SAMSUNG

PT10V CRP 1V

CRP

(REF IVR-PT11V)

Intended Use

The PT10V CRP 1V, used with the PT10V analyzer, is intended to be used for the *in vitro* quantitative determination of canine CRP (C-reactive protein) concentration in plasma or serum. For veterinary use only.

Order Information (IVR-PT11V)

[Provided Product]

- PT10V CRP 1V (IVR-PT11V) cartridges
- Packing unit : 20 cartridges per box

[Materials/Equipment required but not provided]

- PT10V Analyzer
- General lab tools necessary for the test

Clinical Significance and Testing Principles

[C-reactive protein (CRP)]

C-reactive protein (CRP) is a positive acute phase protein produced by the liver in response to stress such as infection, tissue damage, inflammation and other clinical disorders. Measurements of CRP are used to detect the severity and monitor systemic inflammation. Increased levels of CRP were described in dogs that suffered from pneumonia, pancreatitis, parvovirus infection. Blood concentrations of C-reactive protein in dogs with various diseases or undergoing various procedures were measured by specific immunoassay. PT10V CRP 1V adopted the antigen-antibody aggregation method. The aggregation is occurred by increasing CRP concentration, and is measured by reading the absorbance.

Test Procedure

[Calibration]

The calibration data for the test can be found using the QR code attached to the cartridge. You do not need to perform a separate calibration for the test.

[Sample Collection and Preparation]

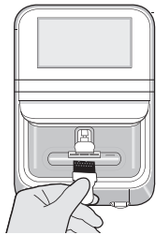
Always use a designated vessel (Lithium heparin) to collect and analyze a specimen. You can use either serum or plasma as a specimen. Perform the test as soon as the specimen is collected. This test requires a specimen volume of 70 ㎕.

[Testing]

1. Before opening, allow the refrigerated cartridge to reach room temperature (15 to 25 °C/59 to 77 °F).
2. Check that the PT10V Analyzer is turned on.
3. Open the product and dispense the sample into the cartridge. Keep the filled cartridge in horizontal position.

   CAUTION :
   - Do not touch the cartridge except for its handle with your hands. Contaminants from fingerprints or foreign substances may affect the results.
   - Dispense the sample into the center of the sample well. The entire sample well must be fully covered by the sample.
4. Open the door and insert the cartridge containing the sample into the analyzer. Close the door.
5. After pressing the **RUN** button on the analyzer, select the species and sample types to perform the analysis.

   CAUTION : If you cancel the test while it is in progress, the cartridge cannot be reused.
6. After completing the test, the test results will be displayed on the screen and the analyzer will beep.



For more information, refer to the user manual for the PT10V analyzer. We cannot guarantee the validity of any results obtained from unauthorized tests or protocol.

Quality Control

The frequency of equipment maintenance for quality control depends on the regulations of each individual lab.

Range of Analysis and Reference Values

Analyte (Unit)	Analysis Range	Reference Range
		Canine
CRP (mg/L)	7 - 120	0 - 10

The lower limit of the analysis range indicates the minimum measurable concentration for the substance.

If you are using the test results for diagnostic purposes, always consider other factors, such as the patient's clinical history, the results of clinical experiments, and other test results, before making a diagnosis.

CAUTION : For optimal analysis, refer to the user manual for the PT10V analyzer and perform the analysis according to the recommended procedure.

Reagent Components in the Cartridge

Analyte	Reagent
CRP	Anti-canine CRP antibody
	Stabilizer

Performance

[Precision]

We obtained the following results after performing the test for 20 days using the quality control materials according to CLSI EP5-A2.

Analyte	Level	Mean	SD	CV (%)
CRP	LOW	15.8 mg/L	0.8	5.0
	HIGH	62.1 mg/L	2.7	4.3

[Correlation]

We obtained the following results after comparing PT10V with Gentian canine CRP immunoassay on Roche P-modular using patient samples according to CLSI EP9-A2.

Analyte	Species	N	R	Slope	Intercept	Sample Range
CRP	Canine	291	0.97	0.99	0.60	7 - 120 mg/L

[Interference Substance]

Potential physiological interferents (from hemolysis, icterus, and lipemia) were tested at concentrations based on the testing levels in CLSI EP7-A2.

Analyte	Bilirubin (Icterus)	Intralipid (Lipemia)	Hemoglobin (Hemolysis)
CRP	400 mg/L	2,000 mg/L	5,000 mg/L

The highest tested concentrations may not cause significant interference. No significant interference with the PT10V CRP 1V was observed for the endogenous materials listed above if kept below the noted limit.

Interference with the results may occur in the following cases:

1. Presence of conjugated/unconjugated bilirubin (Icterus)
2. High hemoglobin concentration (Hemolysis)
3. Turbid specimen (Lipemia)

Precautions and Warnings

1. For veterinary *in vitro* diagnostic use only.
2. The PT10V cartridge is designed for professional use only.
3. Carefully read the analyzer and reagent manual before using the PT10V cartridge.
4. The results obtained from the PT10V cartridge do not provide a definitive diagnosis and should be interpreted by a veterinarian in conjugation with other appropriate test results and patient clinical finding.
5. Wear disposable gloves while handling specimen.
6. For preparation of specimens, it is recommended to follow the appropriate blood separation protocol.
7. Comply with the general precautions required in all laboratories, and refer to the Material Safety Data Sheet.
8. Samples and used cartridges should be treated as potentially infectious. The used cartridges and other wastes should be disposed according to the related regulations and guidelines.
9. Products left at room temperature should be used on the day of opening.
10. Keep the product in a sealed condition until testing. Use opened cartridges immediately.
11. An excessive or insufficient sample volume may result in the contamination or malfunction of the cartridge. You must comply with the recommended sample volume (65 - 80 ㎕).
12. Do not touch the cartridge except for its handle.
13. Do not reuse the cartridges. Cartridges may only be used once.
14. Do not use whole blood.
15. Close the door when is not using the analyzer.

Storage and Stability

Store the PT10V CRP 1V between 2 and 8 °C (35 to 46 °F).

- The product is usable until the expiration date indicated on the label.
- Do not use expired products. We cannot guarantee the validity of any results obtained from expired products.

For information on Samsung's environmental commitments and product specific regulatory obligations e.g. REACH, WEEE, Batteries, visit: Samsung.com/uk/aboutsamsung/samsungelectronics/corporatecitizenship/data_corner.html

State of California Proposition 65 Warning (US only)

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

Warranty

All specifications indicated on the cartridge label of the PT10V CRP 1V are warranted. This product can be exchanged or compensated in accordance with national regulations. If the product is expired or degraded upon purchase, we will exchange it through a vendor.

Symbols Used on the Label

SAMSUNG ELECTRONICS CO., LTD.
129, Samsung-ro, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea
Service E-mail: ivd.support@samsung.com