

Canine CRP



Application Note for the Gentian Canine CRP Immunoassay on the DxC 700 AU¹

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 <ul style="list-style-type: none">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

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 3 weeks in a study based on the CLSI guideline EP25 [1].

Performance characteristics

All results refer to validation of the Gentian Canine CRP Immunoassay on one instrument site with one lot of reagents.

Measuring range

The measuring range of the Gentian Canine CRP Immunoassay was found to be 10-346 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 9 mg/L.

Linearity

The linearity range of the Gentian Canine CRP Immunoassay was found to be 10-346 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 900 mg/L was observed for the Gentian Canine CRP Immunoassay in a study based on the CLSI guideline EP34 [4]. Samples with a CRP concentration above the highest calibrator and up to 900 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]. 3 serum pools and 2 controls were measured 5 times with 5 replicates (n=25).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
S1	16	4	6	7
S2	42	2	2	3
S3	194	1	1	1
CL	31	3	0	3
CH	101	1	1	1

Recovery

Recovery was analysed by spiking a low analyte sample with a high analyte sample according to Westgard [6]. The Gentian Canine CRP Immunoassay had a recovery of 84-106 %.

Analytical specificity and limitations

Interference was tested in a study based on the CLSI guideline EP07 [7]. As the antibodies in the Gentian Canine CRP 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	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 Cobas c501 instrument (Roche) in a study based on the CLSI guideline EP09 [9].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
41	9.58-291.34	Intercept	-1.79	[-3.10, -0.61]
		Slope	1.01	[0.99, 1.01]
		R ²	1.00	



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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

- First version.

Date of issue

2025-03-14

Instrument Settings for the Gentian Canine CRP Immunoassay on the DxC 700 AU¹

General		LIH		ISE		Calculated Test		Range	
Test Name: *		Test No		Type: Serum***		Operation: Yes			
Sample Volume	1.5 µL	Dilution	0 µL	OD Limit					
Pre-Dilution Rate	1			Reagent OD Limit		Min. OD		Max OD	
Reagent Volume	R1 (R1-1) 250 µL	Dilution	0 µL	1 st		Low	-2.0000	High	3.0000
	R1-2	Dilution		Last		Low	-2.0000	High	3.0000
	R2 (R2-1) 62 µL	Dilution	0 µL	Analytical Measuring Range		Low	10	High	346
Common Reagent	Type: None	Name	None	Correlation Factor		A	1	B	0
Wavelength	Pri: 600 nm	Sec	None nm	Manufacturer Factor		A	1	B	0
Method	END			Onboard Stability Period		28	Day	0	Hour
Reaction Slope	+			LIH Influence Check		No			
Measuring Point-1	1st: 12	Last	27	Lipemia		+			
Measuring Point-2	1st:	Last:		Icterus		+			
Linearity Limit	%			Hemolysis		+			
Lag Time Check									

General		LIH		ISE		Calculated Test		Range	
Test Name: *		Test No		Type: Serum***					
Value/Flag	Value	Level		Low	-99999.99	High	99999.99		
Specific Ranges									
	Sex	Year	Month	Year	Month	Other Type	Low	High	
<input type="checkbox"/> 1:	*	*	*	*	*	None	*	*	
<input type="checkbox"/> 2:	*	*	*	*	*	None	*	*	
<input type="checkbox"/> 3:	*	*	*	*	*	None	*	*	
<input type="checkbox"/> 4:	*	*	*	*	*	None	*	*	
<input type="checkbox"/> 5:	*	*	*	*	*	None	*	*	
<input type="checkbox"/> 6:	*	*	*	*	*	None	*	*	
7:	Standard demographics						*	*	
8:	Not within expected values						*	*	
Critical Limits	Low	*	High	*	Unit	mg/L	Select	Decimal Places	1

* User defined

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

*** Valid for both serum and plasma

Calibrators	General	ISE	
Test Name: <input style="width: 80%;" type="text" value="*"/>		Type: <input style="width: 80%;" type="text" value="Serum***"/>	
<input type="checkbox"/> Use Serum Cal.			
Calibration Type: <input style="width: 50%;" type="text" value="6AB"/>		Formula: <input style="width: 50%;" type="text" value="Spline"/> Counts: <input style="width: 50%;" type="text" value="2"/>	
<Calibrator Parameters>			
		Slope Check <input style="width: 50%;" type="text" value="None"/>	
	Calibrator	OD	Conc
			Range
			Low High
Point-1	Cal 1		** -2.0000 3.0000
Point-2	Cal 2		** -2.0000 3.0000
Point-3	Cal 3		** -2.0000 3.0000
Point-4	Cal 4		** -2.0000 3.0000
Point-5	Cal 5		** -2.0000 3.0000
Point-6	Cal 6		** -2.0000 3.0000
Point-7	Cal 7		** -2.0000 3.0000
MB Type Factor <input style="width: 50%;" type="text"/>		1-Point Calibration Point <input style="width: 50%;" type="text" value="None"/>	
		<input type="checkbox"/> with Conc-0	
		Stability	
		Reagent Blank <input style="width: 50%;" type="text" value="21"/> Day <input style="width: 50%;" type="text" value="0"/> Hour	
		Calibration <input style="width: 50%;" type="text" value="21"/> Day <input style="width: 50%;" type="text" value="0"/> Hour	
		<input type="checkbox"/> Reagent Blank <input style="width: 50%;" type="text"/> <input type="checkbox"/> Calibration <input style="width: 50%;" type="text"/> Advanced Calibration Operation <input style="width: 50%;" type="text" value="No"/> Interval (RB) <input style="width: 50%;" type="text"/> Interval (ACAL) <input style="width: 50%;" type="text"/>	

* User defined

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

*** Valid for both serum and plasma

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.