 mg/L. The exact measuring range is specific to the calibrator, please refer to the analytical value sheet for the lot specific calibrator values 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 [7]. 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 0.28 mg/L.

Linearity

The linearity range of the Gentian Cystatin C Immunoassay was found to be 0.44–7.30 mg/L in a linearity study based on the CLSI guideline EP06 [8].

Security zone

No antigen excess effect in samples below 12 mg/L was observed for the Gentian Cystatin C Immunoassay in a study based on the CLSI guideline EP34 [9]. Samples with a cystatin C concentration above the highest calibrator and up to 12 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 study based on the CLSI guideline EP5 [10]. 4 serum pools and 2 controls were measured 2 times with 2 replicates (n=20).

Cystatin C

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
P1	0.75	0.79	2.08	2.44
P2	1.96	0.43	1.73	1.88
P3	0.80	1.09	1.35	2.00
P4	4.98	0.67	1.00	1.57
CL	1.07	0.42	1.66	2.26
CH	3.28	0.25	1.00	1.51

Recovery
Recovery was analysed by spiking a low analyte sample with a high analyte sample according to Westgard [11]. The Gentian Cystatin C Immunoassay had a recovery of 86-92 %.

Analytical specificity and limitations
There is no interference detected with the drugs tested on the recommendations from Sonntag and Scholer [12]. As the antibodies in the Gentian Cystatin C Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [13]. Interference was tested in a study based on the CLSI guideline EP07 [14]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	8.5 g/L
Intralipid	16 g/L
Bilirubin	0.2 g/L

Instrument variation
Results obtained with the Gentian Cystatin C Immunoassay on the AU680 instrument were compared using Passing-Bablok regression with results from the AU400 instrument (Beckman Coulter) in a study based on the CLSI guideline EP09 [15].

n	Range of samples [mg/L]	Term	Co-efficient	95% CI
32	0.79-4.83	Intercept	-0.02	[-0.04, 0.07]
		Slope	1.03	[0.96, 1.05]

Performance characteristics AU480
All results refer to validation of the Gentian Cystatin C Immunoassay on an AU480 instrument at one site with one lot of reagents, unless otherwise stated.

Measuring Range
The measuring range of the Gentian Cystatin C Immunoassay was found to be 0.43–7.32 mg/L. The exact measuring range is specific to the calibrator, please refer to the analytical value sheet for the lot specific calibrator values 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 [7]. 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 0.43 mg/L.

Linearity
The linearity range of the Gentian Cystatin C Immunoassay was found to be 0.40–7.32 mg/L in a linearity study based on the CLSI guideline EP06 [8].

Security zone
No antigen excess effect in samples below 9.4 mg/L was observed for the Gentian Cystatin C Immunoassay in a study based on the CLSI guideline EP34 [9]. Samples with a cystatin C concentration above the highest calibrator and up to 9.4 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 study based on the CLSI guideline EP5 [10]. 3 serum pools and 2 controls were measured 2 times with 2 replicates (n=12).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
P1	1.09	1.57	1.21	3.60
P2	3.65	0.67	0.62	1.82
P3	1.24	1.73	0.00	3.47
CL	0.87	3.10	0.00	3.72
CH	3.39	1.18	0.94	3.03

Recovery
Recovery was analysed by spiking a low analyte sample with a high analyte sample according to Westgard [11]. The Gentian Cystatin C Immunoassay had a recovery of 90-95 %.

Analytical specificity and limitations
There is no interference detected with the drugs tested on the recommendations from Sonntag and Scholer [12]. As the antibodies in the Gentian Cystatin C Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [13]. Interference was tested in a study based on the CLSI guideline EP07 [14]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	10 g/L
Intralipid	15 g/L
Bilirubin	0.6 g/L

Instrument variation
Results obtained with the Gentian Cystatin C Immunoassay on the AU480 instrument were compared using Passing-Bablok regression with results from the Architect c16000 instrument (Abbott Laboratories) in a study based on the CLSI guideline EP09 [15].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
40	0.71-6.38	Intercept	0.03	[0.01, 0.04]
		Slope	0.95	[0.94, 0.97]

Cystatin C

Performance characteristics DxC 500 AU

All results refer to validation of the Gentian Cystatin C Immunoassay on a DxC 500 AU instrument at one site with one lot of reagents, unless otherwise stated.

Measuring range

The measuring range of the Gentian Cystatin C Immunoassay was found to be 0.38–7.84 mg/L. The exact measuring range is specific to the calibrator, please refer to the analytical value sheet for the lot specific calibrator values 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 [7]. 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 0.32 mg/L.

Linearity

The linearity range of the Gentian Cystatin C Immunoassay was found to be 0.38–7.84 mg/L in a linearity study based on the CLSI guideline EP06 [8].

Security zone

No antigen excess effect in samples below 25.7 mg/L was observed for the Gentian Cystatin C Immunoassay in a study based on the CLSI guideline EP34 [9]. Samples with a cystatin C concentration above the highest calibrator and up to 25.7 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 20-day precision study based on the CLSI guideline EP05 [10]. 3 serum pools and 2 controls were measured 2 times with 2 replicates (n=80).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
P1	0.87	0.56	1.46	2.41
P2	1.60	0.80	1.63	2.43
P3	6.37	0.73	1.63	3.66
CL	1.00	0.68	0.61	2.00
CH	3.48	0.46	0.55	1.57

Recovery

Recovery was analysed by spiking a low analyte sample with a high analyte sample according to Westgard [11]. The Gentian Cystatin C Immunoassay had a recovery of 102–109 %.

Analytical specificity and limitations

There is no interference detected with the drugs tested on the recommendations from Sonntag and Scholer [12]. As the antibodies in the Gentian Cystatin C Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [13]. Interference was tested in a study based on the CLSI guideline EP07 [14]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	8 g/L
Intralipid	10 g/L
Bilirubin	0.2 g/L

Instrument variation

Results obtained with the Gentian Cystatin C Immunoassay on the DxC 500 AU instrument were compared using Passing-Bablok regression with results from the AU5800 instrument in a study based on the CLSI guideline EP09 [15].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
42	0.57– 5.72	Intercept	-0.01	[-0.05, 0.03]
		Slope	1.00	[0.97, 1.04]

Performance characteristics DxC 700 AU

All results refer to validation of the Gentian Cystatin C Immunoassay on a DxC 700 AU instrument at one site with one lot of reagents, unless otherwise stated.

Measuring range

The measuring range of the Gentian Cystatin C Immunoassay was found to be 0.40–8.07 mg/L. The exact measuring range is specific to the calibrator, please refer to the analytical value sheet for the lot specific calibrator values 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 [7]. 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 0.40–8.07 mg/L in a linearity study based on the CLSI guideline EP06 [8].

Security zone

No antigen excess effect in samples below 10 mg/L was observed for the Gentian Cystatin C Immunoassay in a study based on the CLSI guideline EP34 [9]. Samples with a cystatin C concentration above the highest calibrator and up to 10 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 EP5 [10]. 3 serum pools and 2 controls were measured 2 times with 2 replicates (n=80).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
P1	0.73	0.58	0.00	0.75
P2	1.70	0.49	0.28	0.59
P3	6.13	0.44	0.18	0.60
CL	0.91	0.67	0.60	1.04
CH	3.44	0.39	0.81	0.90

Recovery

Recovery was analysed by spiking a low analyte sample with a high analyte sample according to Westgard [11]. The Gentian Cystatin C Immunoassay had a recovery of 104–105 %.

Analytical specificity and limitations

There is no interference detected with the drugs tested on the recommendations from Sonntag and Scholer [12]. As the antibodies in the Gentian Cystatin C Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [13]. Interference

was tested in a study based on the CLSI guideline EP07 [14]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	10 g/L
Intralipid	10 g/L
Bilirubin	0.2 g/L

Instrument variation

Results obtained with the Gentian Cystatin C Immunoassay on the DxC 700 AU instrument were compared using Passing-Bablok regression with results from the AU5800 instrument and the Architect c4000 instrument (Abbott Laboratories) in a study based on the CLSI guideline EP09 [15].

Instru-ment	n	Range of samples [mg/L]	Term	Co-efficient	95% CI
Archi-techt	40	0.60-6.27	Intercept	0.02	[0.00, 0.02]
			Slope	0.96	[0.95, 0.97]
AU 5800	40	0.59-6.22	Intercept	0.00	[0.00, 0.01]
			Slope	1.00	[0.99, 1.00]

Assay procedure

A detailed instrument parameter list is available in the section "Instrument Settings" below. Instrument set up, maintenance, operation and precautions must be handled in accordance with the Beckman Coulter® AU systems' instrument manuals.

Reagent preparation

The reagents are ready for use. Mix the reagents gently before placing them into the assigned reagent positions. The reagent bottles fit directly into the instrument.

Establishment of the calibration curve

Please refer to the instruction for use of the Gentian Cystatin C Calibrator Kit REF A52763 available on www.gentian.com.

QC controls

Please refer to the instruction for use of the Gentian Cystatin C Control Kit REF A52765 available on www.gentian.com.

Measuring patient samples

When a valid calibration curve has been established and the control values are within the valid range, the plasma or serum sample may be measured. Ensure that the minimum sample volume is present in the sample cups/tubes and assay the samples according to the instructions given in the instrument manual.

Results

The results are calculated automatically by the instrument for all applications established for the Gentian Cystatin C Immunoassay. The results are presented in mg/L.

Clinical performance

Sensitivity and specificity

With an eGFR cut off value of 60 mL/min/1.73 m^2 cystatin C has a sensitivity of 0.94 (95 % CI: 0.90-0.96) and specificity of 0.86 (95% CI: 0.78-0.91) [16].

Reference intervals

The cystatin C reference intervals were determined in a study based on the CLSI guideline C28 [17] on an Architect ci8200 instrument (Abbott Laboratories). The reference interval was determined from a population of ostensibly healthy subjects with no history of CKD. A total of 136 samples from individuals ranging in age from 20 to 84 years were measured. The samples used were serum samples. The reference interval was calculated non-parametrically and was determined to be 0.51-1.05 mg/L. This represents the central 95 % of the population. It is recommended that every laboratory should determine a local reference interval since values may vary depending on the population tested. In a separate study involving 850 healthy children (46 % boys, 54 % girls) in the age from 5 to 15 years, the reference range 0.51-1.05 mg/L was confirmed in all ages down to 5 years of age [18].

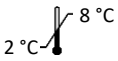
Additional information

For more detailed information on AU Systems, refer to the appropriate system manual. Since Beckman Coulter® does not manufacture the reagent or perform quality control or other tests on individual lots, Beckman Coulter® cannot be held responsible for the quality of the data obtained which is caused by performance of the reagent, any variation between lots of reagent, or protocol changes by the manufacturer.

Shipping damage

Please notify your distributor if this product is received damaged. For technical assistance please contact your local distributor.

Symbols key



Temperature limit


Use by date


Consult Instructions for Use


Manufacturer

CE mark with Notified Body number

UKCA mark

Swiss authorized representative

In Vitro Diagnostic medical device

Lot number

Catalogue number

Unique Device Identifier

Contents

R1 Assay Buffer

R2 Immunoparticles

Cystatin C

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Serious incidents

Please notify the distributor and your competent authority if any serious incidents have occurred in relation to the device.

Modifications from previous version

- Added chapter and instrument settings for the instrument DxC 500 AU.
- Included the information about the SDS available on the Gentian website.

Date of issue

2023-10-12

For other languages visit:
www.gentian.com/products/ifu/cystatin-c/beckmancoulter

Cystatin C

Instrument settings for the Gentian Cystatin C Immunoassay

Cystatin C AU5800 application settings

System Reagent: B08179 Reagent ID: 228

Parameters	Specific Test Parameters				
General	LIH	ISE		Calculated Test	Range

Test Name: CysC ▽ < > Type: Serum ▽ Operation Yes ▽

Sample Volume		2 µL	Dilution	0 µL	OD Limit				
Pre-Dilution Rate		1 ▽	Diluent Bottle	Outside ▽	Min.OD		Max.OD		
Rgt. Volume	R1(R1-1)	150 µL	Dilution	0 µL	Reagent OD Limit				
	R1-2		Dilution	µL	First	Low	-2.0	High	2.0
					Last	Low		High	
	R2(R2-1)	30 µL	Dilution	10 µL					
					Dynamic Range	Low	0.49	High	7.07
Common Rgt. Type			Name		Correlation Factor	A	1.00	B	0.00
Wavelength	Pri	540 ▽nm	Sec.	▽nm	Factor for Maker	A		B	
Method		End Point ▽							
Reaction Slope		+ ▽			Onboard Stability Period		60** Day		Hour
Measuring Point1	First	13	Last	27	LIH Influence Check		▽		
Measuring Point2	First		Last		Lipemia		▽		
Linearity Limit		%			Icterus		▽		
Lag Time Check		▽			Hemolysis		▽		

Parameters	Specific Test Parameters				
General	LIH	ISE		Calculated Test	Range

Test Name: CysC ▽ < > Type: Serum ▽

Value/Flag: # ▽

Level Level Low # High #

Specifiel Ranges: From To

	Sex	Year	Month	Year	Month	Low	High
□ 1.	# ▽	#	#	#	#	#	#
□ 2.	# ▽	#	#	#	#	#	#
□ 3.	# ▽	#	#	#	#	#	#
□ 4.	# ▽	#	#	#	#	#	#
□ 5.	# ▽	#	#	#	#	#	#
□ 6.	# ▽	#	#	#	#	#	#
7. Standard demographics						#	#
8. Not within expected values						#	#

Panic Value Low High Unit mg/L Decimal Places #

Parameters	Calibration Parameters		
Calibrators	Calibration Specific	STAT Table Calibration	
General	ISE		

Test Name: CysC ▽ < > Type Serum ▽ Cuvette . ▽

□ Use Serum Cal.

Calibration Type: 6AB ▽ Formula: Spline ▽ Counts: # ▽

<Calibrator Parameters>

	Calibrator	OD	Conc	Factor Range Low	Factor Range High
Point 1:	1 ▽		*		
Point 2:	2 ▽		*		
Point 3:	3 ▽		*		
Point 4:	4 ▽		*		
Point 5:	5 ▽		*		
Point 6:	6 ▽		*		
Point 7	▽				
Point 8	▽				
Point 9	▽				
Point 10	▽				

Slope Check + ▽

Allowance Range Check

□ Reagent Blank

□ Calibration

Advanced Calibration Operation # ▽

Interval (RB/ACAL) # ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ □ Lot Calibration

	Calibrator	OD	Conc	OD Range Low	OD Range High
Point-1	▽				
Point-2	▽				

Stability: Reagent Blank 28 Day 0 Hour; Calibration 28 Day 0 Hour

MB Type Factor: 1-Point Calibration Point ▽ □ with Conc-0

\# User defined

* Lot specific, see analytical value sheet available on www.gentian.com

** Based on results from instrument AU400 (Beckman Coulter®)

Cystatin C

Cystatin C AU680 application settings

System Reagent: B08179 Reagent ID: 228

Parameters | Specific Test Parameters

General | LIH | ISE | Calculated Test | Range

Test Name: CysC ▽ < > Type: Serum ▽ Operation Yes ▽

Sample Volume	2 µL	Dilution	0 µL	OD Limit				
Pre-Dilution Rate	1 ▽				Min.OD		Max.OD	
Rgt. Volume R1(R1-1)	150 µL	Dilution	0 µL	Reagent OD Limit				
				First	Low	-2.0	High	2.0
				Last	Low		High	
R2(R2-1)	30 µL	Dilution	10 µL					
				Dynamic Range	Low	0.44	High	7.30
Common Rgt. Type		Name		Correlation Factor	A	1.00	B	0.00
Wavelength Pri	540 ▽nm	Sec.	▽nm	Factor for Maker	A		B	
Method	End Point ▽							
Reaction Slope	+ ▽			Onboard Stability Period		60** Day		Hour
Measuring Point1 First	13	Last	27	LIH Influence Check		▽		
Measuring Point2 First		Last		Lipemia		▽		
Linearity Limit	%			Icterus		▽		
Lag Time Check	▽			Hemolysis		▽		

Parameters | Specific Test Parameters

General | LIH | ISE | Calculated Test | Range

Test Name: CysC ▽ < > Type: Serum ▽

Value/Flag: # ▽ Low High

Level # #

Specific Ranges: From To

Panic Value: Low # High #

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ▽	#	#	#	#	#	#
☐ 2.	# ▽	#	#	#	#	#	#
☐ 3.	# ▽	#	#	#	#	#	#
☐ 4.	# ▽	#	#	#	#	#	#
☐ 5.	# ▽	#	#	#	#	#	#
☐ 6.	# ▽	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Unit mg/L Decimal Places #

Parameters | Calibration Parameters

Calibrators | Calibration Specific | STAT Table Calibration

General | ISE

Test Name: CysC ▽ < > Type Serum ▽ ☐ Use Serum Cal.

Calibration Type: 6AB ▽ Formula: Spline ▽ Counts: # ▽

<Calibrator Parameters> Factor Range

	Calibrator	OD	Conc	Low	High
Point 1:	1 ▽		*		
Point 2:	2 ▽		*		
Point 3:	3 ▽		*		
Point 4:	4 ▽		*		
Point 5:	5 ▽		*		
Point 6:	6 ▽		*		
Point 7	▽				
Point 8	▽				
Point 9	▽				
Point 10	▽				

Slope Check + ▽

Allowance Range Check

☐ Reagent Blank

☐ Calibration

Advanced Calibration Operation # ▽

Interval (RB/ACAL) # ▽

<Point Cal. For Master Curve> No. of Correction Points ▽ Use Master Curve ▽ ☐ Lot Calibration

OD Range

	Calibrator	OD	Conc	Low	High
Point-1	▽				
Point-2	▽				

Stability

Reagent Blank	28	Day		Hour
Calibration	28	Day		Hour

MB Type Factor: 1-Point Calibration Point ▽ ☐ with Conc-0

\# User defined

* Lot specific, see analytical value sheet available on www.gentian.com

** Based on results from instrument AU400 (Beckman Coulter®)

Cystatin C

Cystatin C AU480 application settings

System Reagent: B08179 Reagent ID: 228

Parameters | Specific Test Parameters
General | LIH | ISE | Calculated Test | Range

Test Name: CysC ∇ < > Type: Serum ∇ Operation Yes ∇

Sample Volume	2 µL	Dilution	0 µL	OD Limit				
Pre-Dilution Rate	1 ∇				Min.OD		Max.OD	
Rgt. Volume R1(R1-1)	150 µL	Dilution	0 µL	Reagent OD Limit				
				First	Low	-2.0	High	2.0
				Last	Low		High	
R2(R2-1)	30 µL	Dilution	10 µL					
				Dynamic Range	Low	0.43	High	7.32
Common Rgt. Type		Name		Correlation Factor	A	1.00	B	0.00
Wavelength Pri	540 ∇nm	Sec.	∇nm	Factor for Maker	A		B	
Method	End Point ∇							
Reaction Slope	+ ∇			Onboard Stability Period		60** Day		Hour
Measuring Point1 First	13	Last	27	LIH Influence Check		∇		
Measuring Point2 First		Last		Lipemia		∇		
Linearity Limit	%			Icterus		∇		
Lag Time Check	∇			Hemolysis		∇		

Parameters | Specific Test Parameters
General | LIH | ISE | Calculated Test | Range

Test Name: CysC ∇ < > Type: Serum ∇

Value/Flag: # ∇ Low High
Level # #
Specific Ranges: From To

Panic Value: Low # High #

	Sex	From Year	From Month	To Year	To Month	Low	High
☐ 1.	# ∇	#	#	#	#	#	#
☐ 2.	# ∇	#	#	#	#	#	#
☐ 3.	# ∇	#	#	#	#	#	#
☐ 4.	# ∇	#	#	#	#	#	#
☐ 5.	# ∇	#	#	#	#	#	#
☐ 6.	# ∇	#	#	#	#	#	#
7. No demographics						#	#
8. Not within expected values						#	#

Unit mg/L Decimal Places #

Parameters | Calibration Parameters
Calibrators | Calibration Specific | STAT Table Calibration
General | ISE

Test Name: CysC ∇ < > Type Serum ∇ ☐ Use Serum Cal.

Calibration Type: 6AB ∇ Formula: Spline ∇ Counts: # ∇

<Calibrator Parameters> Factor Range

	Calibrator	OD	Conc	Low	High
Point 1:	1 ∇		*		
Point 2:	2 ∇		*		
Point 3:	3 ∇		*		
Point 4:	4 ∇		*		
Point 5:	5 ∇		*		
Point 6:	6 ∇		*		
Point 7	∇				
Point 8	∇				
Point 9	∇				
Point 10	∇				

Slope Check + ∇

Allowance Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration Operation # ∇

Interval (RB/ACAL) # ∇

<Point Cal. For Master Curve> No. of Correction Points ∇ Use Master Curve ∇ ☐ Lot Calibration

OD Range

	Calibrator	OD	Conc	Low	High
Point-1	∇				
Point-2	∇				

Stability

Reagent Blank	28	Day		Hour
Calibration	28	Day		Hour

MB Type Factor: 1-Point Calibration Point ∇ ☐ with Conc-0

\# User defined
* Lot specific, see analytical value sheet available on www.gentian.com
** Based on results from instrument AU400 (Beckman Coulter®)

Cystatin C

Cystatin C DxC 500 AU application settings

System Reagent: B08179 Reagent ID: 228

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry
Test ID	CYS		Calculated Result	☐
LIS Code	CYS			

UNITS AND RANGE SETTINGS

Plasma

Use Settings from: Serum | Units: mg/L | Decimal Places: x.xx

Test Kind: General | Revision: 01 | ☒ Multi Reagent Switch

Reagent Name: CYS | Reagent ID: 228 | ☐ FSE Test

ABB Name: CYS1G | Parameter Long Name: Cystatin C B08179 CYS1G CYSC Serum

Region: ☒US ☒OUS ☒AP ☐JP ☒EU ☐Other

GENERAL PARAMETERS

SAMPLE VOLUME
Sample Volume: 2.0 µL | Dilution: 0 µL
Predilution Rate: 1

REAGENT VOLUME
R1-1: 150 µL | Dilution: 0 µL
R2-1: 30 µL | Dilution: 10 µL

WAVELENGTH
Primary: 540 nm | Secondary: None nm

METHOD: END

REACTION SLOPE: +

MEASURING POINT
Point 1: First: 13 | Last: 27
Point 2: First: | Last:

Linearity Limit: %

Lag Time Check
☐ Perform Lag Time Check

REACTION OD LIMIT
Low: | High:

REACTION BLANK OD LIMIT
First: Low: -2.0000 | High: 2.0000
Last: Low: -2.0000 | High: 2.0000

ANALYTICAL MEASURING RANGE
Low: 0.38 | High: 7.84

MANUFACTURER FACTOR
A: 1 | B: 0

REAGENT ONBOARD STABILITY
60** Days | 0** Hours

LIH INFLUENCE CHECK
☐ Perform LIH check
Lipemia: +
Icterus: +
Hemolysis: +

CALIBRATION PARAMETERS

Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
mg/L	2	None	0	None	0	None	0	None	0

CALIBRATOR SPECIFIC

Calibration Type: 6AB | Counts: 2

Formula: Spline | MB Factor:

Calibrator Name | Positive Cutoff:

Add: CYS

☒SLOPE CHECK | Number of Levels: 6

Slope Check: +

STABILITY AND INTERVAL

Reagent Blank Stability: 28 Days | 0 Hours | Interval: Lot

Calibration Stability: 28 Days | 0 Hours | Interval: Lot

CALIBRATION OD AND CONCENTRATION PARAMETERS

☐ Use highest calibrator for Upper AMR

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	CYS CAL-1	*	-2.0000	2.0000
Point 2	CYS CAL-2	*	-2.0000	2.0000
Point 3	CYS CAL-3	*	-2.0000	2.0000
Point 4	CYS CAL-4	*	-2.0000	2.0000
Point 5	CYS CAL-5	*	-2.0000	2.0000
Point 6	CYS CAL-6	*	-2.0000	2.0000
Point 7				

OD DELTA CHECK

☐Reagent Blank: 0.0000

☐Calibration: 0.0000

PROZONE CHECK PARAMETERS

☐Logic Check 1
Check Points: Point 1: # | Point 2: # | Point 3: #
Decision Values: Value 1: # | Value 2: # | Value 3: #
Limit Points: Limit 1: # | Limit 2: #
Check Pattern: Pattern: #

☐Logic Check 2
Check Points: Point 1: # | Interval: #
Decision Values: Value 1: # | Value 2: #
Limit Points: Limit 1: # | Limit 2: #

☐Logic Check 3
Check Points: Point 1: # | Interval: #
Decision Values: Value 1: # | Value 2: #
Limit Points: Limit 1: # | Limit 2: #

\# User defined
* Lot specific, see analytical value sheet available on www.gentian.com
** Based on results from instrument AU400 (Beckman Coulter®)

Cystatin C

Cystatin C DxC 700 AU application settings

System Reagent: B08179 Reagent ID: 228

General | LIH | ISE | Calculated Test | Range

Test Name: CYS1G ▼ Test No **Type:** Serum ▼ Operation Yes ▼

Sample Volume		2.0 µL	Dilution	0 ▼ µL	OD Limit					
Pre-Dilution Rate		1 ▼						Min. OD		Max OD	
Reagent Volume	R1 (R1-1)	150 µL	Dilution	0 µL	Reagent OD Limit 1st	Low	-2.0000	High	2.0000
	R1-2	µL	Dilution	µL	Last	Low	-2.0000	High	2.0000
	R2 (R2-1)	30 µL	Dilution	10 µL	Analytical Measuring Range	Low	0.40	High	8.07
Common Reagent	Type	None	Name	None	Correlation Factor	A	1	B	0
Wavelength	Pri	540 ▼ nm	Sec	None ▼ nm	Manufacturer Factor	A	1	B	0
Method		END ▼							
Reaction Slope		+ ▼			Onboard Stability Period	60 ** Day	0 Hour		
Measuring Point-1	1st	13	Last	27	LIH Influence Check	No ▼			
Measuring Point-2	1st		Last		Lipemia ▼				
Linearity Limit		%			Icterus ▼				
Lag Time Check		▼			Hemolysis ▼				

General | LIH | ISE | Calculated Test | Range

Test Name: CYS1G ▼ Test No **Type:** Serum ▼

Value/Flag: Value — Level: Low -99999.99 High 99999.99

Specific Ranges

	Sex	From Year	From Month	To Year	To Month	Other Type	Low	High
☐ 1:	# ▼	#	#	#	#	None	#	#
☐ 2:	# ▼	#	#	#	#	None	#	#
☐ 3:	# ▼	#	#	#	#	None	#	#
☐ 4	# ▼	#	#	#	#	None	#	#
☐ 5:	# ▼	#	#	#	#	None	#	#
☐ 6:	# ▼	#	#	#	#	None	#	#
7:	Standard demographics						#	#
8:	Not within expected values						#	#

Critical Limits: Low # High # Unit mg/L Select Decimal Places 2

Calibrators | General | ISE

Test Name: CYS1G ▼ **Type:** Serum ▼

☐ Use Serum Cal.

Calibration Type: 6AB ▼ Formula: Spline ▼ Counts: 2

<Calibrator Parameters>

	Calibrator	OD	Conc	Range Low	Range High
Point-1	CYSC Calibrator Level 1 ▼		*	-2.0000	2.0000
Point-2	CYSC Calibrator Level 2 ▼		*	-2.0000	2.0000
Point-3	CYSC Calibrator Level 3 ▼		*	-2.0000	2.0000
Point-4	CYSC Calibrator Level 4 ▼		*	-2.0000	2.0000
Point-5	CYSC Calibrator Level 5 ▼		*	-2.0000	2.0000
Point-6	CYSC Calibrator Level 6 ▼		*	-2.0000	2.0000
Point-7	▼				

Slope Check + ▼

Allowable Range Check
☐ Reagent Blank
☐ Calibration

Advanced Calibration Operation No ▼

Interval (RB) ▼

Interval (ACAL) ▼

MB Type Factor — 1-Point Calibration Point None ▼ — ☐ with Conc-0

Stability
Reagent Blank 28 Day 0 Hour
Calibration 28 Day 0 Hour

\# User defined
* Lot specific, see analytical value sheet available on www.gentian.com
** Based on results from instrument AU400 (Beckman Coulter®)