Cystatin C

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

REF B08179

This document describes the general use and instrument specific settings of the product above and is applicable for USA only.

Intended use

The Cystatin C Immunoassay on the Beckman Coulter® AU Systems is an *in vitro* diagnostic test for quantitative determination of cystatin C in human serum and plasma. 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].

Principles of the procedure

Serum or plasma sample from human is mixed with cystatin C immunoparticles. Cystatin C from the sample and anti-cystatin C from the immunoparticles aggregates. 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. The AU platforms will automatically calculate the results.

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

For *in vitro* diagnostic use by laboratory professionals.
Caution: Federal law restricts this device to sale by or on the order of a physician.

1. Contains substances from human or animal origin and should be considered as potentially infectious material. Serum used in Gentian Cystatin C Controls and calibrators is tested for hepatitis HBsAG, anti-HCV, anti-HIV1 and anti-HIV2 and found to be negative. Handle with caution and discard following local regulations.
2. Contains antibiotics and must be handled with due caution.
3. The sodium azide concentration of the assay is not characterized 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.
4. Exposure may result in irritation of skin and eyes.
5. Avoid contact with incompatible materials.
6. Avoid exposure to heat and direct sunlight.

To obtain the SDS (Safety Data Sheet), 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.

Directions for reconstitution/dilution

The product is ready to use.

Storage instructions

Shelf life of unopened reagents at 2-8 °C: See expiry date on the label.

Specimen collection and preparation

The required sample material is human serum or EDTA/heparinized plasma. It is recommended to analyze 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), 21 days if stored at 2-8 °C. If stored below -70 °C the samples are stable for at least 5 years [5]. Mix samples well before analyzing them.

Procedure

A detailed instrument parameter list is available in the section "Instrument settings for Cystatin C Immunoassay" below. Instrument set up, maintenance, operation and precautions must be handled in accordance with the Beckman Coulter® AU system's instrument manuals.

Reagent preparation

Gentian Cystatin C reagents are supplied ready for use. Mix gently before loading into instrument. Reagents should be stored capped at 2-8 °C when not in use.

Assay kit components

Materials provided	
Gentian Cystatin C Reagent Kit for Beckman Coulter® • R1 Assay Buffer (58 mL) • R2 Immunoparticles (10 mL)	REF B08179
Materials required, but not provided	
Gentian Cystatin C Calibrator Kit (6 levels x 1 mL)	REF A52763
Gentian Cystatin C Control Kit (2 levels x 1 mL)	REF A52765

Cystatin C

All materials are ready for use.

Stability

Stability after opening: Until expiry date at 2-8 °C. On-board stability: 9 weeks at correct temperature (2-8 °C).

Calibrator standardization

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

Establishment of the calibration curve

Please refer to the package insert of the Gentian Cystatin C Calibrator Kit REF A52763.

QC controls

Please refer to the package insert of the Gentian Cystatin C Control Kit REF A52765.

Measuring patient samples

When a valid calibration has been performed and the control values are within the valid range, serum or plasma samples may be measured. Ensure that minimum volume of sample is present and assay the samples according to the instructions given in the Beckman Coulter® AU Systems instrument manuals.

Results

The results are calculated automatically by the Beckman Coulter® AU Systems. The results are presented in mg/L.

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 [6]. The equation is valid for people above 14 years.

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

Limitations of the procedure

The materials should not be used past the expiration date.

Expected values

Gentian follows the CLSI Guideline, C28 [7] to determine the transferability of the reference interval. The reference interval is based on a reference interval study performed at Växjö Hospital, Sweden, including serum samples from 136 self-declared healthy subjects 20-80 years of age. The samples were analyzed for cystatin C on the AU2700 platform. The reference interval was calculated non-parametrically and was determined to be 0.53-1.01 mg/L. This represents the central 95 % of the whole population tested. It is recommended that every laboratory should determine a local reference interval since values may vary depending on the population tested.

Specific 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.

Interference

The interference study was designed in accordance with the protocol EP07 from CLSI [8]. Previously, no significant interference was detected with the drugs tested as recommended in a publication by Sonntag and Scholer [9]. There is no RF interference present in the Gentian Cystatin C Immunoassay because the antibodies are made using avian antibodies (chicken) [10].

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

Precision

The Gentian Cystatin C Immunoassay was used in a study designed in accordance with CLSI protocol EP05 [11]. Three serum pools and 2 control levels were measured on the Beckman Coulter® AU5800 system (n=20).

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

Sensitivity

Using the Gentian Cystatin C Immunoassay on an AU5800 instrument, a lower limit of quantification was measured to be 0.23 mg/L.

Linearity

Using the Gentian Cystatin C Immunoassay, linearity was measured within acceptable limits in the range of 0.49-7.07 mg/L on the AU5800 system. Linearity samples above this range were not tested.

Hook effect

In a study on AU5800, the security zone for antigen excess extended up to 32 mg/L using the Gentian Cystatin C Immunoassay. No samples above this value were measured.

Analytical recovery

Using the Gentian Cystatin C Immunoassay on a Beckman Coulter® AU5800 instrument, a recovery of 96-100 % was observed.

Instrument variation

Instrument variation between Gentian Cystatin C Immunoassay on AU5800 and Architect c16000 instruments was measured and the results analyzed using Passing-Bablok regression analysis:

Passing-Bablok regression	N	Range of samples [mg/L]	Term	Coefficient
AU5800 vs. Architect	32	0.76 -1.88	Intercept	0.01
			Slope	0.95

Cystatin C

Specific 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.

Interference

The interference study was designed in accordance with the protocol EP07 from CLSI [8]. Previously, no significant interference was detected with the drugs tested as recommended in a publication by Sonntag and Scholer [9]. There is no RF interference present in the Gentian Cystatin C Immunoassay because the antibodies are made using avian antibodies (chicken) [10].

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

Precision

The Gentian Cystatin C Immunoassay was used in study designed in accordance with CLSI protocol EP05 [11]. Four serum pools were measured on the Beckman Coulter® AU680 system (n=20).

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

Sensitivity

Using the Gentian Cystatin C Immunoassay on an AU680 instrument, a lower limit of quantification was measured to be 0.28 mg/L.

Linearity

Using the Gentian Cystatin C Immunoassay, linearity was measured within acceptable limits in the range of 0.44-7.30 mg/L on the AU680 system.

Hook effect

In a study on AU680, the security zone for antigen excess extended up to 12 mg/L using the Gentian Cystatin C Immunoassay.

Analytical recovery

Using the Gentian Cystatin C Immunoassay on a Beckman Coulter® AU680 instrument, a recovery of 86-92 % was observed.

Instrument variation

Instrument variation between Gentian Cystatin C Immunoassay on AU680 and Architect c16000 instruments was measured and the results analyzed using Passing-Bablok regression analysis:

Passing-Bablok regression	N	Range of samples [mg/L]	Term	Coefficient
AU680 Vs. Architect	40	0.71 – 6.38	Intercept	0.03
			Slope	0.95

Specific 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.

Interference

The interference study was designed in accordance with the protocol EP07 from CLSI [8]. Previously, no significant interference was detected with the drugs tested as recommended in a publication by Sonntag and Scholer [9]. There is no RF interference present in the Gentian Cystatin C Immunoassay because the antibodies are made using avian antibodies (chicken) [10].

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

Precision

The Gentian Cystatin C Immunoassay was used in a n study designed in accordance with CLSI protocol EP05 [11]. Three serum pools and 2 control levels were measured on the Beckman Coulter® AU480 system (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

Cystatin C

Sensitivity
Using the Gentian Cystatin C Immunoassay on an AU480 instrument, a lower limit of quantification was measured as 0.43 mg/L.

Linearity
Using the Gentian Cystatin C Immunoassay, linearity was measured within acceptable limits in the range of 0.40-7.32 mg/L on the AU480 system.

Hook effect
In a study on AU480, the security zone for antigen excess extended up to 9.4 mg/L using the Gentian Cystatin C Immunoassay.

Analytical recovery
Using the Gentian Cystatin C Immunoassay on a Beckman Coulter® AU480 instrument, a recovery of 90-95 % was observed.

Instrument variation
Instrument variation between Gentian Cystatin C Immunoassay on AU480 and Architect c16000 instruments was measured and the results analyzed using Passing-Bablok regression analysis:

Passing-Bablok regression	N	Range of samples (mg/L)	Term	Coefficient
AU480 vs. Architect	40	0.71 – 6.38	Intercept	0.03
			Slope	0.95

Performance characteristics DxC 500 AU/DxC 500i
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.

Interference
The interference study was designed in accordance with the protocol EP07 from CLSI [8]. Previously, no significant interference was detected with the drugs tested as recommended in a publication by Sonntag and Scholer [9]. There is no RF interference present in the Gentian Cystatin C Immunoassay because the antibodies are made using avian antibodies (chicken) [10].

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

Precision
The Gentian Cystatin C Immunoassay was used in a n study designed in accordance with CLSI protocol EP05 [11]. 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

Sensitivity
Using the Gentian Cystatin C Immunoassay on a DxC 500 AU instrument, a lower limit of quantification was measured as 0.32 mg/L. The study was designed in accordance with EP17 [12.

Linearity
Using the Gentian Cystatin C Immunoassay, linearity was measured within acceptable limits in the range of 0.38-7.84 mg/L on the DxC 500 AU system. Linearity samples above this range were not tested.

Hook effect
In a study on DxC 500 AU, the security zone for antigen excess extended up to 25.7 mg/L using the Gentian Cystatin C Immunoassay.

Analytical recovery
Using the Gentian Cystatin C Immunoassay on a DxC 500 AU instrument, a recovery of 102-109 % was observed.

Instrument variation
Instrument variation between Gentian Cystatin C Immunoassay on the DxC 500 AU and AU5800 instruments was measured and the results analyzed using Passing-Bablok regression analysis:

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.

Interference
The interference study was designed in accordance with the protocol EP07 from CLSI [8]. Previously, no significant interference was detected with the drugs tested as recommended in a publication by Sonntag and Scholer [9]. There is no RF interference present in the Gentian Cystatin C Immunoassay because the antibodies are made using avian antibodies (chicken) [10].

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

Cystatin C

Precision

The Gentian Cystatin C Immunoassay was used in a study designed in accordance with CLSI protocol EP05 [11]. Three serum pools and 2 control levels were measured on the Beckman Coulter® DxC 700 AU system (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

Sensitivity

Using the Gentian Cystatin C Immunoassay on an DxC 700 AU instrument, a lower limit of quantification was measured as 0.40 mg/L. The study was designed in accordance with EP17 [12].

Linearity

Using the Gentian Cystatin C Immunoassay, linearity was measured within acceptable limits in the range of 0.40-8.07 mg/L on the DxC 700 AU system. Linearity samples above this range were not tested.

Hook effect

In a study on DxC 700 AU, the security zone for antigen excess extended up to 10 mg/L using the Gentian Cystatin C Immunoassay.

Analytical recovery

Using the Gentian Cystatin C Immunoassay on a Beckman Coulter® DxC 700 AU instrument, a recovery of 104 – 105 % was observed.

Instrument variation

Instrument variation between Gentian Cystatin C Immunoassay on DxC 700 AU and Architect c4000, and between DxC 700 AU and AU5800 instruments was measured and the results analyzed using Passing-Bablok regression analysis:

Instrument	N	Range of samples [mg/L]	Term	Co-efficient
Architecht	40	0.60-6.27	Intercept	0.02
			Slope	0.96
AU 5800	40	0.59-6.22	Intercept	0.00
			Slope	1.00

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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.

Serious incidents

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

Shipping damage

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

Symbols key

2°C 8°C	Temperature limit
	Use by date
	Consult instructions for use
	Manufacturer
CE 0123	CE mark with Notified Body number
UK CA	UKCA mark
IVD	*In Vitro* Diagnostic medical device
LOT	Lot number
REF	Catalogue number
UDI	Unique Device Identifier
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R1 Assay Buffer

R2 Immunoparticles

RxOnly Caution: Federal law restricts this device to sale by or on the order of a physician.

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 #

Specificl 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®)

*** based on results from instrument DxC 700 AU

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 # #

Panic Value: Low # High #

Specific Ranges:

	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>

	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		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®)

*** based on results from instrument DxC 700 AU

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 # #

Panic Value: Low # High #

Specific Ranges:

	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>

	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 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®)

*** based on results from instrument DxC 700 AU

Cystatin C

Cystatin C DxC 500 AU/DxC 500i application settings

System Reagent: B08179 Reagent ID: 228

TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name: Test: CYS Rev: | Discipline: Calculated Result ☐ | Chemistry

Test ID: CYS

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®)