Canine CRP



Application Note for the Gentian Canine CRP Immunoassay on the Alinity¹

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	REF 1501
 R1 Assay Buffer (45 mL) 	
R2 Immunoparticles (10.5 mL)	
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 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 9-292 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 8 mg/L.

Linearity

The linearity range of the Gentian Canine CRP Immunoassay was found to be 9-292 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 913 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 913 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).

		Within	Between	Total
Sample	Mean	run CV	run CV	CV
ID	[mg/L]	[%]	[%]	[%]
S1	13	4	4	5
S2	37	1	3	3
S3	184	0	2	2
CL	30	1	0	1
СН	100	1	2	2

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 86-102 %.

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
		Intercept	-0.31	[-1.01, 0.45]
40	9.7-294.1	Slope	1.04	[1.03, 1.06]
		R^2	1.00	





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References

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- 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
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- 8. Larsson A, et al. Poultry Science 1993;72:1807-12
- 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

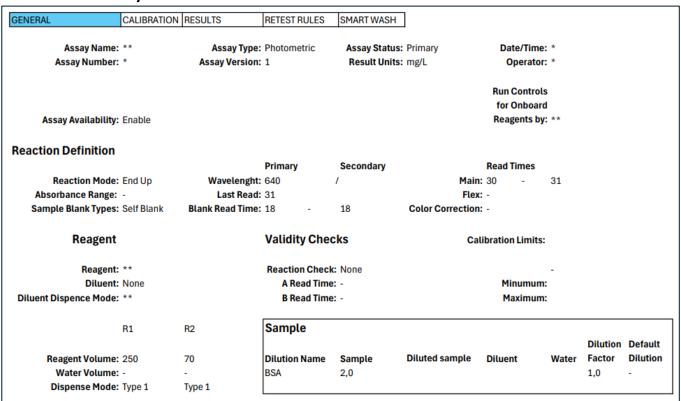
• First version.

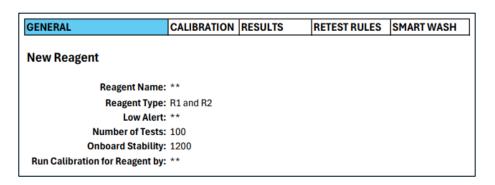
Date of issue

2025-03-19



Instrument Settings for the Gentian Canine CRP Immunoassay on the Alinity¹





^{*} Default by instrument

^{**} User defined

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



GENERAL SMART WASH CALIBRATION RESULTS RETEST RULES Assay Name: ** Assay Type: Photometric Assay Status: Primary Date/Time: * Assay Number: * Assay Version: * Result units: mg/L Operator: * Calibration Calibration Method: Spline Full Calibration Interal: 999 (Hours) **Default Ordering Type:** Factor: **Use Cal Factor From:** Adjust Type: None Calibration Expiration (Hours) Warning: Adjust Interval: (Hours) Adjust Level: **Calibrators** Validity Checks Calibrator Set: ** Replicates: 2 **Blank Absorbance Range:** Span: Blank -Calibrator Level: Sample Diluted Sample Diluent Water Span absorbance range: Blank: *** 2,0 **Expected Cal Factor:** Cal 1: *** 2,0 **Expected Cal Factor Tolerance %:** Cal 2: **Maximum Curve Fit:** 2,0 Cal 3: 2,0 Cal 4: 2,0 Cal 5: 2,0 Cal 6:

GENERAL	CALIBRATION	RESULTS	RETEST RULES	SMART WASH		
	Assay Name: **		Assav Type:	Photometric	Assay Status: Primary	Date/Time: *
	Assay Number: *		Assay Version:		Result units: mg/L	Operator: *
Daniska Hai						
Results Uni	Results Units: mg/L		Decimal Places:	1	Resuls Unit UCUM:	
	Correlation factor: 1,0000		Intercept:	0,0000		
Dazulta						
Results	Low Line	arity:			High Linearity:	
Gender	Age Unit:	Age Range	Normal Range		Extreme Range	
Interpretati						
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^{*} Default by instrument

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