Canine CRP

Application Note for the Gentian Canine CRP Immunoassay on the Thermo Scientific Konelab Prime 60[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 1 week 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 13-252 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 6.57 mg/L.

Linearity

The linearity range of the Gentian Canine CRP Immunoassay was found to be 13-252 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 869 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 869 mg/L return a value above the highest calibrator and are flagged for rerun with automatic dilution.

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 [%]
Pr 1	21.06	5.57	1.57	5.78
Pr 2	40.91	1.51	2.33	2.77
Pr 3	121.47	4.01	3.16	5.10
Pr-CL	32.42	1.80	4.84	5.17
Pr-CH	104.31	1.11	4.11	4.26

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 82-103 %.

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	600 mg/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
50	4.9-297.1	Intercept	0.18	[-0.81, 1.10]
		Slope	1.04	[1.00, 1,08]
		R^2	0.99	

[1)] Registered trademark of Thermo Scientific, part of Thermo Fisher Scientific

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References / Bibliography

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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 the product table.

Date of issue

2025-11-28

Instrument Settings for the Gentian Canine CRP Immunoassay on the Thermo Scientific Konelab Prime 60[1)]

Test type	Photometric		**Test in use**	Yes		
Full name	C-reactive protein			Low	High	
Online name			**Test limit**	**	**	mg/l
			Initial absorbance	0**	5**	A
Result unit	mg/l		**Dilution limit**	*	800	mg/l
Number of decim.	1		**Secondary dil. 1+**	0**	9**	
Acceptance	**					
Dilution 1+	0**					

Ref. class	Low	High	Unit	In use

Serum sample

X	Serum	X	Plasma		Urine
	CSF		Other		

Ref. class	Low	High	In use
			Yes

Correction factor	1**		
Correction bias	0**	mg/l	more >>

Blank	Yes					
Antigen excess	No	Normal cuvette	**Dispensed vol. (µl)**	250		

Reagent	Sample	Incubation	End point	Reagent	Incubation	End point
Reagent	**Volume (µl)**	**Time (sec.)**		**Reagent**	**Time (sec.)**	**Wavelength (nm)**
R1**	2	216		R2**	480	600 nm
Volume (µl)			**Blank**	**Volume**		**Side wavel. (nm)**
180				68		None
Disp.with	**Disp.with**		**Resp. min (A)**	**Disp. With**		
Extra	Extra			Extra		
Volume (µl)	**Volume (µl)**		**Resp. max (A)**	**Volume (µl)**		
20	5			10		
Wash reagent	**Dilution with**			**Wash reagent**		**Meas. Type**
[none]	none			[none]		Normal
	Wash reagent					
	[none]					

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Calibration type	Nonlinear	**Factor**		**Bias**	
Repeat time (d)	0**	**Abs.error (mA)**	*	**Bias correction in use**	NO
Points/Calibrator	Duplicate	**Rel. error (%)**	*	**Bias corr. repeat time (dd:hh)**	
Acceptance	**	**Response limit (mA)**		**Bias corr. limit (mA)**	
Curve direction	Ascending	**Min**	*	**Total**	
		Max	*	**Incremental**	
Type of calibrator	Separate				
Calibrator id				**Bias cal. id**	
Concentration					
Dil. Ratio 1+					

Calibrator	Conc.	Dil. Ratio
CRP1	***	0.0
CRP2	***	0.0
CRP3	***	0.0
CRP4	***	0.0
CRP5	***	0.0
CRP6	***	0.0

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.

* Default by instrument
** User defined
*** Lot specific. See analytical value sheet available on www.gentian.com.