GCAL®

Application Note for the Gentian Calprotectin Immunoassay on the Cobas Pure c303[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
Additional material required but not provided	
Instrument-specific bottles	

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 5 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 5 weeks 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 0.43-21.76 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 0.43 mg/L.

Linearity

The linearity range of the Gentian GCAL® Calprotectin Immunoassay was found to be 0.35-22.85 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 89 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 89 mg/L return a value above the highest calibrator and are flagged for rerun.

Precision

Precision of the Gentian GCAL® Calprotectin Immunoassay was tested in a 3-day precision study based on the CLSI guideline EP05 [5]. 1 serum pool (PR-1), 2 lithium heparin plasma pools (PR-2, PR-3) and 2 controls (PR-CL, PR-CH) were measured 6 times with 5 replicates (n=30).

Sample ID	Mean [mg/L]	Repeatability [%]	Between run CV [%]	Between day CV [%]	Within day CV [%]	Within -lab CV [%]
PR-1	0.95	4.33	1.43	4.62	4.56	6.49
PR-2	6.41	0.66	4.57	1.40	4.62	4.83
PR-3	13.10	0.42	1.08	0.85	1.15	1.43
PR-CL	0.89	7.10	14.97	10.63	16.56	19.68
PR-CH	9.97	0.54	4.07	0.00	4.10	4.10

Analytical specificity and limitations

Interference was tested in a study based on the CLSI guideline EP07 [6]. As the antibodies in the Gentian GCAL® Calprotectin Immunoassay are of avian origin, there is no interference due to Rheumatoid Factor in the samples [7]. No clinically relevant difference was detected at the tested interferent concentrations.

Potential interferents	Concentration with no interference
Haemoglobin	2.5 g/L
Intralipid	5 g/L
Bilirubin	0.2 mg/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 [8].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
40	0.51 – 20.65	Intercept	0.04	[0.02, 0.06]
		Slope	0.96	[0.95, 0.96]
		R^2	1.00	

[1] Registered trademark of Roche

Gentian AS CE 0123
Bjornasveien 5
N-1596 Moss
Norway
TEL: +47 99 33 99 05
www.gentian.com

References

1. CLSI. Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline. CLSI document EP25-Ed2. 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. 4th ed. CLSI guideline EP05. Clinical and Laboratory Standards Institute; 2025
6. CLSI. Interference Testing in Clinical Chemistry. 3rd ed. CLSI guideline EP07. Wayne, PA: Clinical Laboratory Standards Institute; 2018.
7. Larsson A, et al. Poultry Science 1993;72:1807-12
8. 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

First version.

Date of issue

2026-06-04

Instrument Settings for the Gentian GCAL® Calprotectin Immunoassay on the Cobas Pure c303[1]

CDC File Creator

Application Name	GCAL

Version of the CDC File Creator	**
Workplace version	**
Data Concept	1.00

System of analysis	Cobas pure, cobas c303
Code	**
Version	**
Laboratory name	*

Analysis parameters

Long Name	Gentian serum/plasma calprotectin
Unit 1	mg/L
Unit 2	None
Conversion factor	1
Sample type	Serum/Plasma

Rerun settings

Result outside the technical limit → Lower limit	0.43	
Result outside the technical limit → Upper limit	21.76	
Technical limits	0.43	21.76

Test

Test	2-Point-End			
Time	10			
Primary wavelength (nm)	660			
Secondary wavelength (nm)	None			
Measuring points	**1**	**2**	**3**	**4**
	20	36	0	0

Reagent volume

Reagent type	Reagent volume	Dilution volume	Mode	Stirring
R1	135	0	Without	8
R2	0	0	Water pressure	1
R3	25	0	Without	8

[1] Registered trademark of Roche

Sample volume

Sample type	Sample volume	Dilution	Diluent	Stirring
Normal	2	0	0	8
Reduced	15	3	135	8
Increased	10	0	0	8

Diluent → Type	Diluent
Diluent → ACN	29060
Diluent → Dilution	10

Cuvette washing

Cuvette wash with	Acid and Base
Higher uncertainty	0

QC Interval

QC interval Timeout	*
QC interval Timeout → Hours	*

Calibration
Change settings

Batch change	*
Automatic masking if calibration failed	*
Reagent pack change	*

Calibration trigger

QC violation → Method	*
Timeout → Method	*
Timeout → Stability	35 days

Limit values

SD limit	0	
Deviation limit	99 %	0.005 Abs
Start sensitivity	1	
End sensitivity	6	
Sensitivity limits	-9.9	9.9
S1 Ext. limit	-3.3	3.3

Calibration type

Type of Curve	Spline
Points	6
Weighting	0
Calibration factor	0

RCM weighting

1	0
2	0
3	0
4	0
5	0
6	0

Calibrators
Standards

Standard ID	Calibrator code	Calibrator volume (µL)	Diluted calibrator volume (µL)	Dilution volume (µL)
S1	**	2	0	0
S2	**	2	0	0
S3	**	2	0	0
S4	**	2	0	0
S5	**	2	0	0
S6	**	2	0	0

Calibrator diluent → type	Water
Calibrator diluent → code	None
Calibrator diluent → dilution factor	0

Reviews
Instability kinetics testing

Module 1

Activated	False
Type	Input module
Lower limit	-99999.99
Upper limit	99999.99
Review type	Outside
MP1	1
MP2	1
Inactive below	0
Priority	10
Action	Only flag
Calculation formula	-

Areas
Linearity limits

4 – 8 point	0%
9 point	0%
Min. total kinetics	0
Min. differential kinetics	0

Reaction limits

Check	Out
Ext. limit	0
Method	Reduce

Application corrector factor	**A**		**B**	
	1		0	
Sample Index Limit	**L**	**H**		**I**
	*	*		*

Reagent pack settings
c packs

c pack	**

Gentian GCAL® Calprotectin Reagent Kit, REF: 1201

Position	**Reagent type**	**Pipetted volume**	**Number of tests**	**Fill volume**	**Max. Volume**
B	R1	135	225***	36.9	95.0
C	R3	25	225***	9.0	30.0

Gentian GCAL® Calprotectin Reagent Kit S, REF: 1202

Position	**Reagent type**	**Pipetted volume**	**Number of tests**	**Fill volume**	**Max. Volume**
B	R1	135	87***	16.7	95.0
C	R3	25	87***	5.0	30.0

c pack	None
No. Tests	-

Position	**Reagent type**	**Pipetted volume (µL)**	**Filling volume (mL)**	**Max. Volume (mL)**
B	-	-	-	95.0
C	-	-	-	30.0

* User defined
** Instrument related
*** Calculated by the software

The specific settings above were 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.

[1] Registered trademark of Roche