Gentian Canine CRP

Application Note for the Gentian Canine CRP Immunoassay on the QuidelOrtho VITROS® 5600[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 33 days 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 20 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 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 9-302 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 9-309 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 934 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 934 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 plasma pools and one canine serum pool and 2 controls were measured 5 times with 5 replicates (n=25).

Sample ID	Mean [mg/L]	Repeatability [%]	Between run CV [%]	Within-lab CV [%]
Pr1	26	3.0	2.0	3.6
Pr2	37	2.6	4.1	4.9
Pr3	149	2.4	1.3	2.7
CL	31	3.0	3.7	4.7
CH	102	1.9	1.9	2.7

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	10 g/L
Intralipid	20 g/L
Unconjugated bilirubin	0.6 mg/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 [8].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
53	14 - 355	Intercept	-1.99	[-6.58, 1.03]
		Slope	1.00	[0.96, 1.03]
		R^2	1.00	

[1] Registered trademark of QuidelOrtho

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References

1. CLSI. Evaluation of Stability of *In Vitro* Diagnostic Reagents; Approved Guideline. CLSI document EP25-Ed2. 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. 4th ed. CLSI guideline EP05. Clinical and Laboratory Standards Institute; 2025
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

2026-06-11

Instrument Settings for the Gentian Canine CRP Immunoassay on the QuidelOrtho Vitros® 5600[1]

CONFIGURATION

	Full Assay Name	Gentian Canine CRP	
	Short Assay Name	cCRP	
	Fluid Type	Serum	
	Assay Model Type	2 Point Rate	
	Template	2PT R1-S-R2	
	Cal Model Type	Cubic Spline	
Calibrators Bottles	6	**Replicates Per Cal**	2

DILUTION PARAMETERS

Diluent	None	**Standard Dilution Factor**	1.0
	REFLEX DILUTION		
Reflex Dilution	Off		

RESULTS PARAMETERS

Reporting Type	Quantitative					
Units	mg/L					
					RANGES	
Significant digits	4	**Precision digits**	0	**Reference**	*	*
				Supplementary	*	*
				Measuring (reportable)	9	302

[1] Registered trademark of QuidelOrtho

Slope	1.00	**Intercept**	0.00
Cuve Tip Expiration Time	35**		
Temperature sensitive	no		

ADDITIONAL PARAMETERS

	Initial Absorbance Limits	
-0.200		2.700
	Blank Absorbance Limits	
-0.200		2.700
	Antigen Excess Factor	
	9.0000	

Monotonicity	Increased		
Max. Response – High	3.000 **	**Max. Response – Low**	-3.000 **
Min. Response – High	3.000 **	**Min. Response – Low**	-3.000 **
		Calibration interval	20

	Measuring Conc. (reportable)	**Triple Read Limit**
Measuring Min. (reportable)	0.00**	400.0**
Critical Conc.	5000**	8.00**
Measuring Max. (reportable)	9999**	8.00**

CALIBRATORS

Kit Lot Number	Bottle Number	Dilution Factor	Calibrator Value	Response Area
***	1	1.0	***	0.20000
***	2	1.0	***	0.20000
***	3	1.0	***	0.20000
***	4	1.0	***	0.20000
***	5	1.0	***	0.20000
***	6	1.0	***	0.20000

PROTOCOL

1.	**Reagent**	Volume (µL)	175.0	Pack/Bottle = UD01 / A
2.	**Incubation**	Seconds	0.00	
3.	**Sample**	Volume (µL)	2.0	
4.	**Incubation**	Seconds	304.00	
5.	**Reagent**	Volume (µL)	73.0	Pack/Bottle = UD01 / B
6.	**Incubation**	Seconds	38.00	
7.	**Read**	Wavelength (nm)	700	
8.	**Incubation**	Seconds	494.00	
9.	**Read**	Wavelength (nm)	700	

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

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