

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.

- 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.
- The sodium azide concentration of the assay is not characterized as hazardous. Although, accumulated NaN3 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

- 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.
- Do not mix reagents of different lots or interchange caps of reagents, controls, calibrators, and lots.
- 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 $^{\circ}\text{C}$ when not in use.

Assay kit components

Materials provided				
Gentian Cystatin C Reagent Kit for Beckman	REF B08179			
Coulter®				
 R1 Assay Buffer (58 mL) 				
R2 Immunoparticles (10 mL)				
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 A				

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 RFF 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.

GFR [mL/min/1.73 m²] =
$$\frac{79.901}{\text{Cystatin C (mg/L)}^{1.4389}}$$

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
Р3	2.08	0.43	1.62
CL	0.86	1.10	3.42
СН	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.	32	0.76 -1.88	Intercept	0.01
Architect	32	0.70 1.00	Slope	0.95

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
Р3	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
СН	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.	40	0.71 – 6.38	Intercept	0.03
Architect	70	0.71-0.36	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
Р3	1.24	1.73	0.00	3.47
CL	0.87	3.10	0.00	3.72
СН	3.39	1.18	0.94	3.03

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.	40	0.71 – 6.38	Intercept	0.03
Architect	40	0 0.71-6.38	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
Р3	6.37	0.73	1.63	3.66
CL	1.00	0.68	0.61	2.00
СН	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]
42	0.57-5.72	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			

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
Р3	6.13	0.44	0.18	0.60
CL	0.91	0.67	0.60	1.04
СН	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:

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

Bibliography

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Date of issue

21 MAR. 2025

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.

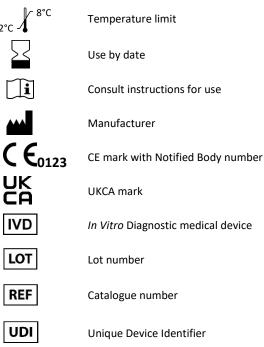
Serious incidents

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



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R1 Assay Buffer

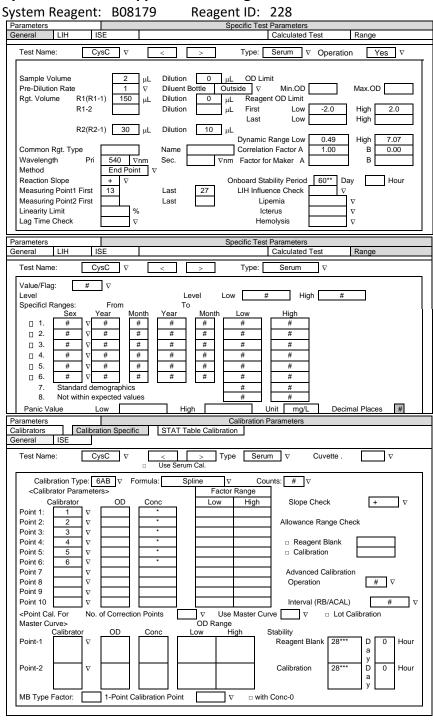
R2 Immunoparticles

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



Instrument settings for the Gentian Cystatin C Immunoassay

Cystatin C AU5800 application settings



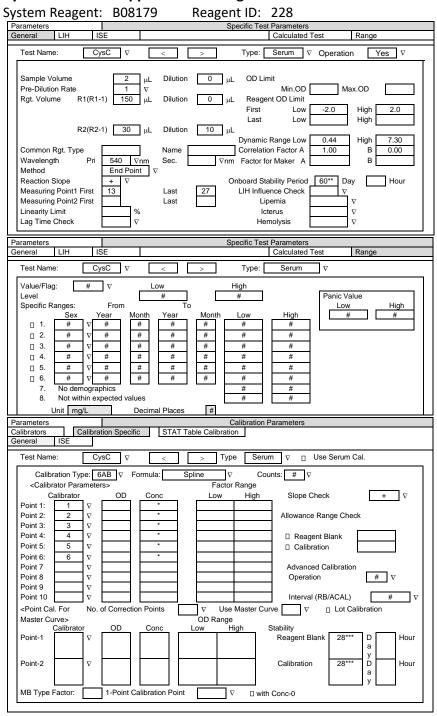
Lot specific, see analytical value sheet available on www.gentian.com

based on results from instrument AU400 (Beckman Coulter®)

^{***} based on results from instrument DxC 700 AU



Cystatin C AU680 application settings

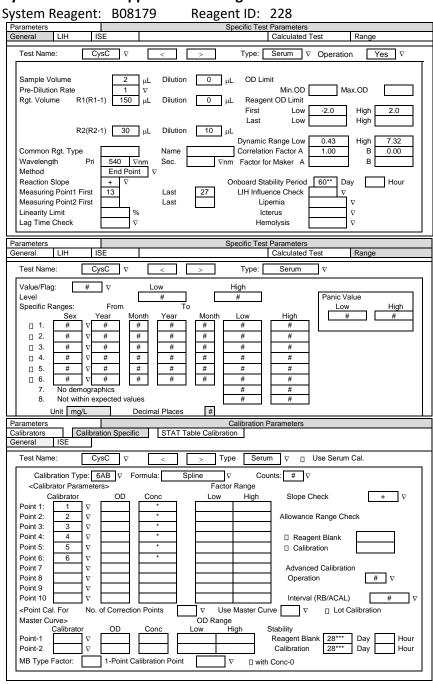


^{*} Lot specific, see analytical value sheet available on www.gentian.com
** based on results from instrument AU400 (Beckman Coulter*)

^{***} based on results from instrument DxC 700 AU



Cystatin C AU480 application settings



[#] User defined

^{*} Lot specific, see analytical value sheet available on <u>www.gentian.com</u>

^{**} based on results from instrument AU400 (Beckman Coulter®)

^{***} based on results from instrument DxC 700 AU



Cystatin C DxC 500 AU/DxC 500i application settings

System Reagent: B08179 Reagent ID: 228

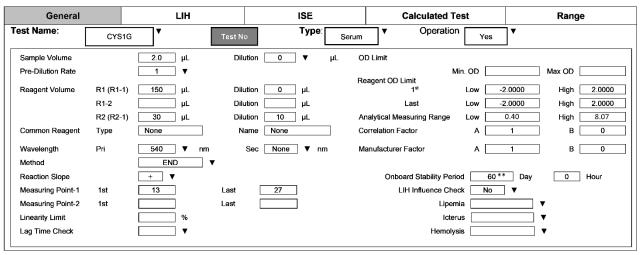
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Base Unit Decimal mg/L ▼ 2 CALIBRATOR SPE Cali Cali	Place Unit 1 Factor None 0 CCIFIC bration Type 8AB Formula Spline brator Name Add CYS Number of Lev	CALIBRATION F 1 Unit 2 I None ▼ (Counts 2 MB Factor Positive Cutoff	CALIBRA* CALIBRA* Po Po Po Po Po Po Po	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na OYS CAL-1 cint 2 CYS CAL-2 cint 3 CYS CAL-3 cint 4 CYS CAL-4 cint 5 CYS CAL-4	ENTRATION Par Upper AMR The Conc T	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	0 S OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CCIFIC bration Type 8AB Formula Spline brator Name Add CYS Number of Lev Slope Check +	CALIBRATION F 1 Unit 2 I None ▼ (Counts 2 MB Factor Positive Cutoff	CALIBRA CALIBRA Po	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na OYS CAL-1 OYS CAL-2 Oint 2 OYS CAL-3 Oint 4 OYS CAL-4 OYS CAL-6 OYS CAL-6	ENTRATION PA	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000	0 S OD Range High 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CCIFIC bration Type 8AB Formula Spline brator Name Add CYS Number of Lev Slope Check	CALIBRATION F 1 Unit 2 I None () Counts (2) MB Factor Positive Cutoff els 6	CALIBRA CALIBRA Po	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na OYS CAL-1 cint 2 CYS CAL-2 cint 3 CYS CAL-3 cint 4 CYS CAL-4 cint 5 CYS CAL-4	ENTRATION Par Upper AMR The Conc T	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	0 S OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CCIFIC bration Type 6AB Formula Spline brator Name Add CYS Number of Lev Slope Check + RVAL ity 28 Days 0 Hours	CALIBRATION F 1 Unit 2 I None ▼ (Counts 2 MB Factor Positive Cutoff els 6 Interval Lot ▼	CALIBRA' CALIBRA' Po Po Po Po Po Po Po Po Po	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na OYS CAL-1 CYS CAL-2 CYS CAL-3 CYS CAL-4 CYS CAL-4 CYS CAL-5 CYS CAL-6 CYS CAL-6	ENTRATION Par Upper AMR The Conc T	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	0 S OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CCIFIC bration Type 6AB Formula Spline brator Name Add CYS Number of Lev Slope Check + RVAL ity 28 Days 0 Hours	CALIBRATION F 1 Unit 2 I None () Counts (2) MB Factor Positive Cutoff els 6	CALIBRA' CALIBRA' Po Po Po Po OD DELTA	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na CYS CAL-1 CYS CAL-2 CYS CAL-3 CYS CAL-4 CYS CAL-5 CYS CAL-6	ENTRATION Par Upper AMR The Conc T	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	0 S OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CCIFIC bration Type 6AB Formula Spline brator Name Add CYS Number of Lev Slope Check + RVAL ity 28 Days 0 Hours	CALIBRATION F 1 Unit 2 I None ▼ (Counts 2 MB Factor Positive Cutoff els 6 Interval Lot ▼	CALIBRA* CALIBRA* Po Po Po Po OD DELT. □ Reage	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na CYS CAL-1 CYS CAL-2 CYS CAL-3 CYS CAL-4 CYS CAL-8	ENTRATION Par Upper AMR The Conc T	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	0 S OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CCIFIC bration Type 6AB Formula Spline brator Name Add CYS Number of Lev Slope Check + RVAL ity 28 Days 0 Hours	CALIBRATION F 1 Unit 2 I None	CALIBRA CALIBRA Po Po Po Po Po COD DELT. Reage	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na OYS CAL-1 OYS CAL-2 OYS CAL-3 OYS CAL-3 OYS CAL-4 CYS CAL-6 OYS CAL-7 OYS CAL-7 OYS CAL-8	ENTRATION Par Upper AMR The Conc T	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	0 S OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L ▼ 2 CALIBRATOR SPE Cali Cali	Place Unit 1 Factor None 0 CCIFIC bration Type 6AB Formula Spline brator Name Add CYS Number of Lev Slope Check + RVAL ity 28 Days 0 Hours	CALIBRATION F 1 Unit 2 I None	CALIBRA CALIBRA Po Po Po Po Po COD DELT. Reage	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na Ory CAL-1 CYS CAL-2 CYS CAL-3 CYS CAL-3 CYS CAL-4 CYS CAL-5 CYS CAL-6 CYS CAL-6 CYS CAL-6 CYS CAL-7 CYS CAL-7 CYS CAL-8 CYS CAL-9 CYS	ENTRATION Proper AMR The conc	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	0 S OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CCIFIC bration Type 8AB Formula Spline brator Name Add CYS Number of Lev Slope Check + RVAL ity 28 Days 0 Hours ity 28 Days 0 Hours	CALIBRATION F 1 Unit 2 None	CALIBRA CALIBRA Po Po Po Po Po CALIBRA CALIBRA Po	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na CYS CAL-1 CYS CAL-2 coint 2 CYS CAL-2 coint 3 CYS CAL-3 coint 4 CYS CAL-4 coint 5 CYS CAL-5 coint 6 CYS CAL-8 coint 7 A CHECK ent Blank on 0000 TERS □ Logic Check Point Check Point □ Logic Check Point CHECK	ENTRATION PA	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CCIFIC bration Type 6AB Formula Spline Place Unit 1 Factor None 0 CIFIC bration Type 6AB Formula Spline Value 1 #	CALIBRATION F 1 Unit 2 I None	CALIBRA CALIBRA Po Po Po Po Po CALIBRA CALIBRA Po	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na CYS CAL-1 CYS CAL-2 CYS CAL-3 CYS CAL-3 CYS CAL-6 CYS CAL-6 CYS CAL-8	ENTRATION PA	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CIFIC bration Type 6AB Formula Spline Place Unit 1 Factor None 0 CIFIC bration Type 6AB Formula Spline Value 1 ##	CALIBRATION F 1 Unit 2	CALIBRA CALIBRA Po Po Po Po Po CALIBRA CALIBRA Po	Unit 3 Finance ▼ 0 TION OD AND CONC Use highest calibrator for Calibrator Na CYS CAL-1 CYS CAL-2 coint 2 CYS CAL-3 coint 4 CYS CAL-3 coint 5 CYS CAL-4 coint 5 CYS CAL-5 coint 6 CYS CAL-6 coint 7 A CHECK ent Blank 0.0000 TERS □ Logic Check Check Point ###################################	ENTRATION Par Upper AMR or Upper AMR	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L ▼ 2 CALIBRATOR SPE Cali	Place Unit 1 Factor None 0 CCIFIC bration Type 8AB Formula Spline Place 1 Factor Name Add CYS Number of Lev Slope Check RVAL ity 28 Days 0 Hours ity 28 Days 0 Hours Decision Values Value 1 # Value 2 #	CALIBRATION F 1 Unit 2	CALIBRA CALIBRA Po Po Po Po Po CALIBRA CALIBRA Po	Unit 3 Finance Finance Finance Finance Finance Finance Calibrator Na CYS CAL-1 CYS CAL-2 CYS CAL-3 CYS CAL-4 CYS CAL-4 CYS CAL-5 CYS CAL-6 CYS CAL-6 CYS CAL-6 CYS CAL-6 CYS CAL-6 CYS CAL-7 CYS CAL-8 CYS CAL-8 CYS CAL-8 CYS CAL-8 CYS CAL-1 CYS CAL-2 CYS CAL-3 CYS CAL-3	ENTRATION Por Upper AMR ame Conc	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000
Base Unit Decimal mg/L	Place Unit 1 Factor None 0 CCIFIC bration Type 8AB Formula Spline Place 1 Factor Name Add CYS Number of Lev Slope Check RVAL ity 28 Days 0 Hours ity 28 Days 0 Hours Decision Values Value 1 # Value 2 #	CALIBRATION F 1 Unit 2	CALIBRA CALIBRA Po Po Po Po Po CALIBRA CALIBRA Po	Unit 3 Finance Finance Finance Finance Finance Finance Calibrator Na CYS CAL-1 CYS CAL-2 CYS CAL-3 CYS CAL-4 CYS CAL-4 CYS CAL-5 CYS CAL-6 CYS CAL-6 CYS CAL-6 CYS CAL-6 CYS CAL-6 CYS CAL-7 CYS CAL-8 CYS CAL-8 CYS CAL-8 CYS CAL-8 CYS CAL-1 CYS CAL-2 CYS CAL-3 CYS CAL-3	ENTRATION Par Upper AMR ame Conc	None ▼ ARAMETER: OD Range Low -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000 -2.0000	OD Range High 2.0000 2.0000 2.0000 2.0000 2.0000

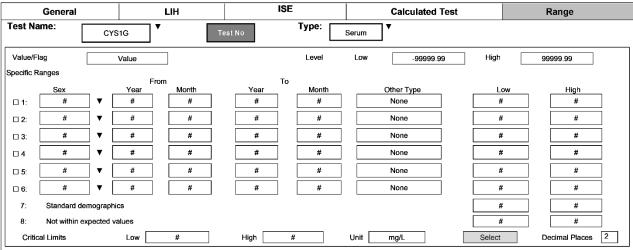
^{*} Lot specific, see analytical value sheet available on www.gentian.com
** Based on results from instrument AU400 (Beckman Coulter*)

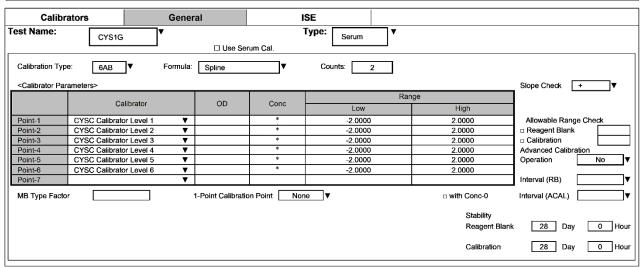


Cystatin C DxC 700 AU application settings

System Reagent: B08179 Reagent ID: 228







[#] User defined

^{*} Lot specific, see analytical value sheet available on $\underline{\text{www.gentian.com}}$

^{**} based on results from instrument AU400 (Beckman Coulter®)