Canine CRP

Application Note for the Gentian Canine CRP Immunoassay on the Alinity[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

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).

Sample ID	Mean [mg/L]	Within run CV [%]	Between run CV [%]	Total CV [%]
S1	13	4	4	5
S2	37	1	3	3
S3	184	0	2	2
CL	30	1	0	1
CH	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
40	9.7-294.1	Intercept	-0.31	[-1.01, 0.45]
		Slope	1.04	[1.03, 1.06]
		R^2	1.00	

[1] Registered trademark of Abbott

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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

- First version.

Date of issue

2025-03-19

Instrument Settings for the Gentian Canine CRP Immunoassay on the Alinity[1]

GENERAL | CALIBRATION | RESULTS | RETEST RULES | SMART WASH

Assay Name:	**	**Assay Type:**	Photometric	**Assay Status:**	Primary	**Date/Time:**	*
Assay Number:	*	**Assay Version:**	1	**Result Units:**	mg/L	**Operator:**	*
Assay Availability:	Enable					**Run Controls for Onboard Reagents by:**	**

Reaction Definition

			Primary		Secondary		Read Times		
Reaction Mode:	End Up	**Wavelenght:**	640	/		**Main:**	30	-	31
Absorbance Range:	-	**Last Read:**	31			**Flex:**	-		
Sample Blank Types:	Self Blank	**Blank Read Time:**	18	-	18	**Color Correction:**	-		

Reagent

	R1	R2
Reagent:	**	
Diluent:	None	
Diluent Dispence Mode:	**	
Reagent Volume:	250	70
Water Volume:	-	-
Dispense Mode:	Type 1	Type 1

Validity Checks

Reaction Check:	None
A Read Time:	-
B Read Time:	-

Calibration Limits:

	-
Minumum:	
Maximum:	

Sample

Dilution Name	Sample	Diluted sample	Diluent	Water	Dilution Factor	Default Dilution
BSA	2,0				1,0	-

GENERAL | CALIBRATION | RESULTS | RETEST RULES | SMART WASH

New Reagent

Reagent Name:	**
Reagent Type:	R1 and R2
Low Alert:	**
Number of Tests:	100
Onboard Stability:	1200
Run Calibration for Reagent by:	**

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

GENERAL | CALIBRATION | RESULTS | RETEST RULES | SMART WASH

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)**
Factor: **Default Ordering Type:**
Use Cal Factor From: **Adjust Type:** None
Calibration Expiration Warning: ** **(Hours)** **Adjust Interval:** **(Hours)** **Adjust Level:**

Calibrators

Calibrator Set: ** **Replicates:** 2

Calibrator Level:		Sample	Diluted Sample	Diluent	Water
Blank:	***	2,0			
Cal 1:	***	2,0			
Cal 2:	***	2,0			
Cal 3:	***	2,0			
Cal 4:	***	2,0			
Cal 5:	***	2,0			
Cal 6:					

Validity Checks

Blank Absorbance Range: -
Span: Blank -
Span absorbance range: -
Expected Cal Factor:
Expected Cal Factor Tolerance %:
Maximum Curve Fit:

GENERAL | CALIBRATION | RESULTS | RETEST RULES | SMART WASH

Assay Name: ** **Assay Type:** Photometric **Assay Status:** Primary **Date/Time:** *
Assay Number: * **Assay Version:** * **Result units:** mg/L **Operator:** *

Results Unit

Results Units: mg/L **Decimal Places:** 1 **Resuls Unit UCUM:**
Correlation factor: 1,0000 **Intercept:** 0,0000

Results

Low Linearity: **High Linearity:**

Gender	Age Unit:	Age Range	Normal Range	Extreme Range

Interpretation

Name		Range	Review Required
<NotDefined>	<	0,00	-
<NotDefined>	>=	0,00	-
<NotDefined>	>=	0,00	-
<NotDefined>	>=	0,00	-
<NotDefined>	>=	0,00	-

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

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.