

Canine CRP

Gentian Canine CRP Control Kit

REF 1519

For *in vitro* diagnostic use by laboratory professionals.

This document describes the general use of the product above. For instrument specific settings, please refer to the application notes available upon request from marketing@gentian.com.

Intended purpose

The Gentian Canine CRP Immunoassay is an *in vitro* diagnostic test for quantitative determination of canine CRP in dog serum and plasma. The measurement of canine CRP is used to detect and monitor inflammation activity in dogs.

Control kit indication for use

The Gentian Canine CRP Controls are intended to monitor and evaluate the quality of the calibration curve established from the Gentian Canine CRP Calibrator with the Gentian Canine CRP Immunoassay.

Control value assignment

The control values, given in the enclosed analytical value sheet, are assigned according to Gentian's value transfer protocol as recommended in ISO 17511 [1] for calibrators and controls. The controls are composed of canine CRP isolated from dog blood.

Calibrator standardisation

No international standard is available for canine CRP. Gentian Canine CRP Calibrator values are established based on internal canine CRP reference material.

Assay kit components

Products provided	
Gentian Canine CRP Control Kit (2 levels x 0.5 mL)	REF 1519
Products required, but not provided	
Gentian Canine CRP Calibrator Kit (6 levels x 0.5 mL)	REF 1551
Gentian Canine CRP Reagent Kit	REF 1501
<ul style="list-style-type: none">R1 Assay Buffer (45 mL)R2 Immunoparticles (10.5 mL)	

All products are ready for use.

Composition

The Gentian Canine CRP Controls are composed of BSA buffer with calcium spiked with canine CRP antigen. ProClin® 950 is used as preservation.

Hazards identification



Hazard pictograms (CLP):

GHS07

Signal word (CLP): Warning

Contains: 2-methylisothiazol-3(2H)-one

Hazard statements (CLP):

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP):

P280 - Wear eye protection, protective gloves, protective clothing.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 - If eye irritation persists: Get medical advice/attention.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

SDS (safety data sheet) is available on www.gentian.com.

Warnings and precautions

1. Contains substances from animal origin and should be considered as potentially infectious material. Handle with caution and discard following local regulations.
2. Do not ingest. Wash thoroughly after handling.
3. Use protection goggles, lab coat and gloves for personal protection.

Additional handling instructions

1. This test is for *in vitro* use only and must be handled by qualified personnel.
2. Use only validated and approved instrument applications.
3. Do not use products after the expiration date has passed.
4. Do not mix reagents of different lots or interchange caps of reagents, controls, calibrators, and lots.
5. Tighten caps carefully back on after use of reagents, calibrators, and controls to avoid evaporation.

Reagent storage and stability

All products provided for the Gentian Canine CRP Immunoassay must be stored at 2-8°C. The expiry date is printed on the labels. Using a BS-380 instrument (Mindray), the in-use stability of the Gentian Canine CRP Control Kit was found to be at least 24 months performed as an open trial study (at 2-8 °C) based on the CLSI guideline EP25 [2]. For calibration curve stability, please refer to the instrument specific application notes.

Procedure

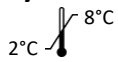
Application notes

Applications of the Gentian Canine CRP Immunoassay have been established on several clinical chemistry analysers. Detailed, validated application notes describing the procedures for installation and analysis on specific instruments are available upon request to marketing@gentian.com. For instructions on how to install a new application, consult the instrument manual. Maintenance, operation, and precautions must be handled in accordance with the specific instrument manual.

QC controls

The Gentian Canine CRP Controls should be assayed every day the test is in use to validate the calibration curve. The controls are ready to use. The controls have lot specific concentration ranges that must be met before measuring samples. The assigned value ranges are given in the analytical value sheet available on www.gentian.com. If the control values measured are not valid, repeat the control measurements. Recalibrate if necessary. If the calibration cannot be performed without error, or valid control values cannot be reproduced, contact the local distributor for support.

Symbols key



Temperature Limit



Use by Date



Consult Instructions for Use



Manufacturer



Veterinary Use



Lot Number



Catalogue Number



Contents



Control Low



Control High



Warning



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References

1. EN ISO 17511:2021 In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples. (ISO 17511:2020).
2. CLSI. Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline. CLSI document EP25-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.

Serious incidents

Please notify the manufacturer and competent authority if any serious incidents have occurred in relation to the device.

Modification from previous version

- Included CLSI references
- Minor editorial changes and corrections throughout the document

Date of issue

2024-08-28