GCAL®

Application Note for the Gentian Calprotectin Immunoassay on the DxC 500 AU[1]

For *in vitro* diagnostic use by laboratory professionals.

This document describes the instrument specific settings and performance of the product on the instrument above. For assay information, please refer to the IFU available on www.gentian.com.

Assay kit components

Products available	
Gentian GCAL® Calprotectin Reagent Kit • R1 Assay Buffer (54 mL) • R2 Immunoparticles (9 mL)	REF 1201
Gentian GCAL® Calprotectin Reagent Kit S • R1 Assay Buffer (30 mL) • R2 Immunoparticles (5 mL)	REF 1202
Gentian GCAL® Calprotectin Calibrator Kit (6 levels x 1 mL)	REF 1251
Gentian GCAL® Calprotectin Control Kit (2 levels x 1 mL)	REF 1219

All products are ready for use.

Reagent stability

The in-use stability of the Gentian GCAL® Calprotectin Reagent Kit was found to be at least 4 weeks in an on board study based on the CLSI guideline EP25 [1]. If the instrument remains unused for more than a week, please ensure the reagents are gently inverted every 7 days.

Calibration stability

The calibration curve stability of the Gentian GCAL® Calprotectin Calibrator Kit was found to be at least 1 week in a study based on the CLSI guideline EP25 [1].

Performance characteristics

All results refer to validation of the Gentian GCAL® Calprotectin Immunoassay on one instrument site with one lot of reagents, unless otherwise stated.

Measuring range

The measuring range of the Gentian GCAL® Calprotectin Immunoassay was found to be 0.48-19.16 mg/L. The exact measuring range is specific to the calibrator lot, please refer to the analytical value sheet available on www.gentian.com.

Analytical sensitivity

The analytical sensitivity of the Gentian GCAL® Calprotectin Immunoassay was tested in a study based on the CLSI guideline EP17 [2]. 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 GCAL® Calprotectin Immunoassay was found to be 0.45 mg/L for lithium heparin plasma and 0.43 mg/L for serum.

Linearity

The linearity range of the Gentian GCAL® Calprotectin Immunoassay was found to be 0.41-21.39 mg/L in lithium heparin plasma and 0.38-20.25 mg/L in serum in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 88 mg/L was observed for the Gentian GCAL® Calprotectin Immunoassay in a study based on the CLSI guideline EP34 [4]. Samples with a calprotectin concentration above the highest calibrator and up to 88 mg/L return a value above the highest calibrator and are flagged for rerun with automatic dilution.

Precision

Precision of the Gentian GCAL® Calprotectin Immunoassay was tested in a 3-day precision study based on the CLSI guideline EP05 [5]. 2 lithium heparin plasma (P1 and P1) and 2 serum (S1 and S2) pools and 2 controls (CL, CH) were measured 5 times with 5 replicates (n=25).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
PR-S1	0.90	4.74	1.10	4.86
PR-S2	8.21	0.82	1.00	1.29
PR-P1	5.18	1.15	0.98	1.51
PR-P2	13.62	1.23	0.54	1.35
CL	0.99	3.21	0.00	3.21
CH	9.98	0.74	0.22	0.77

Recovery

Recovery was analysed by spiking a low analyte sample with a high analyte sample according to Westgard [6]. The Gentian GCAL® Calprotectin Immunoassay had a recovery of 101-114 %.

Analytical specificity and limitations

Interference was tested in a study based on the CLSI guideline EP07 [7]. As the antibodies in the Gentian GCAL® Calprotectin Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [8]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	2.5 g/L
Intralipid	10 g/L
Bilirubin	0.6 g/L

Instrument variation

Results obtained with the Gentian GCAL® Calprotectin Immunoassay were compared using Passing-Bablok regression with results from the Cobas c501 instrument (Roche) in a study based on the CLSI guideline EP09 [9].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
50	0.42-20.07	Intercept	0.01	[-0.08, 0.07]
		Slope	1.10	[1.09, 1.13]
		R^2	1.00	

[1]Registered trademark of Beckman Coulter

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References

1. CLSI. Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline. CLSI document EP25-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.
2. CLSI. Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition. CLSI document EP17-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2012
3. CLSI. Evaluation of Linearity of Quantitative Measurement Procedures. 2nd ed. CLSI guideline EP06. Clinical and Laboratory Standards Institute; 2020
4. CLSI. Establishing and verifying an extended measuring interval through specimen dilution and spiking. 1st ed. CLSI guideline EP34. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.
5. CLSI. Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition. CLSI document EP05-A3. Wayne, PA: Clinical Laboratory Standards Institute; 2014
6. Westgard JO. Basic Method Validation, 3rd Edition. 2008; ISBN13: 9781886958258
7. CLSI. Interference Testing in Clinical Chemistry. 3rd ed. CLSI guideline EP07. Wayne, PA: Clinical Laboratory Standards Institute; 2018.
8. Larsson A, et al. Poultry Science 1993;72:1807-12
9. CLSI. Measurement Procedure Comparison and Bias Estimation Using Patient Samples. 3rd ed. CLSI guideline EP09c. Wayne, PA: Clinical and Laboratory Standards Institute; 2018.

Modification from the previous version

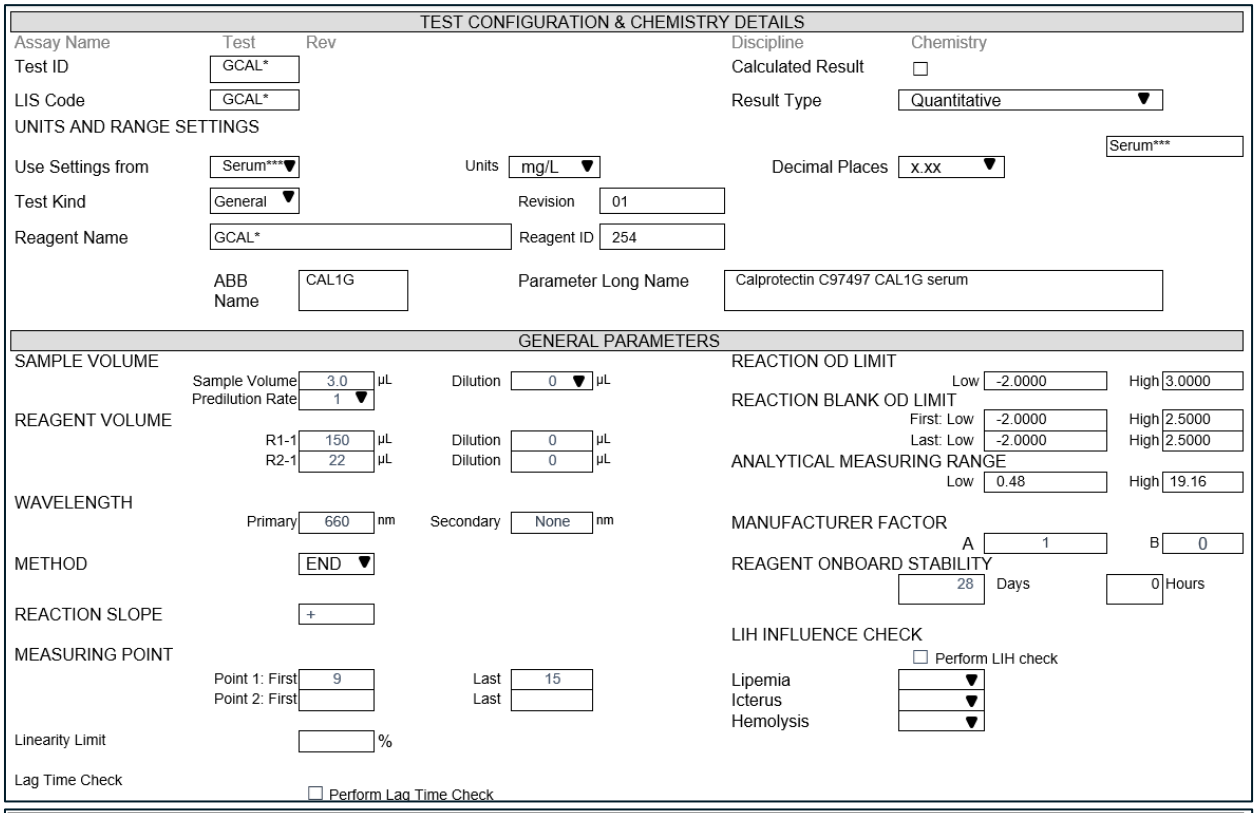
- Harmonised analytical measuring range across Beckman Coulter instruments

Date of issue

2024-11-26

Instrument Settings for the Gentian GCAL® Calprotectin Immunoassay on the DxC 500 AU[1] (serum/plasma)

Reagent ID: 254



TEST CONFIGURATION & CHEMISTRY DETAILS

Assay Name	Test	Rev	Discipline	Chemistry	
Test ID	GCAL*		Calculated Result	☐	
LIS Code	GCAL*		Result Type	Quantitative	
UNITS AND RANGE SETTINGS					Serum***
Use Settings from	Serum***	Units mg/L	Decimal Places	x.xx	
Test Kind	General	Revision 01			
Reagent Name	GCAL*	Reagent ID 254			
ABB Name	CAL1G	Parameter Long Name	Calprotectin C97497 CAL1G serum		

GENERAL PARAMETERS

SAMPLE VOLUME				REACTION OD LIMIT	
Sample Volume	3.0 µL	Dilution 0 µL		Low -2.0000	High 3.0000
Predilution Rate	1			REACTION BLANK OD LIMIT	
REAGENT VOLUME				First: Low -2.0000	High 2.5000
R1-1	150 µL	Dilution 0 µL		Last: Low -2.0000	High 2.5000
R2-1	22 µL	Dilution 0 µL		ANALYTICAL MEASURING RANGE	
				Low 0.48	High 19.16
WAVELENGTH					
Primary	660 nm	Secondary None nm		MANUFACTURER FACTOR	
				A 1	B 0
METHOD	END			REAGENT ONBOARD STABILITY	
				28 Days	0 Hours
REACTION SLOPE	+				
				LIH INFLUENCE CHECK	
MEASURING POINT				☐ Perform LIH check	
Point 1: First	9	Last 15		Lipemia	
Point 2: First		Last		Icterus	
				Hemolysis	
Linearity Limit	%				
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 OD AND CONCENTRATION PARAMETERS	
Calibration Type	6AB	Counts 2		☐ Use highest calibrator for Upper AMR	
Formula	Spline	MB Factor			
Calibrator Name		Positive Cutoff			
Add	*				
☐ SLOPE CHECK		Number of Levels 6			
Slope Check	None				
STABILITY AND INTERVAL					
Reagent Blank Stability	7 Days	0 Hours	Interval *		
Calibration Stability	7 Days	0 Hours	Interval *		

	Calibrator Name	Conc	OD Range Low	OD Range High
Point 1	*	**	-2.0000	2.5000
Point 2	*	**	-2.0000	2.5000
Point 3	*	**	-2.0000	2.5000
Point 4	*	**	-2.0000	2.5000
Point 5	*	**	-2.0000	2.5000
Point 6	*	**	-2.0000	2.5000
Point 7				

OD DELTA CHECK

☐ Reagent Blank

☐ Calibration

PROZONE CHECK PARAMETERS

☐ Logic Check 1			☐ Logic Check 2			☐ Logic Check 3		
Check Points		Decision Values	Check Points		Decision Values	Check Points		Decision Values
Point 1	*	Value 1 *	Point 1	*	Value 1 *	Point 1	*	Value 1 *
Point 2	*	Value 2 *	Interval	*	Value 2 *	Interval	*	Value 2 *
Point 3	*	Value 3 *						
Limit Points			Limit Points			Limit Points		
Limit 1	*		Limit 1	*		Limit 1	*	
Limit 2	*		Limit 2	*		Limit 2	*	
Check Pattern								
Pattern	*							

Disclaimer: The specific settings shown below is what used to validate the application on the specific instrument. For any instrument specific settings, please refer to the instrument manual. Please be aware that illustrations or settings might be affected in case of an instrument software update.

* User defined

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

***Valid for both serum and lithium heparin plasma

[1]Registered trademark of Beckman Coulter