Canine CRP

Application Note for the Gentian Canine CRP Immunoassay on the Roche 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 Canine CRP Reagent Kit • R1 Assay Buffer (45 mL) • R2 Immunoparticles (10.5 mL)	REF 1501
Gentian Canine CRP Calibrator Kit (6 levels x 0.5 mL)	REF 1551
Gentian Canine CRP Control Kit (2 levels x 0.5 mL)	REF 1519
Additional material required but not provided	
Instrument-specific bottles	

All products are ready for use.

Reagent stability

The in-use stability of the Gentian Canine CRP Reagent Kit was found to be at least 4 weeks in an on board study based on the CLSI guideline EP25 [1].

Calibration stability

The calibration curve stability of the Gentian Canine CRP Calibrator Kit was found to be at least 26 days in a study based on the CLSI guideline EP25 [1].

Performance characteristics

All results refer to validation of the Gentian Canine CRP Immunoassay on a Cobas Pure c303[1] at one site with one lot of reagents, unless otherwise stated.

Measuring range

The measuring range of the Gentian Canine CRP Immunoassay was found to be 9 - 291 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 Canine CRP 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 Canine CRP Immunoassay was found to be 7 mg/L.

Linearity

The linearity range of the Gentian Canine CRP Immunoassay was found to be 9 - 291 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 902 mg/L was observed for the Gentian Canine CRP Immunoassay in a study based on the CLSI guideline EP34 [4]. Samples with a Canine CRP concentration above the highest calibrator and up to 902 mg/L return a value above the highest calibrator and are flagged for rerun.

Precision

Precision of the Gentian Canine CRP Immunoassay was tested in a 3-day precision study based on the CLSI guideline EP05 [5]. Two canine serum pools, one canine plasma pool and two controls were measured 5 times with 5 replicates (n=25).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
PR-1	13	3.4	0	3.4
PR-2	43	2.3	0.5	2.3
PR-3	185	1.2	0.9	1.5
PR-CL	27	2.4	4.4	5.0
PR-CH	103	1.3	1.2	1.7

Analytical specificity and limitations

Interference was tested in a study based on the CLSI guideline EP07 [6]. As the antibodies in the Gentian Canine CRP 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	5 g/L
Intralipid	10 g/L
Bilirubin	0.6 g/L

Instrument variation

Results obtained with the Gentian Canine CRP Immunoassay were compared using Passing-Bablok regression with results from the Roche Cobas c501 instrument in a study based on the CLSI guideline EP09 [8].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
51	11 - 242	Intercept	0.79	[-2.72, 2.97]
		Slope	1.03	[1.00, 1.06]
		R^2	1.00	

[1] Registered trademark of Roche

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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. 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

2025-09-03

Instrument Settings for the Gentian Canine CRP Immunoassay on the Roche Cobas Pure c303[1]

CDC File Creator

Application Name	*

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	*
Unit 1	mg/L
Unit 2	None
Conversion factor	1
Sample type	Serum/Plasma

Rerun settings

Result outside the technical limit → Lower limit	9	
Result outside the technical limit → Upper limit	291	
Technical limits	9	291

Test

Test	2-Point-End			
Time	10			
Primary wavelength (nm)	660			
Secondary wavelength (nm)	None			
Measuring points	**1**	**2**	**3**	**4**
	24	35	0	0

Reagent volume

Reagent type	Reagent volume	Dilution volume	Mode	Stirring
R1	110	0	Without	8
R2	0	0	Water pressure	1
R3	60	0	Without	8

Sample volume

Sample type	Sample volume	Dilution	Diluent	Stirring
Normal	2	0	0	8
Reduced	10	2	90	8
Increased	10	0	0	8

Diluent → Type	Diluent
Diluent → CAN	951
Diluent → Dilution	10

Cuvette washing

Cuvette wash with	Acid and Base
Higher uncertainty	0

QC Interval

QC interval Timeout	*
QC interval Timeout → Hours	*

[1] Registered trademark of Roche

Calibration

Change settings

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

Calibration trigger

QC violation → Method	*
Timeout → Method	*
Timeout → Stability	26 days

Limit values

SD limit	0	
Deviation limit	99 %	3.3 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	**
No. Tests	115

Position	Reagent type	Pipetted volume	Fill volume	Max. Volume
B	R1	110	***	95.0
C	R3	60	***	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

Disclaimer: The specific settings above 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
** Instrument related
*** Calculated by the software