

skyla Reagent Kit



cCRP (Canine C-Reactive Protein)



For Veterinary Use Only

PN : 901-100

Rev : B

1. Intended Use

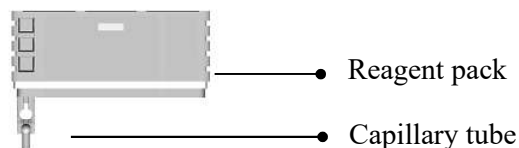
The skyla cCRP reagent kit used with skyla Analyzer, is intended to be used for the quantitative determination of canine C-reactive protein in plasma and serum.

Precaution/Waring

1. This product is for in vitro diagnostic use only
2. The product must not be used individually for diagnostic purpose.
3. The Reagent kit should be stored at 2-8 °C (35.6-46.4 °F).
4. Please were the gloves when performing the test.
5. Do not re-use any part of the test kit.
6. Dispose all waste in accordance with applicable national and/or local regulations.

2. Test Component

The skyla cCRP reagent kit consists of analysis cartridge and reagent pack (including of capillary tip for specimen collection).



3. Principles

The skyla cCRP reagent kit is a turbidimetric immunoassay using polyclonal antibodies against canine c-Reactive Protein (CRP) and allows to accurately determine the concentration of CRP in the sample.

When a sample is mixed with Buffer (R1) and Latex Reagent (R2), CRP in the sample combines specifically with the anti-canine CRP antibody bound to the latex particles in the Latex Reagent to yield an insoluble aggregate which causes increased turbidity in the solution. The degree of turbidity of solution can be measured optically and is proportional to the concentration of CRP in the patient's sample.

Clinical Significance:

C – reactive protein (CRP) is an acute phase protein produced by the liver in response to inflammation, infection and tissue injury. Increased CRP concentrations occur much earlier than with other acute phase reactants- within 4 to 6 hours- and this rapid response to trauma or infection is the distinguishing feature of CRP. In addition, CRP levels return to normal quickly at the end of an acute episode making CRP useful for both the detection of acute episodes as well as in treatment monitoring.

As in humans, canine CRP is mainly for use as an inflammation marker. It has also shown uses in the monitoring of disease and treatments. It can also be used to diagnose viral and bacterial infections and infectious diseases.

4. Reagents

Major Composition:

R1: 75 µL

- Glycine buffer (pH 9.0) 170 mmol/L, Sodium chloride 100 mmol/L, Sodium azide 0.95 g/L.

R2: 100 µL

- Latex particles coated with anti-canine CRP antibody, Glycine buffer (pH 7.4) 170 mmol/L, Sodium chloride 100 mmol/L, Sodium azide 0.95 g/L.

Reagent Storage:

- The reagent disc should be stored at 2~8°C.
- The expiry date of the reagent is printed on the outside of the sealed pouch of kit. Do not

use if the kit has expired.

5. Sample Preparation

- Specimens suitable for skyla cCRP reagent kit include lithium heparinized plasma, serum and quality control materials. The requirement of sample volume for each test is 2 μ L.
- If using a whole blood sample, the sample should be centrifuged with an appropriate centrifuge before the test.
- If applicable, local regulatory or standard operating procedures of your organization should be followed for the collection, preservation and handling of specimens.
- To analysis sample immediately after collection is recommended for good test result.

Note:

1. **The centrifugation of whole blood sample should be done within 60 minutes (at room temperature) in order to prevent cellulose precipitation in the blood.**
2. **Do not use specimens containing other coagulants. That would cause an incorrect test results.**
3. **The lipemic sample may affect result. For good test result, if the sample is cloudy obviously, the high speed centrifuge with force of 10,000 \times g is recommended to remove the lipid layer from the supernatant before the test.**

6. Test Procedures

Reagent kit Preparation

1. Tear the foil pouch from the notch on the edge and take out the skyla reagent kit. (includes an analysis cartridge & a reagent pack)

Note: Please retain the paper for sample collection purpose.

2. Take out the reagent pack from the analysis cartridge and remove the yellow cap on the capillary tube before using.

Sample Collection

3. Get the centrifugal sample.
4. Using a dropper or Pipette take up 1 drop of sample ($> 5 \mu$ L) from the tube.

Note: sample should be taken from the clear portion of the centrifuged sample.

5. Transfer the droplet onto the paper.
6. Within 3 min., use the reagent pack to collect the sample. Touch the sample with the capillary tube for about 3sec. Ensure that the capillary tube is fully-filled with the sample.

Performing a Testt

7. Insert the reagent pack into the analysis cartridge until the reagent pack cannot be pushed in further.
8. Place the analysis cartridge on the analysis carrier. Press “Start” button to eject the disc drawer.
9. Put the carrier on the tray. Press “OK” to begin the analysis.

Note:

- 1. To operate the cartridge or instrument, please wear lab gloves and other protective gear to avoid contamination by specimen.**
- 2. The used kit, tips, tissues should be discarded as biomedical waste, and treat according to the local legal requirements.**
- 3. Please perform the test immediately once the reagent kit is taken out from storage.**
- 4. Reagent kit retrieved from 2-8°C storage can be directly used without warming-up. If the cartridge or its package is damaged or is over the expiry date, do not use it.**

For details on the operating steps and instrument setting, please refer to “skyla Analyzer Operator’s Manual”.

7. Calibration

The barcode on every manufactured reagent kit contains all information required for calibration of the test items. The analyzer will automatically read the barcode information during testing.

8. Quality Control

- Please refer to the instruction manual for the preparation and use of quality control materials. For discrepancy results, the confirmatory test was suggested to carry out with the automated laboratory analyzer, or contact with our technical support.
- External quality control materials can be used for the accuracy monitor of skyla system. The recommended frequency of QC testing is as follow, otherwise please follow local legal requirements or the standard operating procedures of your organization.

- At least every 30 days.
- Before a new batch of reagents is used for testing.
- When the analyzer was moved or the operating environment significantly changes.

9. Reference Interval

The table below shows the reference interval for each test item. It is recommended that every laboratory or test site should establish its own reference interval from its particular patient population.

Test Item	Reference Interval	Reference Interval (SI Unit)
cCRP Canine	< 10 µg/mL	< 10 mg/L

10. Limitation

Physiological interferences in blood include hemolysis, icterus, and lipemia. For every test item, 2 levels of control solution, supplemented with known concentrations of the endogenous substances, were used for the testing. Significant interference is defined as a >20% shift in the test result.

Test Item	Substance concentration with interferences of less than 20%		
	Hemoglobin	Bilirubin	Intralipid
cCRP	400 mg/dL	34 mg/dL	0.4% (988 mg/dL TG)

11. Performance Characteristics

Dynamic range:











The dynamic range of cCRP reagent kit is as follows.

Test Item	Dynamic Range	Dynamic Range (SI Unit)
cCRP	5.0 - 200 µg/mL	5.0 - 200 mg/L

Imprecision:

Precision studies adopt control solution of high and low concentrations as test samples. Tests are performed 3 repeats a day for a total of 5 days. Results are shown in the table below.

Test Item	cCRP	
	Control, Low	Control, High
Level	Control, Low	Control, High
Unit	µg/mL	µg/mL
Mean	22.7	91.8
Std.	1.113	3.256
%CV	4.9%	3.5%

Symbol Index			
	Catalogue number		Consult instruction for use
	Batch code		Use by
	Manufacturer		CE mark
	Temperature limitation		Caution
	Do not reuse		Sufficient for

Supplier : SKYLA CORPORATION HSINCHU SCIENCE PARK BRANCH
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