Canine CRP

Application Note for the Gentian Canine CRP Immunoassay on the Cobas c501[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.

Calibration stability

The calibration curve stability of the Gentian Canine CRP Calibrator Kit was found to be at least 13 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 10-282 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 6.4 mg/L.

Linearity

The linearity range of the Gentian Canine CRP Immunoassay was found to be 10-282 mg/L in a linearity study based on the CLSI guideline EP06 [3].

Security zone

No antigen excess effect in samples below 862 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 862 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 5-day precision study based on the CLSI guideline EP05 [5]. 3 plasma samples 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	16.3	4.68	8.08	9.34
2	46.0	1.42	4.41	4.63
3	129.4	0.84	1.56	1.78
CL	34.4	2.48	8.47	8.83
CH	104.1	1.08	1.34	1.72

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 90-101 %.

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 AU480 instrument (Beckman Coulter) in a study based on the CLSI guideline EP09 [9].

n	Range of samples [mg/L]	Term	Coefficient	95% CI
45	3.4-236	Intercept	-0.53	[-1.27, 0.01]
		Slope	0.98	[0.97, 0.98]
		R^2	1.00	

[1] Registered trademark of Roche

Gentian AS
Bjornasveien 5
N-1596 Moss
Norway
TEL: +47 99 33 99 05
www.gentian.com

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

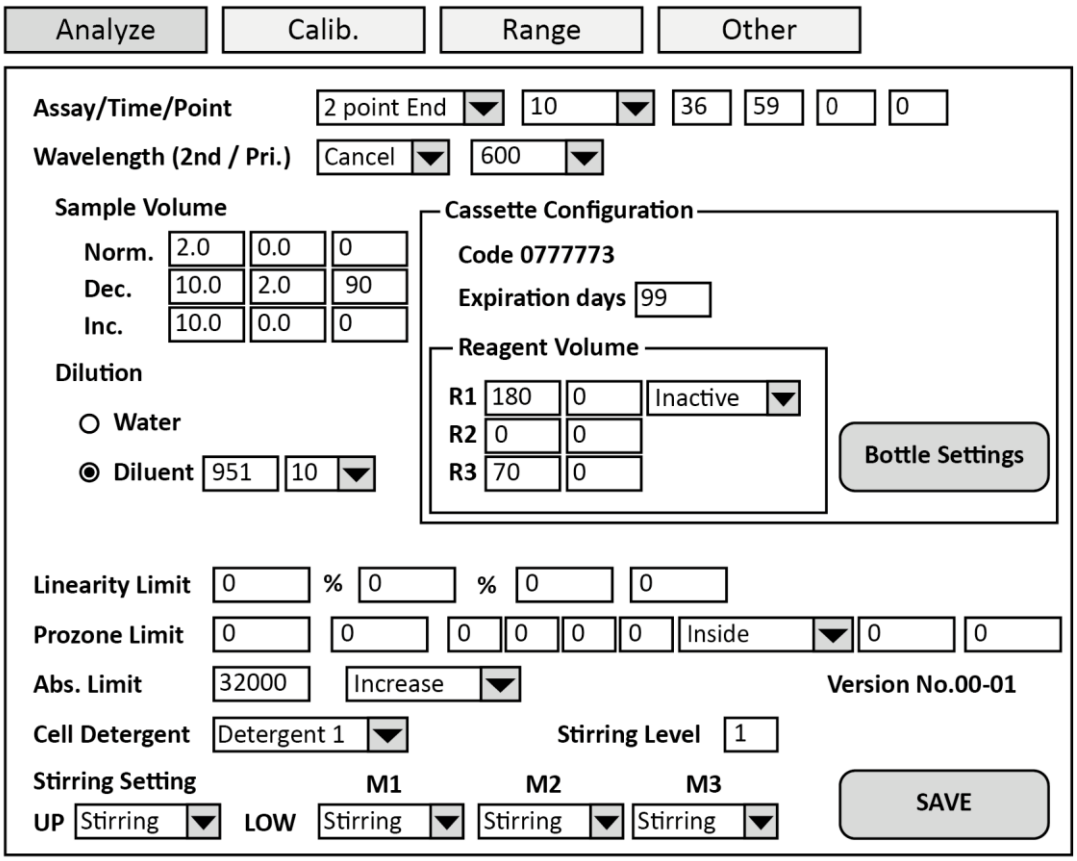
- Updated the product table, references to CLSI guidelines and format

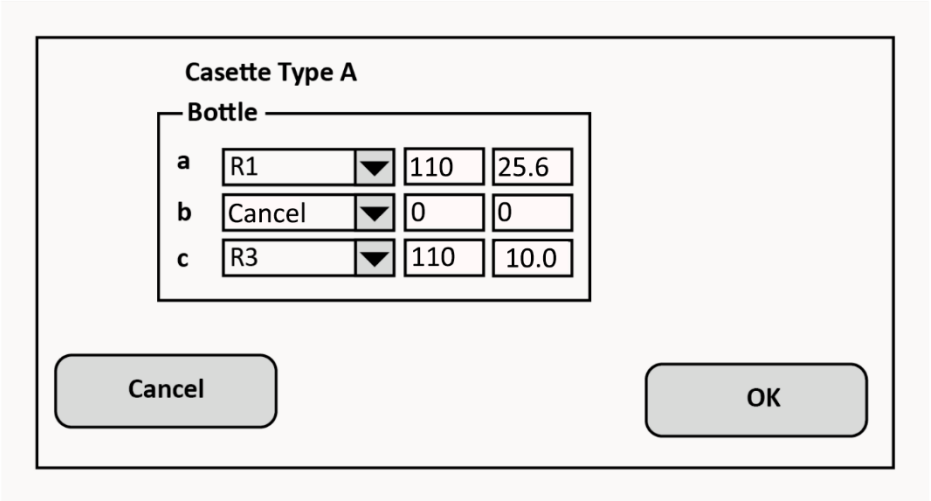
Date of issue

2025-12-01

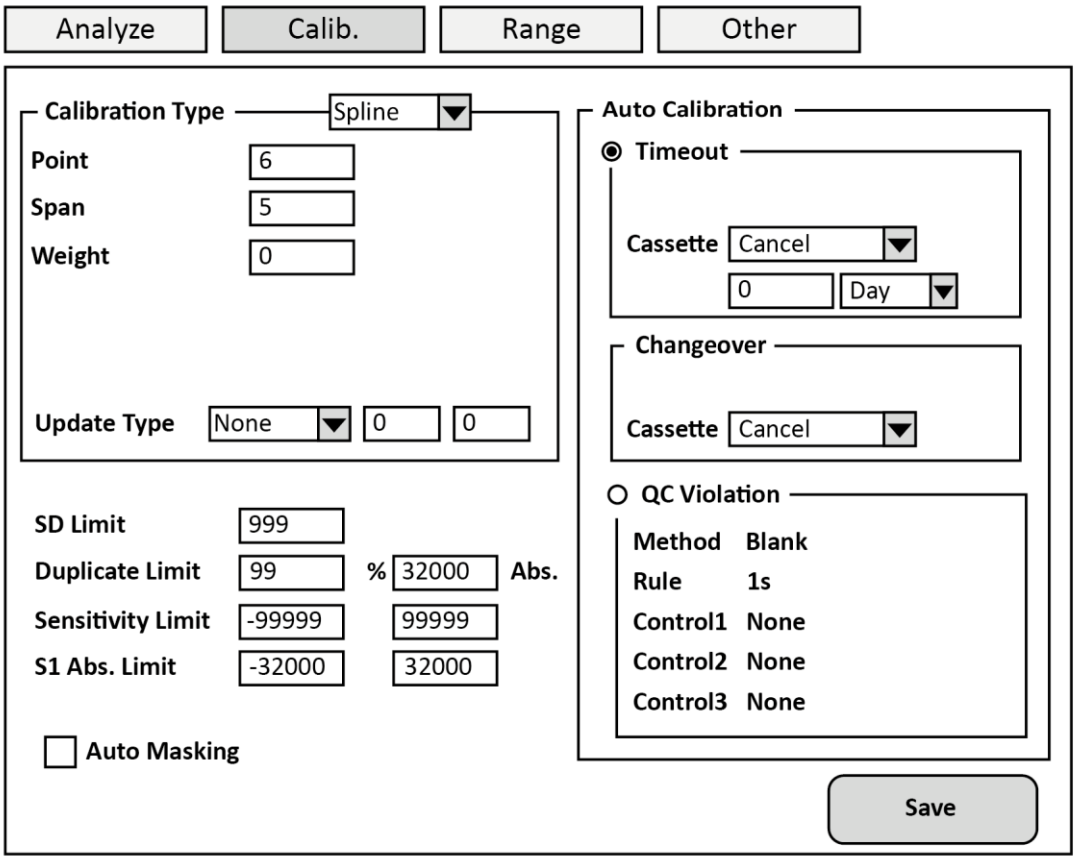
[1] Registered trademark of Roche

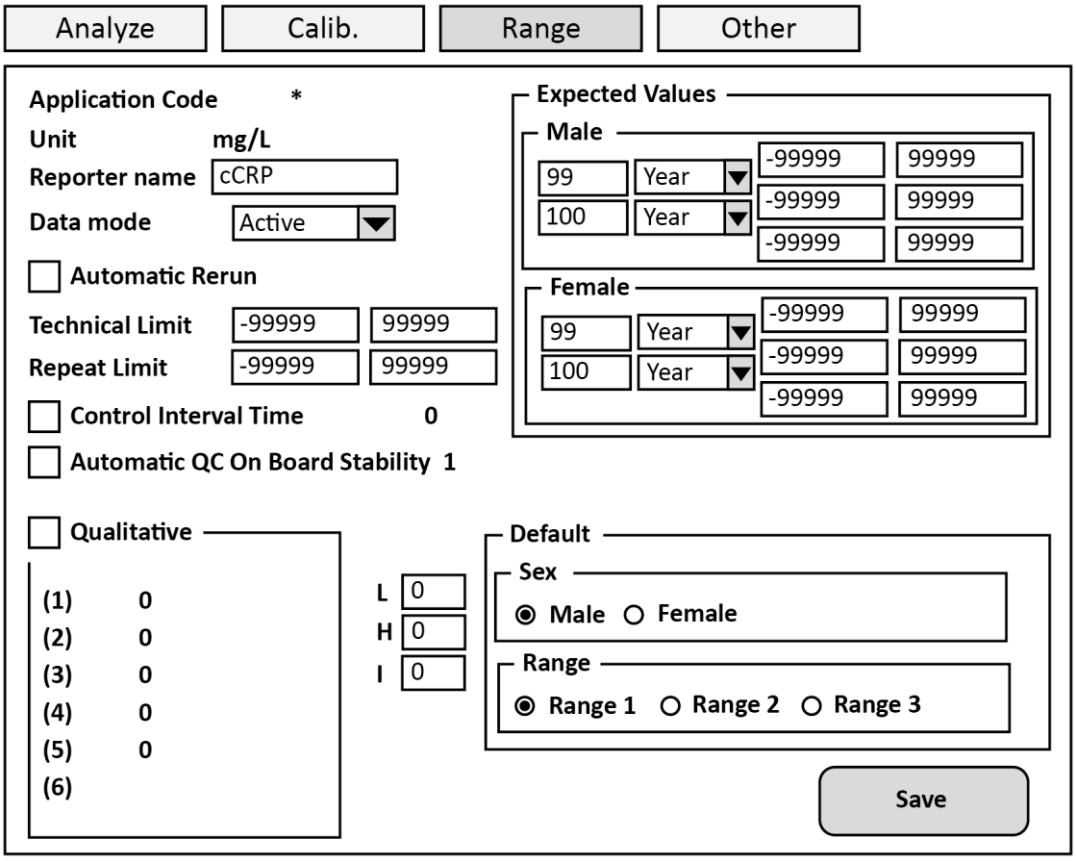
Instrument Settings for the Gentian Canine CRP Immunoassay on the Cobas c501[1]

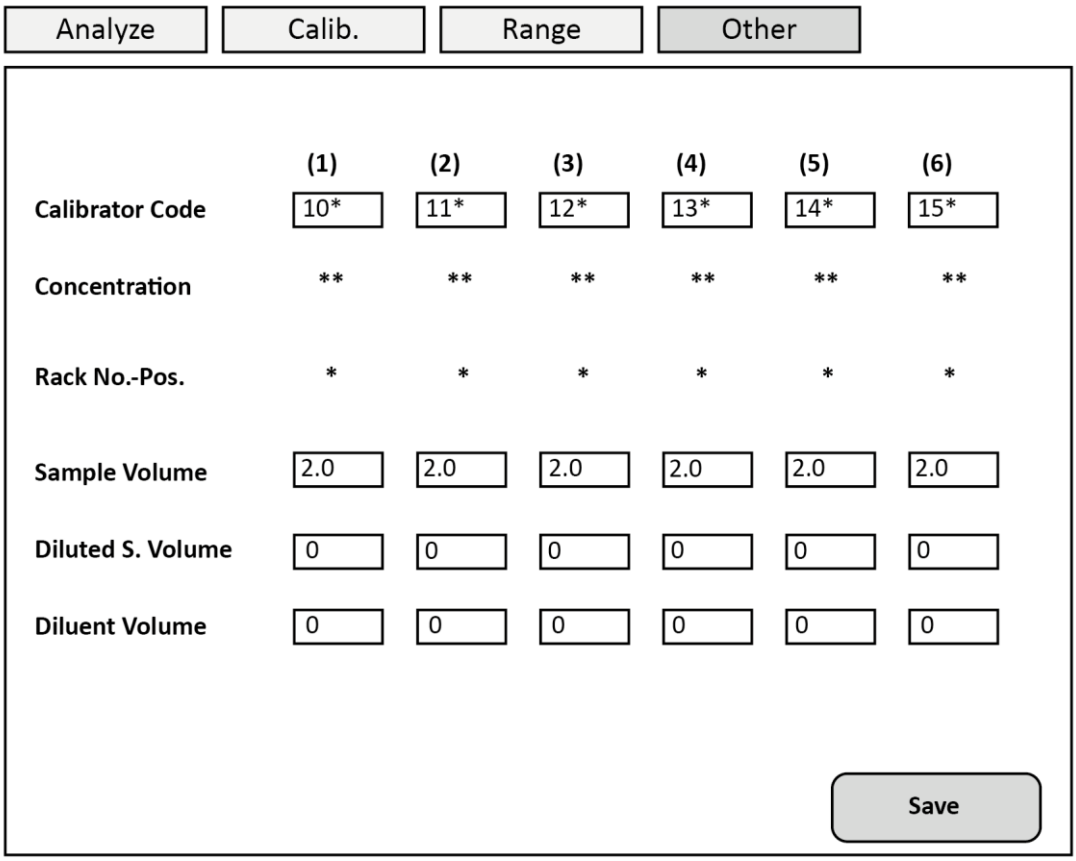




[1] Registered trademark of Roche


Analyze
Calib.
Range
Other
Calibration Type
Spline
Point
6
Span
5
Weight
0
Update Type
None
0
0
SD Limit
999
Duplicate Limit
99
%
32000
Abs.
Sensitivity Limit
-99999
99999
S1 Abs. Limit
-32000
32000
Auto Masking
Auto Calibration
Timeout
Cassette
Cancel
0
Day
Changeover
Cassette
Cancel
QC Violation
Method Blank
Rule 1s
Control1 None
Control2 None
Control3 None
Save


Analyze
Calib.
Range
Other
Application Code
*
Unit
mg/L
Reporter name
cCRP
Data mode
Active
Automatic Rerun
Technical Limit
-99999
99999
Repeat Limit
-99999
99999
Control Interval Time
0
Automatic QC On Board Stability
1
Qualitative
(1) 0
(2) 0
(3) 0
(4) 0
(5) 0
(6)
L 0
H 0
I 0
Expected Values
Male
99 Year -99999 99999
100 Year -99999 99999
-99999 99999
Female
99 Year -99999 99999
100 Year -99999 99999
-99999 99999
Default
Sex
Male
Female
Range
Range 1
Range 2
Range 3
Save



* 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.