Cystatin C

Package Insert for Cystatin C Immunoassay on Beckman Coulter® AU Systems (AU5800, AU680, AU480, DxC 700 AU)

REF B08179

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 by professional users. The measurement of cystatin C is used in the diagnosis and treatment of renal diseases.

Indication for use

The measurement of cystatin C can be used to estimate the glomerular filtration rate (eGFR) of the patient's kidneys. The eGFR is used to determine the patient's kidney function and diagnose chronic kidney disease (CKD).

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, sex, age or diet [2, 3, 4].

Calibrator Standardisation

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

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

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.

Assay Reagents

Items included:	
Gentian Cystatin C Reagent Kit for Beckman Coulter® AU Systems (1x300)	REF B08179
Items required but not included:	
Gentian Cystatin C Control Kit, Low & High, vials of 1 ml	REF A52765
Gentian Cystatin C Calibrator Kit (6 x 1 ml)	REF A52763

Composition

Reaction Buffer 1 (R1)

Cystatin C Reaction buffer, 1 vial of 58 mL. R1 is a MOPS [3-(N-Morpholino)-propane sulfonic acid] buffered saline, preserved with sodium azides (0.09 % (w/v)). The buffer is ready for use.

Reaction Buffer 2 (R2):

Cystatin C Immunoparticles, 1 vial of 10 mL. R2 contains immunoparticles, which is a purified immunoglobulin fraction that is directed against cystatin C, which is covalently attached to uniform polystyrene particles. Human cystatin C was used as immunogen in the process of generating the immunoparticles. It is provided as a ready to use suspension, preserved with 0.09 % (w/v) sodium azide and antibiotics.

Warnings and Precautions

1. This test is for *in vitro* use only, and must be handled by qualified personnel.
2. Reagents contain antibiotics and must be handled with due caution.
3. Reagents contain sodium azide preservative and must be handled with due caution: Do not ingest or allow contact to skin or mucous membranes. The sodium azide concentration of this product is not characterized as dangerous. 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. The immunoparticles contain substances of animal origin. Disposal of any discarded materials should be in accordance to local requirements.
5. Serum used in the manufacture of calibrators and controls was tested for hepatitis HBsAG, anti-HCV, anti-HIV1 and anti-HIV2 and found to be negative. Nevertheless, the materials contain substances of human and animal origin and must be handled with due care. Disposal of any discarded materials should be in accordance to local requirements.

Reagent Storage and Stability

Shelf life of unopened reagents at 2-8°C: See expiry date on the label. Stability after opening: Until expiry date at 2 - 8°C. On-board stability: 9 weeks at correct temperature (2 - 8°C).

Specimen Collection and Handling

Required sample material is human serum or EDTA/heparinized plasma. It is recommended to analyze the samples as fresh as possible. However sample stability testing showed that cystatin C in serum and plasma samples are stable for 26 days at room temperature (8 - 25°C) or 26 days if stored at 2 - 8°C. Additionally, it has been published that samples can be stored below -70°C for up to 5 years [6]. Mix samples well before analyzing.

Measuring Range

The measuring range of cystatin C for the assay is 0.4 – 7.8 mg/L.

Assay Procedure

Application Notes/Assay Installation

A detailed instrument parameter list is available in the section "Instrument Settings" below. These are also available at: www.gentian.com. Instrument set up, maintenance, operation and precautions must be handled in accordance with the Beckman Coulter® AU instrument manuals.

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Reagent Preparation

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

Establishing the Calibration Curve

Use standards 1 to 6 to establish a 6-point standard curve as defined in the Beckman Coulter® AU Systems Instrument Manuals. Calibrator values are lot dependent and a new calibration must be performed whenever a new calibration lot is used. The calibrator's assigned values are given on the analytical value sheet provided with the calibrator. A new calibration should be performed once every 4 weeks.

QC Controls

The controls low and high must be tested each day before any samples are measured in order to validate the calibration curve. The controls have an assigned value range that must be met before measuring samples. The assigned values are given in the Analytical Value sheet included with the Gentian Cystatin C Control Kit. If the control values are not valid, repeat the control measurements. If the calibration cannot be performed without error, or valid control values cannot be reproduced, contact Beckman Coulter® for support.

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. Check 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.

Reference Intervals

Gentian follows the CLSI Guideline, C28-A2; *How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline Second edition 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 AU 2700 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.

Limitations

The materials should not be used past expiration date.

Performance Characteristics AU 5800

All studies were performed at one instrument site, using one lot of Gentian cystatin C reagents unless otherwise stated. For minimum acceptance criteria or further information please contact products@gentian.no.

Precision

The Gentian Cystatin C Immunoassay was used in a 5 - day precision study designed in accordance with CLSI protocol EP5-A. 3 serum pools and 2 control levels were measured on the Beckman Coulter® AU5800 system.

ID	Mean (mg/L)	Within-Run CV (%)	Between run CV (%)	Total CV (%)	n
P1	0.90	0.82	1.78	1.96	20
P2	5.29	0.49	2.05	2.10	20
P3	2.08	0.43	1.56	1.62	20
P4	2.91	0.81	2.26	2.40	20
P5	0.86	1.10	3.24	3.42	20

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.

Analytical Recovery

Using the Gentian Cystatin C Immunoassay on a Beckman Coulter® AU 5800 instrument, a recovery of 96 - 100% was observed.

Limit of Quantification

Limit of Quantification 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 Gentian Cystatin C Immunoassay on an AU 5800 instrument has a Limit of Quantification of 0.23 mg/L.

Security Zone

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

Interference

In a study, no significant interference was detected with Hemoglobin (6 g/L), Intralipid (10 g/L) or Bilirubin (400 mg/L) in cystatin C samples. The interference study was designed in accordance with the protocol EP7-A from CLSI [7]. Previously, no significant interference was detected with the drugs tested as recommended in a publication by Sonntag and Scholer [8]. There is no RF interference present in the Gentian Cystatin C Immunoassay because the antibodies are made using avian antibodies (chicken) [9].

Instrument Comparison

Instrument variation between Gentian Cystatin C on AU 5800 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
AU 5800 Vs. Architect	32	0.76 -1.88	Intercept	0.01
			Slope	0.95

Performance Characteristics AU 680

All studies were performed at one instrument site, using one lot of Gentian cystatin C reagents unless otherwise stated.

Precision

The Gentian Cystatin C Immunoassay was used in a 2-day precision study designed in accordance with CLSI protocol EP5-A. 6 serum pools were measured on the Beckman Coulter® AU 680 system.

ID	Mean (mg/L)	Within run CV (%)	Between run CV (%)	Total CV (%)	n
P1	0.75	0.79	2.08	2.44	20
P2	1.96	0.43	1.73	1.88	20
P3	0.80	1.09	1.35	2.00	20
P4	4.98	0.67	1.00	1.57	20
P5	1.07	0.42	1.66	2.26	20
P6	3.28	0.25	1.00	1.51	20

Linearity

Using the Gentian Cystatin C Immunoassay, linearity was measured within acceptable limits in the range of 0.44 - 9.02 mg/L on the AU 680 system.

Analytical Recovery

Using the Gentian Cystatin C Immunoassay on a Beckman Coulter® AU 680 instrument, a recovery of 86-92% was observed.

Limit of Quantification

Limit of Quantification 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 Gentian Cystatin C Immunoassay on an AU 680 instrument has a Limit of Quantification of 0.28mg/L.

Security Zone

In a study on AU 680, the security zone for antigen excess extended up to 14 mg/L using the Gentian Cystatin C assay.

Interference

In a study, no significant interference was detected with Hemoglobin (8.5 g/L), Intralipid (16 g/L) or Bilirubin (200 mg/L) in cystatin C samples. The interference study was designed in accordance with the protocol EP7-A from CLSI [7]. Previously, no significant interference was detected with the drugs tested as recommended in a publication by Sonntag and Scholer [8]. There is no RF interference present in the Gentian Cystatin C Immunoassay because the antibodies are made using avian antibodies (chicken) [9].

Instrument Comparison

Instrument variation between Gentian Cystatin C 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
AU 680 Vs. Architect	40	0.71 – 6.38	Intercept	0.03
			Slope	0.95

Performance Characteristics AU 480

All studies were performed at one instrument site, using one lot of Gentian cystatin C reagents unless otherwise stated.

Precision

The Gentian Cystatin C Immunoassay was used in a 3-day, multi calibration precision study designed in accordance with CLSI protocol EP5-A. 3 serum pools and 2 control levels were measured on the Beckman Coulter® AU 480 system.

ID	Mean (mg/L)	Within run CV (%)	Between run CV (%)	Total CV (%)	n
P1	1.09	1.57	1.21	3.60	12
P2	3.65	0.67	0.62	1.82	12
P3	1.24	1.73	0.00	3.47	12
P4	0.87	3.10	0.00	3.72	12
P5	3.39	1.18	0.94	3.03	12

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 AU 480 system.

Analytical Recovery

Using the Gentian Cystatin C Immunoassay on a Beckman Coulter® AU 480 instrument, a recovery of 90-96% was observed.

Limit of Quantification

Limit of Quantification 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 Gentian Cystatin C Immunoassay on an AU 480 instrument has a Limit of Quantification of 0.43mg/L.

Security Zone

In a study on AU 480, the security zone for antigen excess extended up to 9.7 mg/L using the Gentian Cystatin C assay.

Interference

In a study, no significant interference was detected with Hemoglobin (10 g/L), Intralipid (15 g/L) or Bilirubin (600 mg/L) in cystatin C samples. The interference study was designed in accordance with the protocol EP7-A from CLSI [7]. Previously, no significant interference was detected with the drugs tested as recommended in a publication by Sonntag and Scholer [8]. There is no RF interference present in the Gentian Cystatin C Immunoassay because the antibodies are made using avian antibodies (chicken) [9].

Instrument Comparison

Instrument variation between Gentian Cystatin C 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
AU 480 Vs. Architect	40	0.71 – 6.38	Intercept	0.03
			Slope	0.95

Performance Characteristics DxC 700 AU

All studies were performed at one instrument site, using one lot of Gentian cystatin C reagents unless otherwise stated. For minimum acceptance criteria or further information please contact products@gentian.no.

Precision

The Gentian Cystatin C Immunoassay was used in a 20 - day precision study designed in accordance with CLSI protocol EP5-A2. 3 serum pools and 2 control levels were measured on the Beckman Coulter® DxC 700 AU system.

ID	Mean (mg/L)	Within-Run CV (%)	Between run CV (%)	Total CV (%)	n
P1	0.73	0.58	0.00	0.75	80
P2	1.70	0.49	0.28	0.59	80
P3	6.13	0.44	0.18	0.60	80
P4	0.91	0.67	0.60	1.04	80
P5	3.44	0.39	0.81	0.90	80

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.

Analytical Recovery

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

Limit of Quantification

Limit of Quantification 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 Gentian Cystatin C Immunoassay on an DxC 700 AU instrument has a Limit of Quantification of 0.40 mg/L. The study was designed in accordance with EP17-A2.

Security Zone

In a study on DxC 700 AU, the security zone for antigen excess extended up to 10.3 mg/L using the Gentian Cystatin C assay.

Interference

In a study, no significant interference was detected with Hemoglobin (10 g/L), Intralipid (10 g/L) or Bilirubin (200 mg/L) in cystatin C samples. The interference study was designed in accordance with the protocol EP7-A2 from CLSI [7]. Previously, no significant interference was detected with the drugs tested as recommended in a publication by Sonntag and Scholer [8]. There is no RF interference present in the Gentian Cystatin C Immunoassay because the antibodies are made using avian antibodies (chicken) [9].

Instrument Comparison

Instrument variation between Gentian Cystatin C on DxC 700 AU and Architect c4000, and between DxC 700 AU and AU 5800 instruments was measured and the results analyzed using Passing-Bablok regression analysis:

Passing Bablok regression	N	Range of samples (mg/L)	Term	Coefficient
DxC 700 AU Vs. Architect	40	0.60 -6.27	Intercept	0.02
			Slope	0.96
DxC 700 AU Vs. AU 5800	40	0.59 -6.22	Intercept	0.00
			Slope	1.00

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.

Symbols Key

LOT	Lot number
2˚C 8˚C	Temperature limit
	Use by date
	Consult instructions for use
	Manufacturer
REF	Catalogue number
IVD	*In vitro* diagnostic medical device
	Caution
	Biological risks

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Shipping Damage

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

For other languages visit:
https://www.gentian.com/clinical-diagnostic-products/beckman-coulter-customers-cystatin-c

Bibliography

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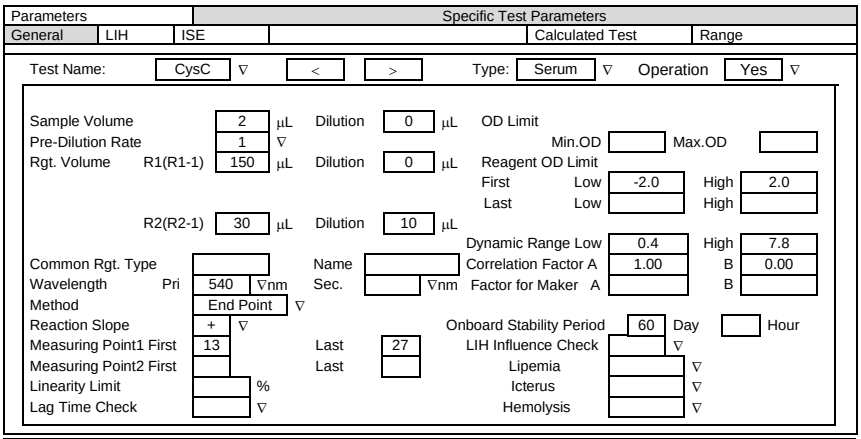
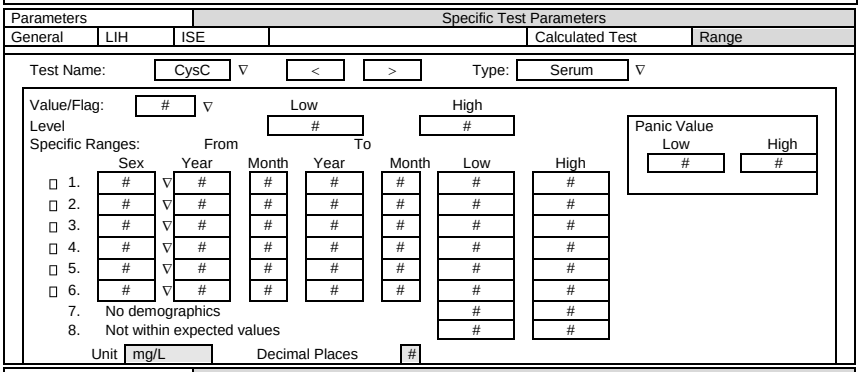
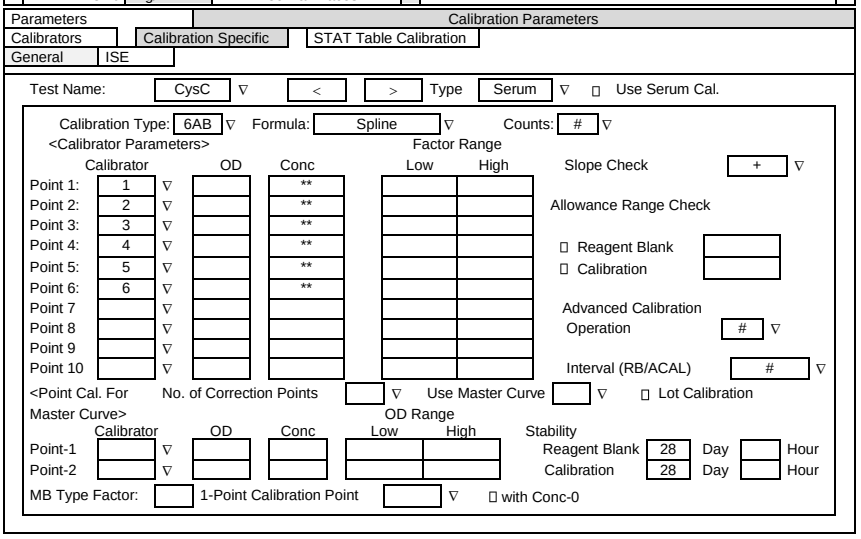
Instrument Settings for Cystatin C Immunoassay

Cystatin C AU680/AU480 Serum and Plasma Application

System Reagent: B08179 Reagent ID: 228







\# User defined

** Lot specific, see analytical value sheet included with calibrator kit

Cystatin C AU5800 Serum and Plasma Application

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 0.4	High 7.8	
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 included with calibrator kit

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Cystatin C, DxC 700 AU Serum and Plasma Application

System Reagent: B08179
Test name: CYS1G
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 OD Limit				
Reagent Volume	R1 (R1-1)	150 µL	Dilution	0 µL	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	0.4	High	7.8
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>

Slope Check: + ▼

	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	▼				

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 included with calibrator kit.