

Canine CRP



Application Note for the Gentian Canine CRP Immunoassay on the Siemens Atellica CH 930¹

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 31 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 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 8-284 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 7.53 mg/L.

Linearity

The linearity range of the Gentian Canine CRP Immunoassay was found to be 7-284 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 747 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 747 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 [%]
1	24.33	2.16	0.00	2.16
2	44.23	1.24	1.94	2.31
3	145.09	0.45	0.26	0.52
CL	31.30	1.60	0.69	1.74
CH	101.63	0.66	1.80	1.92

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 83-89 %.

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
40	3.5-250.6	Intercept	4.02	[2.12, 5.02]
		Slope	0.96	[0.95, 0.99]
		R ²	1.00	



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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

- Added CH 930 to instrument name

Date of issue

2026-09-18

Instrument Settings for the Gentian Canine CRP Immunoassay on the Siemens Atellica CH 930¹

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.

Definition	Sample/Reagent	Calculation	Calibration	Mitigation
Assay Name	*			
ID				
Units	mg/L			
Test version	*			
Display Name	*			
Print Name	*			
LIS Code	*			
LOINC				
	☐ Investigation Only			
	☐ Kinetic Mode			

Serum	Plasma	Urine	CSF	RBC
Measuring Interval				
☒ Serum				
Assay Range		Low	High	
		8	284	
Sample Predilution				
Sample Volume	Dilution Factor	Total Volume		
25 µL	5	125 µL		
Below Measuring Interval Configuration				
Sample Volume	Dilution Factor	Total Volume		
0 µL		0 µL		
Above Measuring Interval Configuration				
Sample Volume	Dilution Factor	Total Volume		
5 µL	10	50 µL		

Definition	Sample/Reagent	Calculation	Calibration	Mitigation
	Component 1 Volume [Well 1]	Component 2 Volume [Well 2]	Diluent Volume	Total Volume
R1 Reagent	R1 ▼ 94.5 µL	- ▼ 0 µL	0 µL	94 µL
Time: 0 seconds				Gentle ▼
Sample	3.5 µL			
Time: 12 seconds				
R2 Reagent	R2 ▼ 24.5 µL	- ▼ 0 µL	0 µL	24 µL
Time: 273 seconds				Moderate ▼
				Total Volume 122 µL
	Test Count	Life Hours	Onboard Life	
	197	744	744 (hours)	☐ Use Well 2
	Pack 1 Volume	Well 1: 23.5 mL	R1 Empty	
	Pack 2 Volume	Well 1: 8.86 mL	R2 Empty	

Definition	Sample/Reagent	Calculation	Calibration	Mitigation
Calculation	High-dose Hook Effect	HIL Calculation		
Analysis Method End Point (EPA)				
Primary Wavelength 596 Blank Wavelength --- Main Start Time 259 Main End Time 561 Absorbance Offset 5 Decreasing Reaction Absorbance ☐ ☐ Start-Point Estimation Blank Start Time Blank End Time 				

Definition	Sample/Reagent	Calculation	Calibration	Mitigation			
Specimen Type	Serum*	☐ Automatically Order Calibration	1	☐ CO Adjust			
Standard Curve	Spline	☐ Lot Calibration Expiration (Days)	1	☐ Semi Quant			
Lot Calibration Interval (Days)	7	☐ Pack Calibration Expiration (Hours)		Calibrator Onboard Stability (Hours)			
Pack Calibration Interval (Days)	7	☐ New Lot		Refrigerated **			
		☐ IFU Changed		Unrefrigerated **			
Calibrator Levels and Predilution		☐ Perform QC with Calibration					
Levels 6							
Level	Weight	Replicates	Dilution Factor	Sample	Sample Volume	Total Volume	
1	1	2	5	1	25 µL	125 µL	☐ CH Diluent Only
2	1	2	5	2	25 µL	125 µL	
3	1	2	5	3	25 µL	125 µL	
4	1	2	5	4	25 µL	125 µL	
5	1	2	5	5	25 µL	125 µL	
6	1	2	5	6	25 µL	125 µL	

* User defined

** Stored at 2-8 °C. The expiry date is printed on the labels