

Canine CRP



Application Note for the Gentian Canine CRP Immunoassay on the Thermo Scientific™ Indiko™ Plus¹⁾

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 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.

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 ²	1.00	

¹⁾ Registered trademark of Thermo Fisher Scientific



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-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

- Updated instrument settings.

Date of issue

2026-07-13

Instrument Settings for the Gentian Canine CRP Immunoassay on the Scientific™ Indiko™ Plus¹⁾

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	☒ Serum ☐ Oral fluid Test version ID *** ☒ Plasma ☐ Whole blood Last time changed *** ☐ Urine ☐ Hemol. Blood User name *** ☐ CSF ☐ Other					

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					

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+		0	
			Dispensed volume		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+		0	
			Dispensed volume		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+		0	
			Dispensed volume		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+		0	
			Dispensed volume		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					

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
dilution with	Water					
Primary dilution 1+	0					
Neat sample	Dispense with		Extra			
	Volume (µL)		0			
Diluent	Sample Diluent ID					
	Dispense with		Extra			
	Volume (µL)		0			

Info	Flow	Dilution	Limits	Reflex/Screening	Calibration	QC
Calibration type	Spline		Abs. error (A)		***	
Repeat time (days)	14		Rel. error (%)		***	
Point/calibrator	Duplicate		Factor limit min.		***	
Acceptance	Automatic		Factor limit max.		***	
Concentration axis	Linear		Bias limit min.		***	
Response axis	Linear		Bias limit max.		***	
Nbr	Calibrator	Curent lot	Concentration	Dilution 1+		
1	cCRP1	**	**	0		
2	cCRP2	**	**	0		
3	cCRP3	**	**	0		
4	cCRP4	**	**	0		
5	cCRP5	**	**	0		
6	cCRP6	**	**	0		
Factor					1.000	
Bias					0.0000	

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

*** Instrument default