

# **Canine C-reactive Protein**

Control Set for control of precision of the quantitative immunoturbidimetric test for C-reactive Protein in canine serum or plasma.

#### Order information

Cat. No. TP812-CON

Level 1 Control: 1 x 0.2 ml

Level 2 Control: 1 x 0.2 ml

#### Intended Use

The CRP control set is intended for use with the Tridelta Canine CRP immunoturbidimetric kit (Cat No.TP-812). It is strictly for *in vitro* veterinary use as an aid in monitoring day-to-day assay performance. Components of the kit are available as a kit only.

## **Reagent Description**

#### Quality control materials provided

cCRP Level 1 Control: 1 x 0.2ml cCRP Level 2 Control: 1 x 0.2ml

The control material is prepared using canine CRP in a Tris buffered solution containing NaCl and CaCl<sub>2</sub>. Other additives are included to preserve the products characteristics.

#### **Warnings and Precautions**

For in vitro veterinary use only. Do not use control material if solution is not clear. Follow universal precautions and handle all components as if capable of transmitting infectious agents.

#### Materials required but not provided

Tridelta Canine CRP immunoturbidimetric kit (Cat No. TP-812), automated analyser, 20µl pipettes and disposable tips.

#### Reagent preparation and use

Ensure the control is at room temperature for approximately thirty minutes prior to use to ensure temperature equilibration. Mix by inversion at least 5 times to ensure homogeneity prior to use.

Refer to the Quality Control Procedure for instruction. Store any unused and undiluted material aliquoted at -20 °C. Prior to reuse, mix contents thoroughly.

# Storage instructions and stability

The storage and stability of the control set is as follows:

- Unopened control at -20°C: Unopened control is stable until the last day of the month printed on the outer box label.
- Opened control at -20°C: After opening this product is stable for 2 months if aliquoted at -20°C and free from contamination.

Protect all reagents from extreme heat.

#### **Waste Management**

Please refer to local requirements

#### **Quality Control Procedure**

Treat controls in the same manner as unknown samples. A specific lot number and the date the controls are opened should be recorded to identify each control.

The Canine CRP immunoturbidimetric test should be assessed using control material and kit calibrator. It is recommended the controls are tested with every calibration curve.

The required level of performance is achieved when the analyte values obtained for each control are within the "Acceptable Control Range" as determined by each laboratory.

# **Expected Values**

The expected control level is provided in table 1. However, laboratories should establish their own control range. The manufacturers stated ranges give an indication of where a customer's mean and range may be established, but the manufacturer's data is not an appropriate substitute for a mean and QC limits determined from each laboratory's actual data.

Table 1 (values in ug/ml)

Control	Mean	Range*
Level 1	18.02	10.79 - 25.25
Level 2	33.97	23.04 - 44.9

 Note: Ranges are provisional and may change as more information becomes available.

The laboratory should determine the performance of their measurement system and set an appropriate mean and QC limits for the control materials based on their own data. New lots of control material should be analysed in parallel with the control material in current use.

Controls should be monitored and charted routinely to analyse values and trends.

If control values fall outside the designated ranges and repetition of the assay excludes technical error, the following steps should be taken:

- Check expiry date of kit.
- 2. Check reaction temperature.
- 3. Check cleanliness of glassware and pipettes.
- 4. Check analyser settings.
- Check water. Contaminants such as bacterial growth may contribute to inaccurate results.

### **Contact Details**

For further information or technical assistance contact the company

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