Canine C-Reactive Protein
Reagent Kit TP-812-RGT
Polystyrene Immunoturbidimetric test for the quantitative In-Vitro determination of canine C-reactive protein in serum or plasma on photometric systems

Intended Use
This in vitro veterinary research-only assay is designed to quantitatively measure canine C-reactive protein (CRP) concentration in serum and plasma. Components of the package are available as a kit only.

Application
C-reactive protein (CRP) is a positive acute phase protein. The serum level of CRP rises in animals that suffer from different types of infection or inflammation and is generally correlated with degree and activity of the causative disease. For this reason measurements of serum CRP are used to aid the evaluation of the inflammation associated with infection, tissue damage and other clinical disorders.

Materials required but not provided
Canine CRP immunoturbidimetric calibrator kit (Tridelta, Cat no. TP-812-CAL), Canine CRP immunoturbidimetric control kit (Tridelta, Cat no. TP-812-CON), serum or plasma collection equipment, sample containers, distilled H2O, vortex mixer, 20µl, 200µl and 1000µl pipettes, disposable tips, automated chemistry analyser and its requirements for use.

Additional settings can be found on our website at www.trideltaltd.com

Reagent preparation and use
The R1 and R2 reagents are provided ready to use and require no preparation. The R2 reagent should be inverted several times gently prior to use to resuspend any settled microparticles. Inversion of R2 should be performed periodically for extended on-board use.

Test Procedure
The chemistry parameters for this test are entered into the end-user’s system as specified for each respective automated chemistry analyser. Cobas Mira chemistry parameters are as follows and should be used as a guideline:

Sample volume: 2µl
R1: 250µl
R2: 50µl
Cycle: 1: Addition of R1 + sample
Cycle 7: Addition of R2
Read times: First 7: Last 27
Read wavelength: 600nm
Reagent blank: None
Calibration: LOGIT/LOG5
(Cobas Mira cycle time: 25 seconds)

Note: All patient samples and controls must be diluted in equal parts sample/control to equal parts 1X diluent buffer prior to assaying. If this function is not available onboard the analyzer it must be done manually.

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Calibration
The Canine CRP calibrator is provided in a separate kit by Tridelta (Cat no. TP-812-CAL). Calibration should be performed when the C-reactive protein test is established on an automated chemistry analyser. This calibration curve is automatically stored on the automated chemistry analyser once the test has been assigned to a reagent position.

Recalibration is required after a change of reagent bottles, a change of critical components, if control results fall outside the acceptable and established ranges or if the instrument undergoes any cleaning or maintenance. Calibration curve stability on the analyzer has been determined to be up to 8 weeks when the proper conditions are met.

The calibrator is supplied as a 60µg/ml stock which must be serial diluted using 1X diluent buffer. This can be done manually or by analysers with this function. The recommended calibration curve points are 60µg/ml, 30µg/ml, 15µg/ml, 7.5µg/ml and 0µg/ml.

Warning and Precautions
The test is for in vitro veterinary research use only. Do not use for determination of CRP concentrations in human specimens or for diagnostic use.

Avoid contact with eyes, skin and clothing. Wash thoroughly after handling. Avoid ingestion of reagents. Never pipette by mouth and wear disposable latex gloves and eye protection where appropriate.
**Sample Handling**

Use serum or lithium-heparin plasma. Serum and plasma samples may be stored for 24 hours at 2°C-8°C or for long-term at -20°C. It is important that frozen or refrigerated samples are brought to room temperature and mixed to ensure accurate determination of CRP concentration.

**Measuring range**

All samples and controls must be diluted with equal parts 1X diluent buffer prior to assaying. For samples returning values higher than the top calibrator (60µg/ml), the sample must be diluted 1 in 5 and reassayed.

**Quality Control**

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Controls results must fall within the established ranges, as determined by your laboratory. If results fall outside of the established ranges, assay results are invalid. Canine CRP immunoturbidimetric controls are provided by Tridelta in a separate kit (Cat no. TP-812-CON).

**Storage instructions and stability**

- **Unopened and stored at 2°C-8°C:** Unopened CRP reagents are stable until the last day of the month of the expiration date printed on the product label.
- **Opened and stored at 2°C-8°C:** Opened CRP reagents are stable for three months from date of first use of kit if kept closed in their original containers, free from contamination and at the recommended storage temperature.
- **On-board stability:** Opened CRP reagents have on-board stability at room temperature for up to forty-eight hours.
- **Protect all reagents from extreme heat or freezing.** In order to ensure maximum stability of the cCRP reagents on each automated chemistry analyser, it is important to use proper boats and anti-evaporation tray covers.

**Waste management**

Please refer to local legal requirements.

**Performance Characteristics**

Typical assay performance data provided has been established on a Cobas Mira and an Advia 1650. However, similar performance data should be attainable on other instruments.

**Calibration Curve:** A typical 5-point calibration curve

**ELISA (TP803) Vs Turbidimetric (Sample Comparison Evaluation)**

Additional performance characteristics are available from the Tridelta Development Ltd. website [www.trideltaltd.com](http://www.trideltaltd.com)

**Contact Details**

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