

Cystatin C

Package Insert for Cystatin C Immunoassay on Beckman Coulter® AU Systems (AU5800, AU680, AU480, AU2700, 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. 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, 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.

Reagents Provided in Reagent Kit

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.

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

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 NaN₃ 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.

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.no. Instrument set up, maintenance, operation and precautions must be handled in accordance with the Beckman Coulter® AU instrument manuals.

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.

Limitations

The materials should not be used past expiration date.

Measuring Range

The measuring range of cystatin C for the assay is 0.4 – 7.8 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 138 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.

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.

Hook Effect

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.

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

Using the Gentian Cystatin C assay on an AU 5800 instrument, a lower limit of quantification was measured as 0.23 mg/L.

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 Variation

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.

Hook Effect

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

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

Using the Gentian Cystatin C assay on an AU 680 instrument, a lower limit of quantification was measured as 0.28mg/L.

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 Variation

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.

Hook Effect

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.

Limit of Quantification

Using the Gentian Cystatin C assay on an AU 480 instrument, a lower limit of quantification was measured as 0.43mg/L.

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 Variation

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 AU 2700

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 5-day, multi calibration precision study designed in accordance with CLSI protocol EP5-A. 4 serum pools and 2 control levels were measured on the Beckman Coulter® AU 2700 system.

ID	Mean (mg/L)	Within run CV (%)	Between run CV (%)	Total CV (%)	n
P1	0.77	2.16	1.01	2.54	20
P2	5.94	0.67	1.08	1.45	20
P3	1.45	1.58	1.58	1.95	20
P4	2.72	1.22	0.25	1.37	20
P5	0.46	3.96	1.67	4.77	20
P6	3.82	1.81	2.00	3.05	20

Linearity

Using the Gentian Cystatin C Immunoassay, linearity was measured within acceptable limits in the range of 0.36 – 6.90 mg/L on the AU 2700 system.

Analytical Recovery

Using the Gentian Cystatin C Immunoassay on a Beckman Coulter® AU 2700 instrument, a recovery of 98-101% was observed.

Hook Effect

In a study using an AU 2700 instrument, the security zone for antigen excess extended past the highest calibrator value and up to 80 mg/L using one lot of Gentian cystatin C reagents.

Limit of Quantification

Using the Gentian Cystatin C assay on an AU 2700 instrument, a lower limit of quantification was measured as 0.15 mg/L.

Interference

In a study, no significant interference was detected with Hemoglobin (8 g/L), Intralipid (16 g/L) or Bilirubin (800 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 Variation

Instrument variation between Gentian Cystatin C on AU 2700 and Architect c18200 instruments was measured and the results analyzed using Passing-Bablok regression analysis:

Passing Bablok regression	N	Range of samples (mg/L)	Term	Coefficient
AU 2700 Vs. Architect	48	0.60 – 7.98	Intercept	0.04
			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.

Hook Effect

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.

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

Using the Gentian Cystatin C assay 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-A2.

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 Variation

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.










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:

<http://gentian.no/products/beckman-coulter-customers/>

Symbols Key

	Lot number
	Temperature limit
	Use by date
	Consult instructions for use
	Manufacturer
	Catalogue number
	In vitro diagnostic medical device
	Caution
	Biological risks



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Bibliography

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Instrument Settings for Cystatin C Immunoassay

Cystatin C AU2700/AU5400 Serum and Plasma Application

System Reagent: B08179 Reagent ID: 228

Specific Test Parameters											
General		LIH	ISE	Range							
Test Name:		CysC	<	>	Type:	Serum	Operation:	Yes			
Sample:	Volume	2	μL	Dilution	0	μL	Pre-Dilution Rate:	1			
Reagents:	R1 Volume	150	μL	Dilution	0	μL	Min OD		Max OD		
	R2 Volume	30	μL	Dilution	10	μL	L		H		
Wavelength:	Pri.	540	∇	Sec.		∇	Reagent OD limit:				
Method:	End Point		∇				First L	-2.0	First H	2.0	
Reaction slope:		+	∇				Last L		Last H		
Measuring Point 1:	First	13		Last	27		Dynamic Range:	L	0.4	H	7.8
Measuring Point 2:	First			Last			Correlation Factor:				
Linearity:			%				A	1.00	B	0.00	
No Lag Time:			∇				On-board stability period:	60			

Specific Test Parameters										
General		LIH	ISE	Range						
Test Name:		CysC	<	>	Type:	Serum				
Value/Flag:	#	∇	Level L:	#	Level H:	#				
Normal Ranges:	Sex	Age L	Year	Month	Age H	Year	Month	L	H	
o 1.	#	∇	#	#	#	#	#	#	#	
o 2.	#	∇	#	#	#	#	#	#	#	
o 3.	#	∇	#	#	#	#	#	#	#	
o 4.	#	∇	#	#	#	#	#	#	#	
o 5.	#	∇	#	#	#	#	#	#	#	
o 6.	#	∇	#	#	#	#	#	#	#	
7.	None Selected									
8.	Out of Range									
Panic Value:			L		H		Unit:	mg/L	Decimal places:	#

Calibration Specific											
General		ISE									
Test Name:		CysC	<	>			Type	Serum	∇		
Calibration Type:		6AB	∇	Formula:	Spline	∇	Counts:	#	Process:	CONC	∇
Point 1:	Cal. No.	1	OD	CONC	Factor/OD-L	Factor/OD-H					
Point 2:	2			**							
Point 3:	3			**							
Point 4:	4			**							
Point 5:	5			**							
Point 6:	6			**							
Point 7:				**							
1-Point Cal. Point:		o	with CONC-0	Slope Check:	+	∇	Advanced Calibration:	#	∇		
MB Type Factor:			Calibration Stability Period:	28							

User defined

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

Cystatin C AU680/AU480 Serum and Plasma Application

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"/> μ L	Dilution	<input type="text" value="0"/> μ L	OD Limit	
Pre-Dilution Rate	<input type="text" value="1"/>			Min.OD	<input type="text" value=""/>
Rgt. Volume	R1(R1-1) <input type="text" value="150"/> μ L	Dilution	<input type="text" value="0"/> μ L	Reagent OD Limit	
				First	Low <input type="text" value="-2.0"/> High <input type="text" value="2.0"/>
				Last	Low <input type="text" value=""/> High <input type="text" value=""/>
R2(R2-1)	<input type="text" value="30"/> μ L	Dilution	<input type="text" value="10"/> μ L	Dynamic Range Low	<input type="text" value="0.4"/> High <input type="text" value="7.8"/>
Common Rgt. Type	<input type="text" value=""/>	Name	<input type="text" value=""/>	Correlation Factor A	<input type="text" value="1.00"/> B <input type="text" value="0.00"/>
Wavelength	Pri <input type="text" value="540"/> ν nm	Sec.	<input type="text" value=""/>	Factor for Maker A	<input type="text" value=""/>
Method	<input type="text" value="End Point"/>				
Reaction Slope	<input type="text" value="+"/> ν			Onboard Stability Period	<input type="text" value="60"/> Day <input type="text" value=""/> Hour
Measuring Point1 First	<input type="text" value="13"/>	Last	<input type="text" value="27"/>	LIH Influence Check	<input type="text" value=""/>
Measuring Point2 First	<input type="text" value=""/>	Last	<input type="text" value=""/>	Lipemia	<input type="text" value=""/>
Linearity Limit	<input type="text" value=""/>			Icterus	<input type="text" value=""/>
Lag Time Check	<input type="text" value=""/>			Hemolysis	<input type="text" value=""/>

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" value=""/>	High	<input type="text" value=""/>
Level					
Specific Ranges:	From	To			Panic Value
					Low <input type="text" value=""/> High <input type="text" value=""/>
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="#"/>
2.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
3.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
4.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
5.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
6.	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>	<input type="text" value="#"/>
7.	No demographics				<input type="text" value="#"/>
8.	Not within expected values				<input type="text" value="#"/>
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="+"/> ν
Point 1:	<input type="text" value="1"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	
Point 2:	<input type="text" value="2"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Allowance Range Check
Point 3:	<input type="text" value="3"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	
Point 4:	<input type="text" value="4"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Reagent Blank <input type="text" value=""/>
Point 5:	<input type="text" value="5"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="checkbox"/> Calibration <input type="text" value=""/>
Point 6:	<input type="text" value="6"/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Advanced Calibration
Point 7:	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Operation <input type="text" value=""/> ν
Point 8:	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	
Point 9:	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Interval (RB/ACAL) <input type="text" value=""/> ν
Point 10:	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	
<Point Cal. For Master Curve>	No. of Correction Points <input type="text" value=""/>	Use Master Curve <input type="checkbox"/>	Use Lot Calibration <input type="checkbox"/>		
Calibrator	OD	Conc	Low	High	Stability
Point-1	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Reagent Blank <input type="text" value="28"/> Day <input type="text" value=""/> Hour
Point-2	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	Calibration <input type="text" value="28"/> Day <input type="text" value=""/> Hour
MB Type Factor:	<input type="text" value=""/>	1-Point Calibration Point <input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/> with Conc-0	

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 μ L	Dilution	0 μ L	OD Limit	
Pre-Dilution Rate	1	Diluent Bottle	Outside	Min.OD	Max.OD
Rgt. Volume R1(R1-1)	150 μ L	Dilution	0 μ L	Reagent OD Limit	
R1-2		Dilution		First Low	-2.0 High 2.0
R2(R2-1)	30 μ L	Dilution	10 μ L	Last Low	
Common Rgt. Type		Name		Dynamic Range Low	0.4 High 7.8
Wavelength Pri	540 nm	Sec.		Correlation Factor A	1.00 B 0.00
Method	End Point			Factor for Maker A	
Reaction Slope	+			Onboard Stability Period	60 Day
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 Low # High #			
Specific Ranges:	From	To	Low	High	
1. Sex	#	#	#	#	#
2. Year	#	#	#	#	#
3. Month	#	#	#	#	#
4. Year	#	#	#	#	#
5. Month	#	#	#	#	#
6. Year	#	#	#	#	#
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: #
		<input type="checkbox"/> Use Serum Cal.			
Calibration Type: 6AB		Formula: Spline		Counts: #	
<Calibrator Parameters>		Factor Range		Slope Check +	
Calibrator	OD	Conc	Low	High	Allowance Range Check
Point 1:	1	**			<input type="checkbox"/> Reagent Blank
Point 2:	2	**			<input type="checkbox"/> Calibration
Point 3:	3	**			Advanced Calibration
Point 4:	4	**			Operation #
Point 5:	5	**			Interval (RB/ACAL) #
Point 6:	6	**			
Point 7:					
Point 8:					
Point 9:					
Point 10:					
<Point Cal. For	No. of Correction Points		Use Master Curve		<input type="checkbox"/> Lot Calibration
Master Curve>		OD Range		Stability	
Calibrator	OD	Conc	Low	High	Reagent Blank 28 Day 0 Hour
Point-1					Calibration 28 Day 0 Hour
Point-2					
MB Type Factor:		1-Point Calibration Point			<input type="checkbox"/> with Conc-0

User defined

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

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	<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="0.4"/> High <input type="text" value="7.8"/>
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"/>			
Reaction Slope	<input type="text" value="+"/> ▼			Onboard Stability Period <input type="text" value="60"/> Day <input type="text" value="0"/> Hour
Measuring Point-1	1st <input type="text" value="13"/>	Last	<input type="text" value="27"/>	LIH Influence Check <input type="text" value="No"/> ▼
Measuring Point-2	1st <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"/> ▼

General	LIH	ISE	Calculated Test	Range
Test Name: CYS1G Test No Type: 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				
	Sex	Year	Month	Year
	From	To		Other Type
<input type="checkbox"/> 1:	<input type="text" value="#"/>	<input type="text" value="#"/>	<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="checkbox"/> 3:	<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="checkbox"/> 5:	<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="#"/>
7:	Standard demographics			<input type="text" value="#"/>
8:	Not within expected values			<input type="text" value="#"/>
Critical Limits	Low <input type="text" value="#"/>	High <input type="text" value="#"/>	Unit <input type="text" value="mg/L"/>	Select <input type="text"/> Decimal Places <input type="text" value="2"/>

Calibrators	General	ISE	
Test Name: CYS1G Type: 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>			Slope Check <input type="text" value="+"/> ▼
	Calibrator	OD	Conc
			Range
			Low High
Point-1	CYSC Calibrator Level 1	▼	†
Point-2	CYSC Calibrator Level 2	▼	†
Point-3	CYSC Calibrator Level 3	▼	†
Point-4	CYSC Calibrator Level 4	▼	†
Point-5	CYSC Calibrator Level 5	▼	†
Point-6	CYSC Calibrator Level 6	▼	†
Point-7		▼	
MB Type Factor	<input type="text"/>	1-Point Calibration Point	<input type="text" value="None"/>
			<input type="checkbox"/> with Conc=0
			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
			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"/> ▼

User Defined
 † Lot specific, see analytical value sheet included with calibrator kit.