eurisTest™

Canine C-Reactive Protein (CRP) - TurboReader™ Assay

Instruction For Use (IFU) manual- Version 6, October 2018

A quantitative point-of-care assay for CRP in canine (dog) plasma or serum using the TurboReader™ instrument.

FOR VETERINARY AND RESEARCH USE ONLY.

1 INTENDED USE

The canine CRP TurboReader™ assay is an immunoturbidimetric point-of-care immunoassay for the quantitative, *in vitro* determination of CRP in dogs, which can be a useful tool for monitoring systemic inflammation.

Art No.		
2530-01	Test Cuvettes (with blue cap)	40 pcs
	R2 cCRP Bottle	1 x 4.2 ml
	Instruction For Use (IFU)	1 pc

2 GENERAL DESCRIPTION[1-4]

CRP is a pentameric serum protein that consists of five 20 kDa subunits (of which two are glycosylated). The protein is a well-known acute phase reactant and its normal plasma concentrations in healthy dogs is <35 mg/l. CRP is a real-time diagnostic marker for systemic inflammation with plasma concentrations increasing approximately 4 hrs after stimulation, peaking around 24 hrs and clearing between 48-72 hrs after cessation of inflammatory conditions. Measurement of CRP has a large diagnostic window, increasing more than 10x the normal plasma concentrations during inflammatory activity. Clinical use of CRP is not limited to monitoring systemic inflammation, but can also be used for efficacy of selected treatment or monitoring post-operative conditions and surgery recovery.

3 ASSAY PRINCIPLE

The canine CRP TurboReader™ assay is a quantitative immunoturbidimetric point-of-care immunoassay for the detection of CRP in canine (dog) plasma or serum. The R2 cCRP bottle contains polyclonal antibodies against canine CRP. Upon mixing of reagents, the CRP antigen present in the canine sample together with the R2 reagent forms a precipitation reaction which yields a turbid solution. The turbidity of the solution is measured nephelometrically and is directly proportional to the concentration of CRP present in the canine sample.

4 COMPOSITION OF SUPPLIED REAGENTS

Contents	**Substance & Concentration**
Test Cuvette (with blue cap)	max 4% Polyethylene Glycol max 50 mM Tris buffer, pH 7.6 150 mM NaCl
R2 cCRP Bottle (1502-36)	goat anti(CRP)serum
Instruction For Use (IFU) (1810-03)	1 copy for laboratory

5 MATERIALS NEEDED BUT NOT SUPPLIED

- Sample (S) pipette (20 µl)
- R2 pipette (100 µl)
- Pipette tips
- cCRP Level 2 Control (2530-10)
- Disposable gloves
- NaCl solution, 0.9 % (w/v)
- TurboReader™ instrument

6 STORAGE & STABILITY

The test cuvette (with blue cap) and R2 cCRP bottle are supplied ready-to-use and are stable up to 12 months when stored at +2-8 °C. They may not be frozen. The test cuvette (with blue cap) can be stored at room temperature for one month. The R2 cCRP bottle must be stored at +2-8 °C, but can be used directly cold. Place caps carefully after use of kit reagents to avoid evaporation.

7 PRECAUTIONS

- FOR VETERINARY AND RESEARCH USE ONLY.
- Do not use after expiration date.
- Do not freeze any test reagents.
- Significant lipemia, hemolytic samples or high levels of detergents in sample may interfere with assay results.
- Follow Good Laboratory Practices. Wear a lab coat, use disposable gloves and keep laboratory area clean.
- Reagents are from animal origin and should always be handled with due caution.
- After use, the test should be discarded according to local regulations regarding biological and hazardous material.
- Make sure to insert the cuvette into the TurboReader™ instrument in the correct orientation (the arrow on the cuvette wall and on instrument must align).
- Avoid evaporation of reagents.

8 SAFETY & WASTE HANDLING

Only qualified laboratory personnel under appropriate laboratory conditions may use the reagents. CAUTION: kit components contain sodium azide (<0.1%) as preservative. Therefore, handle as hazardous material and wear disposable gloves, eye protection and a lab coat. Do not ingest! Avoid contact with skin, mucous membranes and eyes. If uncertain, consult expertise for help. Health and Data Sheets are available at request. Handling of waste should be done in accordance with national laws and local regulations.

9 SPECIMEN COLLECTION

Collect canine (dog) lithium heparin plasma or serum sample using a blood collection tube according to the manufacturer's instructions. Do not use EDTA collection tubes. The stability of canine CRP serum is 2 weeks at +2-8 °C.

European Institute of Science AB, IDEON Science Park, SE-223 70 Lund, Sweden
Phone: +46 46 286 22 30, Fax: +46 46 286 24 99, Email: info@euris.org, Web: www.euris.org

For long-term storage, the specimen must be kept frozen (<-20°C). Repetitive freezing and thawing cycles is not recommended. The sample must be completely thawed, thoroughly mixed and at room temperature before testing can occur.

10 INSTRUMENT PARAMETERS

Recommended parameter settings for the TurboReader™ instrument:

- Volume S (sample): 20 µl
- Volume R2 cCRP Bottle: 100 µl
- Reaction Time 1 (S): 1 min
- Reaction Time 2 (S+R2): 3 min
- Calibration: Multi-point (8 points)

11 PROCEDURE

Start TurboReader™ instrument and select NEW TEST. Scan the bar code on the R2 cCRP bottle to control the lot of reagent matches the stored calibration curve and then press RUN on the instrument touch screen. Use the sample (S) pipette to transfer 20 µl of the dog serum/plasma sample (or control) into an unused cuvette. Turn the cuvette slowly upside down 4 times (no bubbles should be introduced). Place the cuvette into the TurboReader™ and make sure it has the correct orientation (the arrow on the cuvette wall and on instrument must align). Select OK on the touch screen. After 1 minute the TurboReader™ will request the operator to remove the cuvette and add 100 µl R2 using the R2 pipette. Turn the cuvette slowly upside down 4 times (no bubbles should be introduced). Place the cuvette into the TurboReader™ and make sure it has the correct orientation (the arrow on the cuvette wall and on instrument must align). Select OK on the touch screen. After 3 minutes the TurboReader™ will display the concentration of cCRP.

12 CALIBRATION & QUALITY CONTROL

The TurboReader™ instrument is precalibrated (multi-point calibration) for each reagent lot and the lot specific calibration data is automatically transferred into the instrument using the 2D scanner and the bar code below (next column). For more information refer to the Calibration section in the TurboReader™ instrument manual.
In order to survey accuracy and precision, periodic Quality Control is recommended using cCRP Level 2 Control (Art. No. 2530-10). The cCRP Level 2 Control is supplied separately.

13 PERFORMANCE

Assay measuring range: The measuring range of the assay is 5 – 300 mg/l. Samples with canine CRP levels larger than 300 mg/l should be diluted 1:4 with 0.9 % (w/v) NaCl solution and the result multiplied with 4. For samples that are grossly lipemic or hemolytic, the instrument automatically changes the wavelength from 470 nm to 625 nm for measurement and then uses a modified algortihm for result calculation.

Sensitivity: The minimum level of detection is approximately 5 mg/l.

Prozone limit: No prozone effect can be observed for canine CRP concentrations of up to 1000 mg/l (1000 µg/ml).

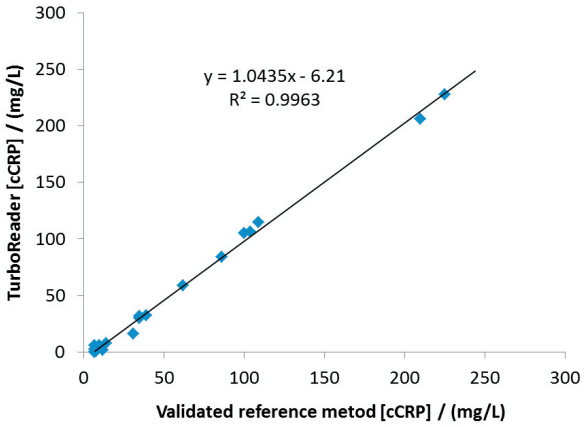
Specificity & Interference: The antiserum used is monospecific for canine CRP. It has not been shown to cross-react with other serum proteins under the conditions of the assay. However, the assay may be interfered by samples containing significant levels of lipemia, hemolysis or detergents.

Precision: The precisions of the assay is given in tables below.

Intra Assays Precision (n=5)	Mean mg/L	SD mg/L	CV %
Canine sample	119	4	4

Inter Assays Precision (n=8)	Mean mg/L	SD mg/L	CV %
Canine sample	102	6	6

Correlation with validated method: The assay performance has been compared with a validated reference method on 19 dog serum samples (see graph below).

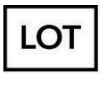


Normal ranges: The normal range of the CRP concentration in healthy dogs is <35 mg/L (35 µg/mL). Each laboratory should establish its own normal range which corresponds to local genetic and environmental factors.

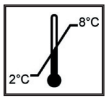
• Repetitive measurement of canine CRP can be used to determine if selective treatment is effective and for the monitoring of post-operative conditions and surgery recovery.

• Canine CRP results should be used with other clinical and diagnostic information for forming a diagnosis and for health management.

14 SYMBOLS KEY



Lot number



Temperature limit


Use by date


Irritant


Consult IFU


Manufacturer

Catalogue number


Content

15 REFERENCES

[1] Ganrot K., Plasma protein respons in experimental inflammation in dogs., Res. Exp. Med., 1973, 161(4), 251-261.

[2] Hansson L.O., Lindquist L. C-Reactive protein: its role in the diagnosis and follow-up od infectious diseases. Curr. Opin. Infect. Diseases, 1997, 10:196-201.

[3] Yamamoto S., Changes in serum C-reactive protein levels in dogs with various disorders and surgical traumas, Vet. Res. Com. 1993, 17:85-93.

[4] Kjelgaard-Hansen M., Lundorff Jensen A.T., Evaluation of a commercially available Human C-Reactive Protein (CRP) turbidimetric immunoassay for determination of Canine Serum CRP concentration, Vet Clin Pathology, 2003, 32:2, 81-84.

Manufactured by: European Institute of Science AB

Lot: 18E-097
Install Canine CRP:

European Institute of Science AB, IDEON Science Park, SE-223 70 Lund, Sweden
Phone: +46 46 286 22 30, Fax: +46 46 286 24 99, Email: info@euris.org, Web: www.euris.org