

Cystatin C



Gentian Cystatin C Immunoassay on Beckman Coulter® AU Systems (AU5800, AU680, AU480, 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 <ul style="list-style-type: none">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.

To obtain the SDS (Safety Data Sheet), please contact Gentian at marketing@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.

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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 stable 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).

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]

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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].

Instrument	n	Range of samples [mg/L]	Term	Co-efficient	95% CI
Architect	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 m² 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].

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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.

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



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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 number of the Notified Body to CE mark.
- Added UKCA mark.
- Added chapter “Representatives”.
- Update on Establishment of the calibration curve and QC control sections.
- Included the Gentian REF number.
- Minor editorial changes and corrections throughout the document.

Date of issue

2023-03-01

For other languages visit:

www.gentian.com/products/ifu/cystatin-c/beckmancoulter

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

Parameters		Specific Test Parameters			
General	LIH	ISE	Calculated Test	Range	
Test Name: <input type="text" value="CysC"/>		Type: <input type="text" value="Serum"/>			
Value/Flag:	<input type="text" value="#"/>				
Level		Level	Low <input type="text" value="#"/>	High	<input type="text" value="#"/>
Specific Ranges:	From	To	Low	High	
<input type="checkbox"/> 1.	Sex <input type="text" value="#"/>	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>	Year <input type="text" value="#"/>	Month <input type="text" value="#"/>
<input type="checkbox"/> 2.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 3.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 4.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 5.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 6.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
<input type="checkbox"/> 7.	Standard demographics				
<input type="checkbox"/> 8.	Not within expected values				
Panic Value	Low <input type="text"/>	High <input type="text"/>	Unit	<input type="text" value="mg/L"/>	Decimal Places <input type="text" value="#"/>

Parameters		Calibration Parameters			
Calibrators	Calibration Specific	STAT Table Calibration			
General	ISE				
Test Name: <input type="text" value="CysC"/>		Type: <input type="text" value="Serum"/>		Cuvette: <input type="text"/>	
		<input type="checkbox"/> Use Serum Cal.			
Calibration Type: <input type="text" value="6AB"/>		Formula: <input type="text" value="Spline"/>		Counts: <input type="text" value="#"/>	
<Calibrator Parameters>					
Point 1:	Calibrator <input type="text" value="1"/>	OD <input type="text"/>	Conc <input type="text" value="*"/>	Factor Range	Slope Check <input type="text" value="+"/>
Point 2:	<input type="text" value="2"/>	<input type="text"/>	<input type="text" value="*"/>	Low	High
Point 3:	<input type="text" value="3"/>	<input type="text"/>	<input type="text" value="*"/>		
Point 4:	<input type="text" value="4"/>	<input type="text"/>	<input type="text" value="*"/>		
Point 5:	<input type="text" value="5"/>	<input type="text"/>	<input type="text" value="*"/>		
Point 6:	<input type="text" value="6"/>	<input type="text"/>	<input type="text" value="*"/>		
Point 7:	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Point 8:	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Point 9:	<input type="text"/>	<input type="text"/>	<input type="text"/>		
Point 10:	<input type="text"/>	<input type="text"/>	<input type="text"/>		
<Point Cal. For Master Curves>					
		No. of Correction Points	<input type="text"/>	Use Master Curve	<input type="text"/>
		OD Range		<input type="checkbox"/> Lot Calibration	
Point-1	Calibrator <input type="text"/>	OD <input type="text"/>	Conc <input type="text"/>	Low	High
Point-2	<input type="text"/>	<input type="text"/>	<input type="text"/>	Stability	
				Reagent Blank	<input type="text" value="28"/> Day <input type="text" value="0"/> Hour
				Calibration	<input type="text" value="28"/> Day <input type="text" value="0"/> Hour
MB Type Factor: <input type="text"/>		1-Point Calibration Point <input type="text"/>		<input type="checkbox"/> with Conc-0	

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

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

Cystatin C AU680 application settings

System Reagent: B08179 Reagent ID: 228

Parameters		Specific Test Parameters			
General	LIH	ISE	Calculated Test	Range	
Test Name: <input type="text" value="CysC"/> < > Type: <input type="text" value="Serum"/> Operation <input type="text" value="Yes"/>					
Sample Volume	<input type="text" value="2"/> μL	Dilution	<input type="text" value="0"/> μL	OD Limit	
Pre-Dilution Rate	<input type="text" value="1"/>			Min.OD	<input type="text"/>
Rgt. Volume	R1(R1-1) <input type="text" value="150"/> μL	Dilution	<input type="text" value="0"/> μL	Reagent OD Limit	
				First	Low <input type="text" value="-2.0"/> High <input type="text" value="2.0"/>
				Last	Low <input type="text"/> High <input type="text"/>
		R2(R2-1) <input type="text" value="30"/> μL	Dilution	<input type="text" value="10"/> μL	
Common Rgt. Type	<input type="text"/>	Name	<input type="text"/>	Dynamic Range Low	<input type="text" value="0.44"/> High <input type="text" value="7.30"/>
Wavelength	Pri <input type="text" value="540"/> nm	Sec.	<input type="text"/>	Correlation Factor A	<input type="text" value="1.00"/> B <input type="text" value="0.00"/>
Method	<input type="text" value="End Point"/>			Factor for Maker	A <input type="text"/> B <input type="text"/>
Reaction Slope	<input type="text" value="+"/> ∇			Onboard Stability Period	<input type="text" value="60**"/> Day <input type="text"/> Hour
Measuring Point1 First	<input type="text" value="13"/>	Last	<input type="text" value="27"/>	LIH Influence Check	<input type="text"/>
Measuring Point2 First	<input type="text"/>	Last	<input type="text"/>	Lipemia	<input type="text"/>
Linearity Limit	<input type="text"/>			Icterus	<input type="text"/>
Lag Time Check	<input type="text"/>			Hemolysis	<input type="text"/>

Parameters		Specific Test Parameters			
General	LIH	ISE	Calculated Test	Range	
Test Name: <input type="text" value="CysC"/> < > Type: <input type="text" value="Serum"/>					
Value/Flag:	<input type="text" value="#"/>	Low	<input type="text"/>	High	<input type="text"/>
Level					
Specific Ranges:	From	To			
<input type="checkbox"/> 1.	Sex <input type="text"/>	Year <input type="text"/>	Month <input type="text"/>	Year <input type="text"/>	Month <input type="text"/>
<input type="checkbox"/> 2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 5.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 6.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 7.	No demographics				<input type="text"/>
<input type="checkbox"/> 8.	Not within expected values				<input type="text"/>
Unit	<input type="text" value="mg/L"/>		Decimal Places	<input type="text" value="#"/>	

Parameters		Calibration Parameters			
Calibrators	Calibration Specific	STAT Table Calibration			
General	ISE				
Test Name: <input type="text" value="CysC"/> < > Type: <input type="text" value="Serum"/> <input type="checkbox"/> Use Serum Cal.					
Calibration Type: <input type="text" value="6AB"/> Formula: <input type="text" value="Spline"/> Counts: <input type="text" value="#"/>					
<Calibrator Parameters>					
Calibrator	OD	Conc	Low	High	Slope Check <input type="text" value="+"/>
Point 1:	<input type="text" value="1"/>	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>	Allowance Range Check <input type="checkbox"/> Reagent Blank <input type="text"/> <input type="checkbox"/> Calibration <input type="text"/>
Point 2:	<input type="text" value="2"/>	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>	
Point 3:	<input type="text" value="3"/>	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>	
Point 4:	<input type="text" value="4"/>	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>	
Point 5:	<input type="text" value="5"/>	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>	
Point 6:	<input type="text" value="6"/>	<input type="text" value="*"/>	<input type="text"/>	<input type="text"/>	
Point 7:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 8:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 9:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 10:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<Point Cal. For No. of Correction Points <input type="text"/> Use Master Curve <input type="checkbox"/> Lot Calibration <input type="checkbox"/>					
Master Curve>					
Calibrator	OD	Conc	Low	High	Stability
Point-1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Reagent Blank <input type="text" value="28"/> Day <input type="text"/>
Point-2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Calibration <input type="text" value="28"/> Day <input type="text"/>
MB Type Factor: <input type="text"/> 1-Point Calibration Point <input type="checkbox"/> with Conc-0 <input type="checkbox"/>					

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

Cystatin C AU480 application settings

System Reagent: B08179 Reagent ID: 228

Parameters		Specific Test Parameters			
General	LIH	ISE	Calculated Test	Range	
Test Name: <input type="text" value="CysC"/> < > Type: <input type="text" value="Serum"/> Operation <input type="text" value="Yes"/>					
Sample Volume	<input type="text" value="2"/> μL	Dilution	<input type="text" value="0"/> μL	OD Limit	
Pre-Dilution Rate	<input type="text" value="1"/>			Min.OD	<input type="text"/>
Rgt. Volume	R1(R1-1) <input type="text" value="150"/> μL	Dilution	<input type="text" value="0"/> μL	Reagent OD Limit	
				First	Low <input type="text" value="-2.0"/> High <input type="text" value="2.0"/>
				Last	Low <input type="text"/> High <input type="text"/>
		R2(R2-1) <input type="text" value="30"/> μL	Dilution	<input type="text" value="10"/> μL	
Common Rgt. Type	<input type="text"/>	Name	<input type="text"/>	Dynamic Range Low	<input type="text" value="0.43"/> High <input type="text" value="7.32"/>
Wavelength	Pri <input type="text" value="540"/> nm	Sec.	<input type="text"/>	Correlation Factor A	<input type="text" value="1.00"/> B <input type="text" value="0.00"/>
Method	<input type="text" value="End Point"/>			Factor for Maker	A <input type="text"/> B <input type="text"/>
Reaction Slope	<input type="text" value="+"/> ∇			Onboard Stability Period	<input type="text" value="60**"/> Day <input type="text"/> Hour
Measuring Point1 First	<input type="text" value="13"/>	Last	<input type="text" value="27"/>	LIH Influence Check	<input type="text"/>
Measuring Point2 First	<input type="text"/>	Last	<input type="text"/>	Lipemia	<input type="text"/>
Linearity Limit	<input type="text"/>			Icterus	<input type="text"/>
Lag Time Check	<input type="text"/>			Hemolysis	<input type="text"/>

Parameters		Specific Test Parameters			
General	LIH	ISE	Calculated Test	Range	
Test Name: <input type="text" value="CysC"/> < > Type: <input type="text" value="Serum"/>					
Value/Flag:	<input type="text" value="#"/>	Low	<input type="text"/>	High	<input type="text"/>
Level					
Specific Ranges:	From	To			Panic Value
					Low <input type="text"/> High <input type="text"/>
<input type="checkbox"/> 1.	Sex <input type="text"/>	Year <input type="text"/>	Month <input type="text"/>	Year <input type="text"/>	Month <input type="text"/>
<input type="checkbox"/> 2.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 3.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 4.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 5.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 6.	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="checkbox"/> 7.	No demographics				<input type="text"/>
<input type="checkbox"/> 8.	Not within expected values				<input type="text"/>
Unit	<input type="text" value="mg/L"/>		Decimal Places	<input type="text" value="#"/>	

Parameters		Calibration Parameters			
Calibrators	Calibration Specific	STAT Table Calibration			
General	ISE				
Test Name: <input type="text" value="CysC"/> < > Type: <input type="text" value="Serum"/> <input type="checkbox"/> Use Serum Cal.					
Calibration Type: <input type="text" value="6AB"/> Formula: <input type="text" value="Spline"/> Counts: <input type="text" value="#"/>					
<Calibrator Parameters>					
Calibrator	OD	Conc	Low	High	Slope Check <input type="text" value="+"/>
Point 1:	<input type="text" value="1"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Allowance Range Check <input type="checkbox"/> Reagent Blank <input type="text"/> <input type="checkbox"/> Calibration <input type="text"/>
Point 2:	<input type="text" value="2"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 3:	<input type="text" value="3"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 4:	<input type="text" value="4"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 5:	<input type="text" value="5"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 6:	<input type="text" value="6"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 7:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 8:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 9:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
Point 10:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
<Point Cal. For No. of Correction Points <input type="text"/> Use Master Curve <input type="checkbox"/> Lot Calibration <input type="checkbox"/>					
Master Curve>					
Calibrator	OD	Conc	Low	High	Stability
Point-1	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Reagent Blank <input type="text" value="28"/> Day <input type="text"/> Hour
Point-2	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	Calibration <input type="text" value="28"/> Day <input type="text"/> Hour
MB Type Factor: <input type="text"/> 1-Point Calibration Point <input type="checkbox"/> with Conc-0 <input type="checkbox"/>					

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

Cystatin C DxC 700 AU application settings

System Reagent: B08179 Reagent ID: 228

General	LIH	ISE	Calculated Test	Range
Test Name: <input type="text" value="CYS1G"/> <input type="button" value="Test No"/>				
Type: <input type="text" value="Serum"/> Operation: <input type="text" value="Yes"/>				
Sample Volume	<input type="text" value="2.0"/> μL	Dilution	<input type="text" value="0"/> μL	OD Limit
Pre-Dilution Rate	<input type="text" value="1"/>			Min. OD <input type="text"/> Max OD <input type="text"/>
Reagent Volume	R1 (R1-1) <input type="text" value="150"/> μL	Dilution	<input type="text" value="0"/> μL	Reagent OD Limit 1 st Low <input type="text" value="-2.0000"/> High <input type="text" value="2.0000"/>
	R1-2 <input type="text"/> μL	Dilution	<input type="text"/> μL	Last Low <input type="text" value="-2.0000"/> High <input type="text" value="2.0000"/>
	R2 (R2-1) <input type="text" value="30"/> μL	Dilution	<input type="text" value="10"/> μL	Analytical Measuring Range Low <input type="text" value="0.40"/> High <input type="text" value="8.07"/>
Common Reagent	Type <input type="text" value="None"/>	Name	<input type="text" value="None"/>	Correlation Factor A <input type="text" value="1"/> B <input type="text" value="0"/>
Wavelength	Pri <input type="text" value="540"/> nm	Sec	<input type="text" value="None"/> nm	Manufacturer Factor A <input type="text" value="1"/> B <input type="text" value="0"/>
Method	<input type="text" value="END"/>			Onboard Stability Period <input type="text" value="60"/> Day <input type="text" value="0"/> Hour
Reaction Slope	<input type="text" value="+"/> μL			LIH Influence Check <input type="text" value="No"/>
Measuring Point-1	1st <input type="text" value="13"/>	Last	<input type="text" value="27"/>	Lipemia <input type="text"/>
Measuring Point-2	1st <input type="text"/>	Last	<input type="text"/>	Icterus <input type="text"/>
Linearity Limit	<input type="text"/> %			Hemolysis <input type="text"/>
Lag Time Check	<input type="text"/>			

General	LIH	ISE	Calculated Test	Range
Test Name: <input type="text" value="CYS1G"/> <input type="button" value="Test No"/>				
Type: <input type="text" value="Serum"/>				
Value/Flag	<input type="text" value="Value"/>	Level	Low <input type="text" value="-99999.99"/> High <input type="text" value="99999.99"/>	
Specific Ranges				
	From	To	Other Type	Low High
<input type="checkbox"/> 1:	Sex <input type="text" value="#"/> Year <input type="text" value="#"/> Month <input type="text" value="#"/>	Year <input type="text" value="#"/> Month <input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/> <input type="text" value="#"/>
<input type="checkbox"/> 2:	<input type="text" value="#"/> <input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/> <input type="text" value="#"/>
<input type="checkbox"/> 3:	<input type="text" value="#"/> <input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/> <input type="text" value="#"/>
<input type="checkbox"/> 4:	<input type="text" value="#"/> <input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/> <input type="text" value="#"/>
<input type="checkbox"/> 5:	<input type="text" value="#"/> <input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/> <input type="text" value="#"/>
<input type="checkbox"/> 6:	<input type="text" value="#"/> <input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="#"/> <input type="text" value="#"/>	<input type="text" value="None"/>	<input type="text" value="#"/> <input type="text" value="#"/>
7:	Standard demographics			<input type="text" value="#"/> <input type="text" value="#"/>
8:	Not within expected values			<input type="text" value="#"/> <input type="text" value="#"/>
Critical Limits	Low <input type="text" value="#"/>	High <input type="text" value="#"/>	Unit <input type="text" value="mg/L"/>	<input type="button" value="Select"/> Decimal Places <input type="text" value="2"/>

Calibrators	General	ISE
Test Name: <input type="text" value="CYS1G"/>		
Type: <input type="text" value="Serum"/>		
<input type="checkbox"/> Use Serum Cal.		
Calibration Type:	<input type="text" value="6AB"/>	Formula: <input type="text" value="Spline"/> Counts: <input type="text" value="2"/>
<Calibrator Parameters>		
	Calibrator	OD Conc Range
		Low 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		
MB Type Factor	<input type="text"/>	1-Point Calibration Point <input type="text" value="None"/>
		<input type="checkbox"/> with Conc-0
		Slope Check <input type="text" value="+"/> Allowable Range Check
		<input type="checkbox"/> Reagent Blank <input type="text"/>
		<input type="checkbox"/> Calibration <input type="text"/>
		Advanced Calibration Operation <input type="text" value="No"/>
		Interval (RB) <input type="text"/>
		Interval (ACAL) <input type="text"/>
		Stability
		Reagent Blank <input type="text" value="28"/> Day <input type="text" value="0"/> Hour
		Calibration <input type="text" value="28"/> Day <input type="text" value="0"/> Hour

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