

The Diasystem Vet canine CRP Immunoassay is an *in vitro* diagnostic test for quantitative determination of canine CRP in dog serum and plasma.

Ordering information

Referens	Cat. Nr	Kit size
Diasystem Vet Canine CRP Immunoassay	1000	R1: 2 x 27mL R2: 1 x 12,6mL
Diasystem Vet Canine CRP Immunoassay	1000b	R1: 1 x 90mL R2: 1 x 25mL

Indication for Use

The measurement of canine CRP is used to detect and monitor inflammation activity in dogs [1,2,3].

Summary

C-reactive protein is an acute phase protein produced in the liver hepatocytes as response to inflammatory stimuli [1]. Increased production of CRP can be detected 4-6 hours after induction with a peak concentration within 24-48 hours. After elimination of the inflammation, CRP levels rapidly decrease due to the short the half-life of CRP [1,4].

Principle

The canine serum or plasma sample is mixed with canine CRP immunoparticles. Canine CRP from the sample and the immunoparticles' anti-canine CRP aggregate. The complex particles created absorb light, and turbidimetric measurements of absorption are related to canine CRP concentration via interpolation on an established standard calibration curve.

Reagents

Components

R1: Canine CRP assay buffer is a MOPS [3-(N-Morpholino)-propane sulfonic acid] buffered saline with Tween, NaCl and PEG, containing avian proteins and preserved with ProClin® 950.

R2: Canine CRP immunoparticles. contains a purified immunoglobulin fraction directed against canine CRP, which is covalently attached to polystyrene nanoparticles in TRIS buffer.

Storage Instructions and Reagent Stability

All materials provided for the Diasystem Vet canine CRP test must be stored at 2-8°C. The expiry date is printed on the labels. Using an Abbott Architect c4000, the on-board stability of the Diasystem Vet canine CRP reagents was found to be at least eight weeks.

Warnings and Precautions

1. This test is for *in vitro* use only and must be handled by qualified personnel.
2. The immunoparticles, calibrators and controls contain potentially infectious substances of animal origin (avian, canine, bovine) and should be handled with due caution. Disposal of any discarded materials should be in accordance to local requirements.
3. R2 contains polystyrene nanoparticles.
4. Use only instrument applications validated and approved by Diasystem Vet AB.
5. Avoid using highly lipemic, icteric or hemolytic samples.
6. Avoid evaporation of controls and calibrators.
7. All reagents in use must be stored at 2-8°C.

8. Reagents containing sodium azide must be handled with due caution. Do not ingest or allow contact to skin or mucous membranes. The sodium azide concentration of this product is not characterized as dangerous. Yet, accumulated NaN₃ in lead and copper pipes may cause generation of explosive metal azides. To prevent this, rinse thoroughly if discarded into the drain.
9. Reagents containing MOPS can be irritating to eye and skin. Handle with caution.
10. Do not interchange screw caps of reagents, controls and calibrators.
11. Do not use reagents after expiration date has passed.
12. Do not mix reagents of different reagent lots.
13. Screw caps carefully after use of reagents, calibrators and controls to avoid evaporation.

Waste Management

Please refer to local legal requirements.

Materials required but not provided

Diasystem Vet Canine CRP Calibrator kit	REF 1001
Diasystem Vet Canine CRP Control kit	REF 1002
General laboratory equipment	

Specimen

Recommended sample material is canine serum, canine heparinized plasma or canine EDTA plasma. Analyze the samples as fresh as possible and mix them well in advance. Sample stability testing showed that canine CRP (in serum) was stable for 14 days at 4-22°C [5]. The samples can be shipped without any special cooling and must then be analyzed within 14 days after shipment. Samples have been tested and shown to withstand up to four freeze and thaw cycles [5].

Discard contaminated specimens!

Measuring Range

The measuring range of the Diasystem Vet Canine CRP assay is 10-300 mg/L on most instruments, with a security zone up to 1000 mg/L. Some analyzers have other valid measuring ranges. See instrument specific application notes for further information.

Normal Values

Healthy dogs have CRP concentrations < 10 mg/L with the Diasystem Vet Canine CRP method. An exact reference range cannot be determined as CRP concentrations in healthy dogs are below the LoQ of the Diasystem Vet Canine CRP assay.

Assay Procedure

Applications of the Diasystem Vet Canine CRP immunoassay have been established on several clinical chemistry analyzers. Detailed, validated application notes describing the procedures for installation and analysis on specific instruments are available upon request from info@diasystem.se The application must be installed with the specific instrument settings provided for the Diasystem Vet Canine CRP assay. 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.

Calibrators and Controls

Referens	Cat nr	Kit size
Diasystem Vet Canine CRP Calibrator	1001	6 x 0,5mL
Diasystem Vet Canine CRP Control kit	1002	2 x 0,5mL

Calibration Curve Establishment

Use the Diasystem Vet Canine CRP calibrator kit to establish a calibration curve as described in the instrument manual. The calibrator values are lot dependent. The assigned values of the calibrators are specified in the Analytical Value Sheet enclosed in the calibrator kit. Recalibration every 4th week is generally recommended. A recalibration must be performed when a new calibrator lot and/or a new reagent kit lot is used.

QC Controls

The Diasystem Vet Canine CRP controls should be assayed every day the test is in use to validate the calibration curve. The controls have lot dependent concentration ranges that must be met before measuring samples. The assigned value ranges are given in the Analytical Value Sheet enclosed in the control kit. 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.

Measuring Patient Samples

When a valid calibration curve has been established and the control values are within the valid range, canine serum or plasma samples may be measured. Check that minimum sample volume is present in sample cups/tubes and assay the samples according to the instructions given in the instrument manual.

Results

The results are calculated automatically by the analyzer and are presented in mg/L.

Reference Intervals

40 healthy dogs were included in a study to determine a reference interval. The lowest value observed was 0.2 mg/L, and the highest was 4.9 mg/L. The LoQ of the assay is 5 mg/L. Therefore, it is expected that healthy dogs measure up to 5 mg/L CRP. Results obtained on the Abbott Architect c4000. Each laboratory is recommended to determine a local reference interval since values may vary depending on the population tested and instrument used.

Performance Characteristics

See analyzer specific application notes.

Limitations

See analyzer specific application notes

Literature

1. Ceron et al. Vet Clin Pathol. 2005; 34: 85-99
2. Kjelgaard-Hansen; PhD Thesis. 2004
3. Eckersall et al. Vet J.2010; 185 (1):23-27
4. Pepys et al. J Clin Invest. 2003;111(12):1805-12
5. Hillström et al. Vet Clin Pathol. 2014; 43(2):235-43

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