# Canine CRP

## Gentian Canine CRP Calibrator Kit

REF 1551

**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.

## Calibrator kit indication for use

The Gentian Canine CRP Calibrator Kit is intended to be used to establish a calibration curve for measuring CRP concentration in canine plasma and serum samples with the Gentian Canine CRP Immunoassay.

## Calibrator value assignment

The calibrator value, given in the enclosed analytical value sheet, is assigned according to Gentian's value transfer protocol as recommended in ISO 17511 [1] for calibrators and controls. The calibrator is 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 Calibrator Kit (6 levels x 0.5 mL) | REF 1551 |
| **Products required, but not provided** | |
| Gentian Canine CRP Control Kit (2 levels x 0.5 mL) | REF 1519 |
| Gentian Canine CRP Reagent Kit<br>• R1 Assay Buffer (45 mL)<br>• R2 Immunoparticles (10.5 mL) | REF 1501 |

*All products are ready for use.*

## Composition

The Gentian Canine CRP Calibrator is 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 googles, 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 an BS-380 instrument (Mindray), the in-use stability of the Gentian Canine CRP Calibrator Kit was found to be at least 24 months performed as an open vial 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.

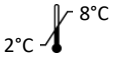
### Establishment of the calibration curve

The calibrator levels 1 to 6 are used to establish a 6-point standard curve as defined in the instrument manual. The calibrators are ready to use, do not program dilution. Calibrator values are lot specific, and calibration must be performed whenever a new lot is used. The values assigned to the calibrators are provided in the analytical value sheet available on www.gentian.com. A new calibration should be performed according to the interval specified in the instrument-specific application note or when a new reagent lot is used.

### QC controls

The Gentian Canine CRP Controls should be assayed every day the test is in use to validate the calibration curve. 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 | Lot Number |
| REF | Catalogue Number |
| CONTENTS | Contents |
| CAL | Calibrator |
| CAL 1 | Calibrator Level 1 |
| CAL 2 | Calibrator Level 2 |
| CAL 3 | Calibrator Level 3 |
| CAL 4 | Calibrator Level 4 |
| CAL 5 | Calibrator Level 5 |
| CAL 6 | Calibrator Level 6 |
|  | 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. CSLI document EP25-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.


## Serious incidents

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

## Modification from previous version

- Included CLSI references
- Included to perform new calibration according to the interval specified in the instrument-specific application notes
- Minor editorial changes and corrections throughout the document

## Date of issue

2024-08-28