

Cystatin C



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

For additional safety information, please refer to the SDS (Safety Data Sheet) available on www.gentian.com.

Additional handling instructions

1. This test is for *in vitro* use only and must be handled by laboratory professionals.
2. Use only validated and approved instrument applications.
3. Do not use products after the expiration date has passed.
4. Do not mix reagents of different lots or interchange caps of reagents, controls, calibrators, and lots.
5. Tighten caps carefully back on after use of reagents, calibrators, and controls to avoid evaporation.

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).

Cystatin C



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 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.

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 0.32 mg/L.

Linearity

The linearity range of the Gentian Cystatin C Immunoassay was found to be 0.38–7.84 mg/L in a linearity study based on the CLSI guideline EP06 [8].

Security zone

No antigen excess effect in samples below 25.7 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 25.7 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 20-day precision study based on the CLSI guideline EP05 [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	0.87	0.56	1.46	2.41
P2	1.60	0.80	1.63	2.43
P3	6.37	0.73	1.63	3.66
CL	1.00	0.68	0.61	2.00
CH	3.48	0.46	0.55	1.57

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 102–109 %.

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 g/L
Intralipid	10 g/L
Bilirubin	0.2 g/L

Instrument variation

Results obtained with the Gentian Cystatin C Immunoassay on the DxC 500 AU instrument were compared using Passing-Bablok regression with results from the AU5800 instrument in a study based on the CLSI guideline EP09 [15].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
42	0.57–5.72	Intercept	-0.01	[-0.05, 0.03]
		Slope	1.00	[0.97, 1.04]

Performance characteristics DxC 700 AU

All results refer to validation of the Gentian Cystatin C Immunoassay on a DxC 700 AU instrument at one site with one lot of reagents, unless otherwise stated.

Measuring range

The measuring range of the Gentian Cystatin C Immunoassay was found to be 0.40–8.07 mg/L. The exact measuring range is specific to the calibrator, please refer to the analytical value sheet for the lot specific calibrator values available on www.gentian.com.

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

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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].

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

Cystatin C



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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

- Included Dx C 500i.

Date of issue

2025-04-03

For other languages visit:

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

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Instrument settings for the Gentian Cystatin C Immunoassay

Cystatin C AU5800 application settings

System Reagent: B08179 Reagent ID: 228

Parameters		Specific Test Parameters																																																																																							
General	LIH	ISE	Calculated Test		Range																																																																																				
Test Name: CysC < > Type: Serum Operation Yes																																																																																									
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User defined

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

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

Cystatin C



Cystatin C AU680 application settings

System Reagent: B08179

Reagent ID: 228

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

Parameters		Specific Test Parameters			
General	LIH	ISE	Calculated Test	Range	
Test Name: CysC < > Type: Serum					
Value/Flag: # Low High Level Specific Ranges: From To Sex Year Month Year Month Low High 1. # 2. # 3. # 4. # 5. # 6. # 7. No demographics 8. Not within expected values Unit mg/L Decimal Places					
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** Based on results from instrument AU400 (Beckman Coulter®)

Cystatin C



Cystatin C AU480 application settings

System Reagent: B08179

Reagent ID: 228

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User defined

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

Cystatin C



Cystatin C DxC 500 AU/DxC 500i application settings

System Reagent: B08179

Reagent ID: 228

TEST CONFIGURATION & CHEMISTRY DETAILS									
Assay Name	Test	Rev	Discipline		Chemistry				
Test ID	CYS		Calculated Result		☐				
LIS Code	CYS								
UNITS AND RANGE SETTINGS									
Use Settings from	Serum	Units	mg/L	Decimal Places	X.XX	Plasma			
Test Kind	General	Revision	01	☒ Multi Reagent Switch					
Reagent Name	CYS	Reagent ID	228	☐ FSE Test					
ABB Name	CYS1G	Parameter Long Name	Cystatin C B08179 CYS1G CYSC Serum						
Region	☒ US	☒ OUS	☒ AP	☐ JP	☒ EU	☐ Other			
GENERAL PARAMETERS									
SAMPLE VOLUME		Sample Volume	2.0	µL	Dilution	0	µL	REACTION OD LIMIT	
		Predilution Rate	1					Low	High
REAGENT VOLUME		R1-1	150	µL	Dilution	0	µL	REACTION BLANK OD LIMIT	
		R2-1	30	µL	Dilution	10	µL	First: Low	High
								Last: Low	High
WAVELENGTH		Primary	540	nm	Secondary	None	nm	ANALYTICAL MEASURING RANGE	
								Low	High
METHOD		END		MANUFACTURER FACTOR					
				A		1	B		
REACTION SLOPE		+		REAGENT ONBOARD STABILITY					
				60**		Days	0**		
MEASURING POINT		Point 1: First	13	Last	27	LIH INFLUENCE CHECK			
		Point 2: First		Last		☐ Perform LIH check			
Linearity Limit						Lipemia			
						Icterus			
						Hemolysis			
Lag Time Check		☐ Perform Lag Time Check							
CALIBRATION PARAMETERS									
Base Unit	Decimal Place	Unit 1	Factor 1	Unit 2	Factor 2	Unit 3	Factor 3	Unit 4	Factor 4
mg/L	2	None	0	None	0	None	0	None	0
CALIBRATOR SPECIFIC									
Calibration Type		6AB		Counts	2	☐ Use highest calibrator for Upper AMR			
Formula		Spline		MB Factor					
Calibrator Name		Add CYS		Positive Cutoff					
☒ SLOPE CHECK		Slope Check		Number of Levels	6				
STABILITY AND INTERVAL		Reagent Blank Stability		28	Days	0	Hours	Interval	Lot
		Calibration Stability		28	Days	0	Hours	Interval	Lot
CALIBRATION OD AND CONCENTRATION PARAMETERS									
	Calibrator Name	Conc	OD Range Low	OD Range High					
Point 1	CYS CAL-1	*	-2.0000	2.0000					
Point 2	CYS CAL-2	*	-2.0000	2.0000					
Point 3	CYS CAL-3	*	-2.0000	2.0000					
Point 4	CYS CAL-4	*	-2.0000	2.0000					
Point 5	CYS CAL-5	*	-2.0000	2.0000					
Point 6	CYS CAL-6	*	-2.0000	2.0000					
Point 7									
OD DELTA CHECK									
☐ Reagent Blank		0.0000							
☐ Calibration		0.0000							
PROZONE CHECK PARAMETERS									
☐ Logic Check 1		Check Points		Decision Values		☐ Logic Check 2		Check Points	
Point 1		#		Value 1		Point 1		#	
Point 2		#		Value 2		Interval		#	
Point 3		#		Value 3					
Limit Points		Limit 1		#		Limit Points		Limit 1	
		Limit 2		#				Limit 2	
Check Pattern		Pattern		#					

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

Cystatin C



Cystatin C DxC 700 AU application settings

System Reagent: B08179

Reagent ID: 228

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

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

Calibrators	General	ISE																																																		
Test Name: CYS1G Type: Serum																																																				
☐ Use Serum Cal.																																																				
Calibration Type: 6AB Formula: Spline Counts: 2																																																				
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