

# Canine CRP

## Application Note for the Gentian Canine CRP Immunoassay on the Thermo Scientific™ Indiko™ Plus<sup>1)</sup>

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](http://www.gentian.com).

### Assay kit components

Products available	
Gentian Canine CRP Reagent Kit	REF 1501
<ul style="list-style-type: none"> <li>R1 Assay Buffer (45 mL)</li> <li>R2 Immunoparticles (10.5 mL)</li> </ul>	
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 2 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, unless otherwise stated.

### Measuring range

The measuring range of the Gentian Canine CRP Immunoassay was found to be 7-292 mg/L. The exact measuring range is specific to the calibrator lot, please refer to the analytical value sheet available on [www.gentian.com](http://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 5 mg/L.

### Linearity

The linearity range of the Gentian Canine CRP Immunoassay was found to be 7-292 mg/L in a linearity study based on the CLSI guideline EP06 [3].

### Security zone

No antigen excess effect in samples below 629 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 629 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 2 controls were measured 5 times with 5 replicates (n=25).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Between day CV [%]	Total CV [%]
PR-1	22	2.6	0.0	0.5	2.6
PR-2	39	2.2	1.0	0.0	2.4
PR-3	130	2.6	1.1	0.0	2.9
PR-CL	28	2.2	0.9	0.0	2.4
PR-CH	98	2.7	1.8	0.0	3.2

### 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	10 g/L
Intralipid	20 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 Beckman Coulter DxC 700 AU instrument (Beckman Coulter) in a study based on the CLSI guideline EP09 [9].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
55	14 - 298	Intercept	-0.96	[-3.54, 1.18]
		Slope	0.99	[0.96, 1.01]
		R <sup>2</sup>	1.00	



Bjornasveien 5  
N-1596 Moss  
Norway  
TEL: +47 99 33 99 05  
[www.gentian.com](http://www.gentian.com)

## 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. 2<sup>nd</sup> ed. CLSI guideline EP06. Clinical and Laboratory Standards Institute; 2020
4. CLSI. Establishing and verifying an extended measuring interval through specimen dilution and spiking. 1<sup>st</sup> 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

2026-04-15

# Instrument Settings for the Gentian Canine CRP Immunoassay on the Scientific™ Indiko™ Plus<sup>1)</sup>

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Name	Canine CRP					
Tag	***					
Version number	***					
Full name	Canine C reactive protein					
Online name	Canine C reactive protein					
Type	Photometric	Number of decimals		0		
In use	Yes	Correction factor		1.000		
Acceptance	*	Correction bias		0.000		
Result unit	mg/l					
Sample type	<input checked="" type="checkbox"/> Serum <input checked="" type="checkbox"/> Plasma <input type="checkbox"/> Urine <input type="checkbox"/> CSF		<input type="checkbox"/> Oral fluid <input type="checkbox"/> Whole blood <input type="checkbox"/> Hemol. Blood <input type="checkbox"/> Other		Test version ID *** Last time changed *** User name ***	

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Blank type	Yes		Primary dilution 1+		0	
			Dispensed volume		255	
Reagent	Reagent		Reagent		R1	
Sample	Sample		Volume (µL)		180	
Incubation	Mix		Dispense with		Extra	
Mix	Incubate		Extra volume (µL)		5	
End point	Reagent		Syringe speed		Normal	
Kinetic	Mix		Replacing reagent		None	
System water	Incubate					
Antigen excess	End-point blank					
	Incubate					
	End-point measurement					

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Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Blank type		Yes			Primary dilution 1+	0
					Dispensed volume	255
Reagent		Reagent			Volume (µL)	2
Sample		Sample			Dispense with	Extra
Incubation		Mix			Extra volume	2
Mix		Incubate			Extra wash	No
End point		Reagent				
Kinetic		Mix				
System water		Incubate				
Antigen excess		End-point blank				
		Incubate				
		End-point measurement				

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Blank type		Yes			Primary dilution 1+	0
					Dispensed volume	255
Reagent		Reagent			Time (sec)	300
Sample		Sample			Actual time (sec)	297
Incubation		Mix				
Mix		Incubate				
End point		Reagent				
Kinetic		Mix				
System water		Incubate				
Antigen excess		End-point blank				
		Incubate				
		End-point measurement				

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Blank type		Yes			Primary dilution 1+	0
					Dispensed volume	255
Reagent		Reagent			Reagent	R2
Sample		Sample			Volume (µL)	73
Incubation		Mix			Dispense with	Extra
Mix		Incubate			Extra volume (µL)	3
End point		Reagent			Syringe speed	Normal
Kinetic		Mix			Replacing reagent	None
System water		Incubate				
Antigen excess		End-point blank				
		Incubate				
		End-point measurement				

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Blank type		Yes			Primary dilution 1+ Dispensed volume	0 255
Reagent		Reagent			Time (sec)	18
Sample		Sample			Actual time (sec)	18
Incubation		Mix				
Mix		Incubate				
End point		Reagent				
Kinetic		Mix				
System water		Incubate				
Antigen excess		End-point blank				
		Incubate				
		End-point measurement				

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Blank type		Yes			Primary dilution 1+ Dispensed volume	0 255
Reagent		Reagent			time (sec)	0.000
Sample		Sample			Actual time (sec)	***
Incubation		Mix				
Mix		Incubate				
End point		Reagent				
Kinetic		Mix				
System water		Incubate				
Antigen excess		End-point blank				
		Incubate				
		End-point measurement				

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Blank type		Yes			Primary dilution 1+ Dispensed volume	0 255
Reagent		Reagent			Time (sec)	480
Sample		Sample			Actual time (sec)	477
Incubation		Mix				
Mix		Incubate				
End point		Reagent				
Kinetic		Mix				
System water		Incubate				
Antigen excess		End-point blank				
		Incubate				
		End-point measurement				

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Blank type		Yes			Primary dilution 1+ Dispensed volume	0 255
Reagent		Reagent			Main wavelength (nm)	620
Sample		Sample			Side wavelength (nm)	None
Incubation		Mix			Residual net abs. (A)	0.000
Mix		Incubate				
End point		Reagent				
Kinetic		Mix				
System water		Incubate				
Antigen excess		End-point blank				
		Incubate				
		End-point measurement				

*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

\*\* Lot specific. See analytical value sheet available on [www.gentian.com](http://www.gentian.com)

\*\*\* Instrument default