Ksmart® CRP

Ref.: 1040012

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RAPID TEST FOR THE QUANTITATIVE DETECTION OF C-REACTIVE PROTEIN (CRP) ANTIGEN IN HUMAN CAPILLARY WHOLE BLOOD AND PLASMA.
For professional in vitro diagnostic use only.

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1 I INTENDED USE

Ksmart® CRP is a rapid fluorescence immunoassay for the quantitative *in vitro* detection of C-reactive Protein (CRP) antigen in human whole blood (capillary and heparinised venous blood) and plasma. This test is intended for use with the LabPad® Evolution only. The use of the Ksmart® CRP test is intended to aid in the rapid diagnosis of elevated CRP levels.

2 I SUMMARY

C-reactive protein (CRP) is an acute phase protein synthesised by the liver and is considered a sensitive systemic marker of inflammation and tissue damage. Concentrations of these acute phase proteins increase in the blood as early as 6 hours in acute inflammatory processes associated with bacterial infections, post-operative conditions or tissue damage.
It is generally accepted that serum CRP levels may rise from <5 mg/L (normal levels) to 500 mg/L during non-specific response to infectious and other acute inflammatory events[1,2,3].

3 I TEST PRINCIPLE

Ksmart® CRP is a rapid test that uses immunofluorescence for the quantitative determination of CRP levels in human whole blood or plasma. It should only be used with the LabPad® Evolution. The test consists of the following components: sample pad, reagent pad, reaction membrane and absorbent pad. The reaction pad contains fluorescently labelled monoclonal antibodies to CRP and the reaction membrane contains secondary monoclonal antibodies to CRP. The test strip is located inside a plastic cassette. When the sample is added to the sample well, the dry conjugates in the reaction buffer are dissolved and migrate with the sample. The CRP in the sample forms a reaction complex with the specific fluorescently labelled monoclonal antibodies. This complex migrates along the nitrocellulose membrane and moves towards the CRP detection line. The reaction complex is captured by the monoclonal antibodies bound at the detection line to form the final reaction. Under the action of the excitation light, a red band is detected by the analyser. As a procedural control, a red line appears in the control line area, indicating that the correct volume of sample has been added and the membrane has performed correctly.
The Ksmart® CRP test result is only intended to be read by the LabPad® Evolution.

4 I KIT CONTENTS

Equipment provided

- Ksmart® CRP tests in individual pouches with desiccant: x25
- Buffer tubes: x25
- End-to-end capillary pipettes: x25
  (for capillary whole blood only)
- Instructions for use: x1

Equipment required but not supplied

- Sterile lancets (gauge 21)
- LabPad® Evolution analyser (ref. 8001661)
  BIOSYNEX SA- 22 Boulevard Sébastien Brant
  67400 Illkirch-Graffenstaden, France
  www.biosynex.com - customers@biosynex.com
- Laboratory pipettes (for venous whole blood/plasma only)
- Timer (for incubation on bench)

5 I PRECAUTIONS

- Do not use after the expiry date.
- The test must be stored in its sealed pouch until its use. Do not use if the packaging is damaged.
- Pipettes, tubes and the test device are for single use only.
- Read carefully this IFU and the user manual of the Labpad® Evolution analyser before performing a test.
- All specimens should be considered as potentially infectious. Observe established precautions against microbiological hazards during the procedure and follow standard procedures for sample disposal.
- Follow good laboratory practice in collecting the sample and performing the test.
- Inadequate humidity and temperature conditions may affect the results. The subsequent steps of the test and the interpretation of the result should be performed in an area free of excessive humidity (< 85%) and with a temperature between 15°C and 30°C.
- Do not interchange or mix components from different batches.
- Safety data sheet available on request.
- An incorrect test procedure or a damaged device can lead to incorrect results. Other factors such as operational errors or sample-related factors can also lead to incorrect results.

6 I STORAGE AND STABILITY

The kit can be stored at room temperature or in the refrigerator. The storage temperature of the kit should be between 2°C and 30°C. DO NOT FREEZE the kit components. Use Ksmart® CRP tests within 2 hours of opening the sealed pouch.

7 I SAMPLE COLLECTION AND STORAGE

The Ksmart® CRP test can be performed on whole blood (capillary or venous) or plasma samples.

➢ Capillary whole blood sample collection:

1. Wash the patient's hand with soap and water or clean with an alcohol wipe and allow to dry.
2. Massage the hand without touching the puncture site from the base to the tip of the ring finger or middle finger.
3. Prick the fingertip with the lancet (gauge 21 recommended).
4. Gently rub the hand from palm to finger to form a round drop of blood on the puncture site. Wipe off this first drop with a paper towel.
5. Repeat step 4 to form another round drop of blood at the puncture site.
6. Use the capillary tube provided: place the end of the capillary horizontally in contact with the blood drop to collect the sample. The capillary fills by capillary action with 10 µL of blood. Repeat steps 5 and 6 until the capillary tube is completely filled with blood.

➢ Venous whole blood sample collection:

Use a heparinised tube to collect the venous blood sample. Perform the test immediately after collection to avoid haemolysis. If the test is to be performed at a later time, the venous blood sample can be stored at 2-8°C for up to 7 days before use.

➢ Plasma sample collection:

Use a heparinised tube to collect the venous blood sample. Separate the plasma as soon as possible after blood collection and test the sample as soon as possible. If the test is to be delayed, the sample can be stored at 2-8°C for 3 days or at -20°C for up to 7 days.

8 I TEST PROCEDURES

Allow the Ksmart®, sample and buffer tube to reach room temperature (15-30°C) prior to testing.

1. Prepare the LabPad® Evolution: turn on the LabPad® Evolution analyser (See LabPad® Evolution user manual for details).
2. Unpack the Ksmart® from the sealed pouch and place it horizontally on a clean, dry surface.

➢ Procedure for capillary blood samples:

3. Unscrew the black cap of the buffer tube and insert the capillary containing the blood sample.
4. Close the tube and invert until the capillary is empty of blood sample (approx. 30 seconds).
5. Unscrew the colorless cap of the buffer tube. Invert the tube vertically and transfer 2 drops of diluted sample into the sample well of the Ksmart®.
6. Leave the Ksmart® on the bench until the migration front reaches the bottom of the cassette, approximately 1 minute, and then insert it into LabPad® Evolution. The reader will automatically read the test at the appropriate time and the result will be displayed after 2 minutes.

➢ Procedure for venous blood or plasma samples:

3. Unscrew the black cap of the buffer tube and insert 10 µL of venous whole blood or 6 µL of plasma using a laboratory pipette.
4. Close the tube and invert for approx. 30 seconds.
5. Unscrew the transparent cap of the buffer tube. Invert the tube vertically and transfer 2 drops of diluted sample into the sample well of the Ksmart®.
6. Leave the Ksmart® on the bench until the migration front reaches the bottom of the cassette, approximately 1 minute, and then insert it into LabPad® Evolution. The reader will automatically read the test at the appropriate time and the result will be displayed after 2 minutes.

CAUTION :

- An air bubble may form when the transparent cap is opened. In this case, wipe the air bubble with a paper towel before placing the 2 drops of diluted sample into the well of the Ksmart®.
- After the sample has been placed in the Ksmart®, a migration front should be visible along the membrane. If this migration front does not appear within 30 seconds, add a third drop of diluted sample to the Ksmart® sample well.
- If the Ksmart® is inserted into the reader before the sample is fully absorbed into the well, this may cause the sample to migrate incorrectly which may result in an error message on the LabPad® Evolution. In this case, repeat the test with a new sample and a new Ksmart®.

9 I INTERPRETATION OF THE RESULTS

- LabPad® Evolution automatically determines the CRP level in the sample and displays the quantitative result on the screen.
- If the LabPad® Evolution displays an error message, please refer to the reader's user manual.

10 I QUALITY CONTROL

Quality control checks should be performed at regular intervals to verify the validity of the test and confirm the results obtained. It is recommended that a quality check be performed every 100 measurements or every 6 months to ensure that the test is performing well.

11 I MATRIX EQUIVALENCE

A matrix equivalence study was performed in the laboratory, using both community and hospital patients. Fingertip capillary blood, venous whole blood (heparin) and plasma (heparin) samples were collected. The data analysed are presented below.

Sample type	n	CRP range (mg/L)	r	Slope	Ordinate at origin
Capillary WB* / Plasma	69	0,5 - 179	0,97	0,93	-0,74
Venous WB* / Plasma	79	0,5 - 191	0,96	0,96	1,5
Capillary WB* / Venous WB	69	0,5 - 197	0,91	0,97	2,02

**WB: whole blood*

12 I LIMITATIONS

1. As with any diagnostic test, a confirmed diagnosis should only be made by a physician after evaluation of all laboratory data and clinical signs.
2. False positive results can be caused by cross-reaction of antibody-like components in the sample, and fluorescently labelled antibodies are captured by antigen-like groups of non-specific components in the sample.
3. False negative results can be caused by the following: some unknown components prevent antigenic determinants from binding to antibodies; the CRP antigen is broken down so that it cannot be recognised by antibodies. Effective test results depend on a good reagent and sample storage environment.

13 I PERFORMANCE CHARACTERISTICS

Measurement range

The Ksmart® CRP test used with the LabPad® Evolution analyser provides a quantitative CRP value in the range of 0.5 to 200 mg/L. The instrument displays CRP < 0.5 mg/L if the CRP concentration is below 0.5 mg/L and CRP > 200 mg/L if the CRP concentration is above 200 mg/L.

Linearity

In the linear range (0.5-200) mg/L, the linear correlation coefficient r≥0.990.

Limit of Detection (LoD)

The limit of detection of the Ksmart® CRP test is ≤ 0.5 mg/L.

Limit of Quantification (LoQ)

The limit of quantification of the Ksmart® CRP test is 0.5 mg/L.

Hook effect

No hook effect was observed with the Ksmart® CRP test at CRP concentrations up to 1,000 mg/L

Precision

Intra-run precision:
The intra-assay coefficient of variation is CV≤15%
Inter-run precision:
The inter-assay coefficient of variation is CV≤20%

Accuracy

The relative deviation should be [85%~115%].

Comparison of methods

A comparison study of the Ksmart® CRP test with the reference method Tina-quant® C-Reactive Protein 4: CRP4, on a Cobas® 6000 analyser, (Roche Diagnostics) was performed in the laboratory. Fingertip capillary blood samples and venous blood samples (heparin) were collected from city patients and hospital patients. Each sample tested on Ksmart® CRP and measured on the LabPad® Evolution was compared to serum tested on Cobas® CRP4 and measured on the Cobas® 6000. The data analysed by Deming regression is presented below:

Sample type	n	CRP range (mg/L)	r	Slope	Ordinate at origin
Capillary WB* / Sérum	69	1 - 179	0,96	1,09	-0,17
Venous WB* / Sérum	70	1 - 174	0,96	1,05	-0,17

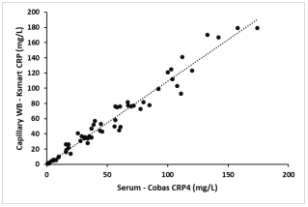

Fig 1 : Correlation between CRP measurement on capillary WB* (Ksmart® CRP; LabPad Evolution) and serum (Cobas® CRP4, Cobas® 6000)

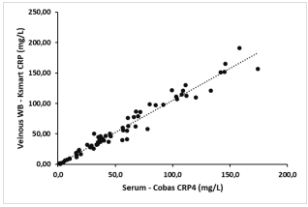

Fig 2 : Correlation between CRP measurement on venous blood (Ksmart® CRP; LabPad Evolution) and serum (Cobas® CRP4, Cobas® 6000).

**WB: whole blood*

Cross reaction

The Ksmart® CRP test has been tested with a range of potentially interfering substances.

Substance	Concentration
PCT	50 ng/mL
IL-6	100 pg/mL
Troponin-I	50 µg/mL
CK-MB	500 ng/mL
RF	575.6 UI/mL
D-dimer	10 µg/mL

The results showed no cross-reactivity.

Interfering substances

The following potentially interfering substances have been added to CRP negative and positive standards.

Substance	Concentration
Triglycerides	30 mg/mL
Bilirubin	5 mg/mL
Cholesterol	15 mg/mL
Haemoglobin	20 mg/mL
Glucose	20 mg/dL

None of the substances at the concentration tested interfered in the assay.

14 I LITERATURE

1. G. Fond; J.A. Micoulaud-Franchi; M. Faugere; L. Boyer; C. Faget-Agius; C. Lanyon; R. Richieri; M. Cermolacce. Abnormal C-reactive protein blood levels as a specific biomarker of major depression and non-remission under antidepressants in schizophrenia. Progress in Neuro-Psychopharmacology and Biological Psychiatry. 2020.97(000):109800-000.
2. Giancarlo Silvio Marenzi; JenessCampodonico; Nicola Cosentino; Claudia Lucci; Valentina Milazzo; Marco Moltrasio; Katia Celentano; Maria Luisa Biondi; Monica De Metrio; Mara Rubino; Ivana Marana; Marco Grazi; Gianfranco Lauri. HIGH-SENSITIVITY C-REACTIVE PROTEIN AND ACUTE KIDNEY INJURY IN PATIENTS WITH ACUTE MYOCARDIAL INFARCTION. Journal of the American College of Cardiology. 2020.75(11-Sup1):163-163.
3. Ming-Qing TANG; Xu-Hua MAO; Yi-Xin-Yue GONG; Lin-Sen QING; Jin XIE. Research Progress of C-reactive Protein Analysis. Chinese Journal of Analytical Chemistry. 2020.48(9):1121-1130

SYMBOLS

	Consult instructions for use	Σ	Contains sufficient for <n> tests	REF	Catalogue number
IVD	In vitro diagnostic medical device		Temperature limit		Do not reuse
	Manufacturer	LOT	Batch code		Use-by date
DIL	Buffer		Keep dry		Importer
CH REP	Swiss authorised representative		Do not use if package is damaged and consult the instructions for use		

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