LIODetect®CRP 10-60 Rapid Test

Rapid test for the semi-quantitative detection of CRP in serum, plasma or whole blood. Intended for professional in vitro diagnostic use.

REF: CRP-10-60_10_EN **Rev. 4.0 / 180524**

USAGE

The **LIODetect®CRP 10-60 Rapid Test** is a test for the semi-quantitative detection of CRP in serum, plasma or whole blood within 5 minutes (latest 10 min).
The test is intended for professional in vitro diagnostic use only.

SUMMARY

CRP (C-reactive protein) is an acute phase protein consisting of 5 identical polypeptide chains arranged in a cyclic pentamer. Each subunit contains a binding site for phosphocholine. When cells are destroyed, phosphocholine is released, bound by CRP, and a phagocytotic immunological response is initiated.
Elevated CRP values are a parameter for a local or systemic inflammatory response that can be caused by various forms of tissue damage such as infection, immunological / allergic reactions, burns, hypoxia-induced apoptosis (arteriosclerosis), trauma, surgery and cancer.

The **LIODetect®CRP 10-60 Rapid Test** is suitable for the semi-quantitative determination of CRP in serum, plasma or whole blood within 5 minutes (latest 10 min).

TEST PRINCIPLE

The test consists of a test strip installed in a cassette (test cassette). This test strip consists of the following components:

A special CRP-binding antibody, coupled with colloidal gold particles (conjugate).

A membrane with a **test line**, a **reference line**, and a **control line**.

Before performing the test, the sample must be diluted. Once the diluted sample (serum, plasma or whole blood) is pipetted into the sample well (S), it passes the gold-labelled CRP antibody (conjugate). The C-reactive protein in the sample binds to the conjugate. The CRP conjugate complex passes through the capillary action to the site on the membrane on which further CRP-binding antibodies are immobilized.

When C-reactive protein is present in the sample, it binds to the antibody on test line and a reddish line appears in the test zone (T) of the window of the Cassette. The remaining complex also migrates through the membrane until the reference zone (R) and then the control zone (C) is reached.

As a reference line, a reddish line appears which is compared with the intensity of the test line. A reddish line will also appear in the control zone indicating that the test has been performed correctly.

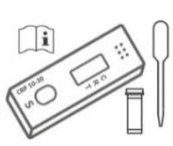
MATERIALS SUPPLIED

Pack sizes:

REF **CRP-10-60_10 (10 Tests):**

10 test cassettes.

TEST COMPONENTS



- Test cassette: individually sealed in an aluminium bag together with a disposable pipette.
- 10 End-to-end capillaries for measuring the samples, (5 µL, Na-Heparin), added according to Directive 93/42/EWG, manufacturer: KABE Labortechnik GmbH, Jägerhofstr. 17, D-51588 Nümbrecht, CE.
- 10 Mixing tubes for diluting the samples, filled with 1.25 mL CRP buffer solution.
- 1 Operating instructions

NOTE: Pictures may differ from the original.

ADDITIONAL REQUIRED MATERIALS, NOT INCLUDED

- Container for sample collection. We recommend the use of standard containers for blood sampling.
- Microliter pipettes and tips for 1-10 µL (optional for serum / plasma).
- Capillary holders or tweezers.
- Stopwatch

PREPARATION OF REAGENTS

Before use, warm all reagents to room temperature (preferably 15 - 30 ° C)! All reagents are ready for use. No further preparation of reagents necessary.

STABILITY AND STORAGE CONDITIONS

Store the test at 2 - 30 ° C. Unopened test components (aluminium bag and CRP buffer solution) are stable until the expiration date. The expiry date is printed on the labels of the aluminium bag, the bag with the mixing tube and the outer packing. Do not use if the aluminium bag is damaged. **DO NOT FREEZE** or expose to temperatures above 30 ° C.

Aluminium bag with test cassette: Store the test in an unopened aluminium bag at 2 - 30 ° C.

Open aluminium bag: Use test cassette within 4 hours!

Mixing vessels with buffer solution: Store the mixing tubes at 2 - 30 ° C. The buffer solution in the tubes is stable until the expiration date.

WARNINGS AND PRECAUTIONS

- In accordance with Good Laboratory Practice (GLP), all laboratory equipment should be regularly checked for accuracy and precision.
- Use all reagents within the shelf life (printed on labels).
- Do not use reagents from different kits or batches and avoid confusion of reagents from different kits or batches.
- Only for serum, plasma or whole blood. Do not use for other body fluids.
- Avoid contamination of reagents. Do not use the same container for multiple samples! Use separate end-to-end capillaries and disposable pipettes for each sample (included in the kit).
- Lipemic or bacterially contaminated samples must not be used.
- Avoid the use of turbid specimens, as it cannot be ruled out that these are bacterially contaminated.
- Avoid repeated thawing and freezing of the samples since the proteins could be denatured by this process.
- Do not pipette samples or buffer solution directly onto the membrane in the test window.
- Only for professional use! Do not swallow! Do not eat, drink or smoke in the lab! Do not work without protective clothing (gloves, goggles and laboratory gloves)! Avoid contact with kit reagents with skin, eyes and mucous membrane.
- All kit components should be considered infectious. Decontaminate and dispose of residues of kit reagents (test cassettes and CRP buffer solution) and samples according to local regulations, e.g. By autoclaving or using a disinfecting solution.
- Avoid touching the membrane with the fingers in the result window of the test cassette (risk of contamination).
- Do not pipet samples and buffer directly on the membrane in the result window.
- For single use only. The test is moisture sensitive. Do not use if the outer packaging (aluminium bag) is damaged. After opening the aluminium bag, the test cartridge must be used up within 4 hours.

SPECIMEN COLLECTION AND PREPARATION

The **LIODetect®CRP 10-60 Rapid Test** is suitable for the semi-quantitative detection of CRP in serum, plasma or whole blood within 5 minutes (latest 10 min). The test works best with fresh samples.

Recovery of whole blood from the vein: Remove the sample under standard laboratory conditions (aseptically and in such a way as to avoid haemolysis).

Recovery of whole blood from the finger:

- Disinfect your hands.
- Wear disposable gloves.
- Ask the patient to sit down.
- Disinfect the puncture site with a skin disinfectant.
- Wait for the disinfectant to evaporate.
- Puncture the skin with a sterile lancet.
- Massage the hand in the direction of the fingertip (Caution: Do not touch the intended puncture site!
- Discard the first drop and gently massage the hand from the wrist to the finger to effect the formation of a drop of blood.
- Hold the puncture point downwards (horizontal or slightly inclined) and take the blood droplets with a capillary (end-to-end?). In doing so, only touch the escaped blood with the capillary and avoid air pockets.

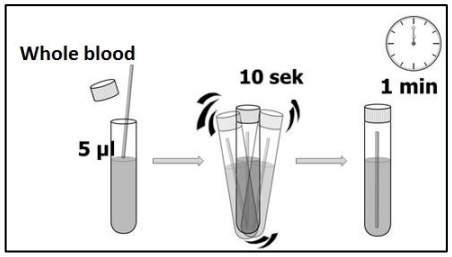
Serum or Plasma: As soon as possible, separate from red blood cells (e.g., by centrifugation).

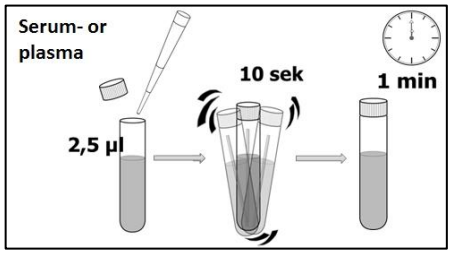
If the test cannot be carried out immediately after sampling, the samples can be stored at 2 - 8 ° C for up to 2 days. For prolonged storage, the whole blood must be centrifuged (separate serum or plasma from red blood cells). Serum and plasma can be stored at temperatures below -20 ° C. Frozen samples must be thawed and thoroughly mixed before the test is carried out. Avoid repeated thawing and freezing of the samples!

PREPARATION OF THE SAMPLES:

Before the test is carried out, the samples must be diluted. The samples are diluted in the supplied mixing tubes.

Short reference guide sample preparation:





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CE

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REF: CRP-10-60_10 **Rev. 4.0 / 180524**

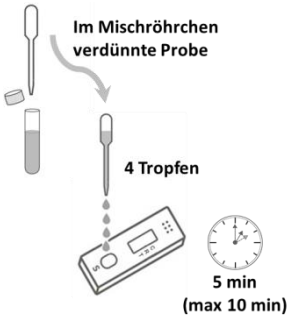
1. For each test to be performed, remove a mixing tube containing buffer solution.
2. Record patient's name or patient number on the mixing tube.
3. **For whole blood:**
   Using an end-to-end capillary, remove 5 µL from the blood sample. Hold the capillary with a capillary holder or tweezers. Caution: the end-to-end capillary must be filled to the upper end. The capillary then appears red. Insert the end-to-end capillary filled with blood into the mixing tube filled with buffer solution.

   For serum- or plasma:
   Using a microliter pipette, remove 2.5 µL from the sample.
   Pipette the 2.5 µL sample into the mixing tube filled with buffer solution.
4. Close the tube and shake the sample vigorously by hand for about 10 seconds to mix the blood with the buffer. The end-to-end capillary should not be red.
5. Allow the sample to rest for about 1 minute. The sample can then either be used immediately or stored for up to 8 h at 2 - 8 ° C.

TEST PROCEDURE

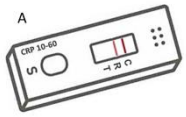
Note: After opening the aluminium bag, the test should be carried out within 4 hours as the test strip is sensitive to humidity.

SHORT INSTRUCTIONS



6. Remove the number of test cartridges to be used. Remove the aluminium bag and place the cassette (s) on a clean, non-absorbent, flat surface.
7. Insert 4 drops from the mixing tube into the sample well (S) on the cassette. Use the disposable pipette included in the pack or alternatively a microliter pipette (sample volume approx. 150 - 160 µL).
8. Start the stopwatch and read the results after 5 minutes (latest 10 min).

INTERPRETATION OF RESULTS



NEGATIVE (Fig. A): Only two reddish lines appear, the control line „C“ and the reference line „R“.

POSITIVE: Three reddish lines appear. One line is in the control zone „C“, a second line in the reference zone „R“, and a third line in the test zone „T“.

The control line „C“ indicates that the test has been performed correctly. The test line „T“ may be stronger or weaker than the reference line „R“.

Fig. B: Test line „T“ with a weaker intensity than the reference line „R“ indicates that the CRP concentration in the sample is between 10-60 mg / L.

Fig. C: Test line „T“ with a comparable intensity to the reference line „R“ indicates that the CRP concentration in the sample is about 60 mg / L.

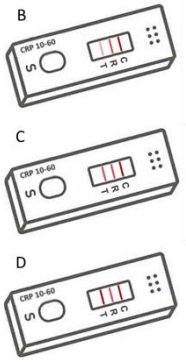


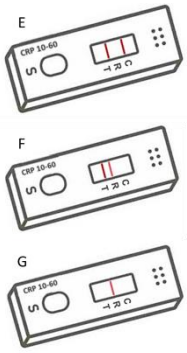
Fig. D: Test line „T“ Test with a stronger intensity than the reference line (R) indicates that the CRP concentration in the sample is more than 60 mg / L.

INVALID: No control line and / or reference line visible (Fig. E-G) and / or formation of background colouring (affects the readability of the test result).

Causes: Insufficient sample volume, incorrect pre-paration, or incorrect application are the most likely reasons for a missing control line and / or background colouring affecting the legibility of the lines. Check the sample preparation and the test procedure and repeat the test with a new test cassette. If the problem persists, do not continue to use the test kit and contact the manufacturer or local sales representative.

Fig. E: No reference line „R“ visible.

Fig. F-G: No control line „C“ visible and / or formation of background colouring (affects the readability of the test result).



QUALITY MONITORING OF RESULTS

The CRP 10-60 RapidTest contains an internal control. A reddish line, which appears in the control zone „C“, serves as a positive process control. It confirms sufficient sample volume and correct test performance. A clear background is an internal negative test control. If a background colouring appears in the result window and the readability of the test result is impaired, the result may be invalid.

PERFORMANCE CHARACTERISTICS

The cut-off of the test is adjusted to aproximate10 mg/L (8 – 10 mg/L; Reference material: international Reference Standard WHO 85/506). At concentrations up to 1000 mg/L no high dose Hook-Effect appears.

To verify the cut-off the results of **LIODetect®CRP 10-60 Rapid Test** are compared by the results of the clinical laboratories. 55 samples with known CRP concentrations are measured to evaluate clinical sensitivity and specificity (Clinical laboratories, ranges of 0.17 – 189.9 mg/L). The results of the comparative study are summarized in the following table:

Method		Clinical laboratory results		
		Negative	Positive	
	Ranges	< 8 - 10 mg/L	10 - 60 mg/L	≥ 60 mg/L
CRP 10-60 Negative	< 8 - 10 mg/L	19	0	0
CRP 10-60 Positive	10 - 60 mg/L	1	24	0
CRP 10-60 Positive	≥ 60 mg/L	0	1	10
Total result		20	25	10
% Concordance		95.00	96.00	100*

*Due to the small number of samples tested exact sensitivity cannot be predicted. Sensitivity is probably > 99 %.

LIMITATIONS

Follow the instructions of the test procedure and interpretation of results carefully!

- **The LIODetect®CRP 10-60 Rapid Test** is a test for the semi-quantitative detection of CRP in serum, plasma or whole blood within 5 minutes (latest 10 min). For the measurement of other body fluids this test is not validated and can give incorrect results.
- The test is only for professional in-vitro diagnostic use.
- The test result should be read after 5 minutes (at the latest 10 minutes). Subsequent lines should not be considered.
- A definitive clinical diagnosis should be based on an evaluation of all clinical and laboratory findings by a doctor, and not only through the results of one single test. If a sample was tested negative further measurements must be done if clinical symptoms are present. If a patient sample was tested as positive, more confirmatory tests should be performed. For a final diagnosis, include all information available for a patient.
- Detection of viral infections is not possible by this test.
- Individual variation of CRP levels is relative high. General values above 10 mg/L should be considered as increased. CRP is not a specific marker for a certain disease.
- A very weak test line „T“ detects, that the CRP-concentration in the sample is near to the cut off (< 10 mg/L).

Interfering Substances:
Samples are spiked by the following interfering substances:

Acetaminophen	20 mg/dL
Acetylsalicyl acid	20 mg/dL
Ascorbin acid	20 mg/dL
Atropin	20 mg/dL
Coffein	20 mg/dL
2,5-Dihydroxybenzoic acid	20 mg/dL
EDTA	20 mg/dL
Glucose	2000 mg/dL
Li-Heparin	3 mg/dL
Mestranol	3 mg/dL
Na-Heparin	3 mg/dL
Tetracycline	20 mg/dL

No interference is observed for one of the substances tested.

LITERATURE

Caswell M. Effect of patient age on tests of the acute-phase response. Arch Pathol Lab Med 1993; 117:906909

Andersson RE et. al. World J Surg. 1999 Feb;23(2):133-40.

Macy EM1, Hayes TE, Tracy RP.. Clin Chem. 1997 Jan;43(1): 52-8.

Morley JJ, Kushner I. Ann N Y Acad Sci. 1982; 389:406-18. PMID: 6953917

	Gebrauchsanweisung beachten	IVD	Only for in-vitro Diagnostik		Expiry/ valid till		Protect from humidity
	Hersteller		For single euse		Do not use if external packing is damaged	CE	Confirms to IVD-Guidline 98/79/EG
2°C 30°C	Lagerung bei 2 - 30°C	LOT	Lot number	Σ	For <x> tests	REF	Catalog Number