Instructions for Use – Combi

RENESA

Rapid Test for h-FABP and cTnI

Immunological rapid test for the determination of heart Fatty Acid-Binding Protein and cardiac Troponin I

Indication
This point of care test is to be used if the occurrence of an acute myocardial infarction (AMI) is suspected. It serves to verify or rule out an AMI by detecting heart Fatty Acid-Binding Protein (h-FABP) and cardiac Troponin I (cTnI).

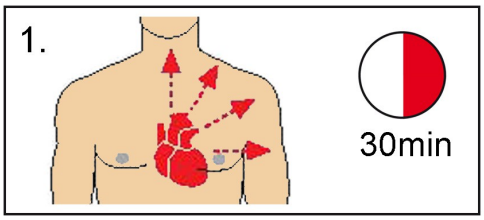
Diagnostic Window
The test can be used between 30 minutes and 10 days after an infarction. The diagnostic window of h-FABP is 30 minutes to 24 hours after the infarction. The diagnostic window of cTnI is 3 hours to 10 days.

Sample Material
The test may be performed with capillary or venous whole blood, serum or plasma.

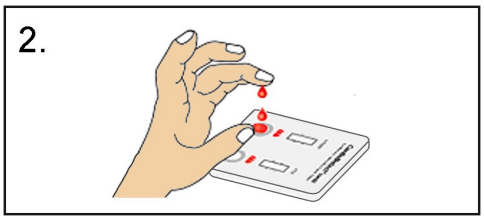
Sample Volume
- h-FABP 70µl. Corresponds to 2 drops of finger blood. Visual control: The funnel should be filled 2/3rd.
- cTnI: 100µl. Corresponds to 3 drops for of finger blood. Visual control: The funnel should be filled completely.

Handling of Samples
Perform the testing as soon as possible after taking the sample. Keep the sample as short as possible at room temperature. Warm up cooled probes to room temperature and mix them carefully prior to testing. The samples must be homogene and not haemolysed. Citrate and Heparin may be used as anticoagulant agent. EDTA may not be used.
Whole blood can be stored for 8h at 2-8°C. Serum and plasma can be stored for 2 days at 2-8°C or be frozen (at -18°C) for later testing.

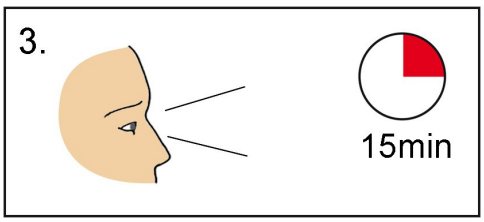
Application
1. Make sure that at least 30 minutes have passed since onset of symptoms.



2. Open a pouch and place the test on a clean and even surface. Apply the sample to both funnels.

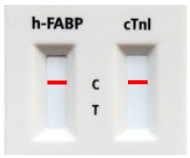


3. Wait for 15 minutes. Then read the result in the test result window above the test field.

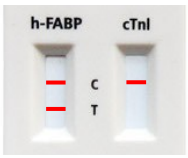


Please Note:
- Pay attention to use the specified sample volume! Insufficient sample volume is the main cause for invalid measurements.
- Peripheral blood draw: It is recommended to massage the finger and to clean it with alcohol prior to the punctuation.
- Open the pouch shortly before using the test. Do not use the test if it is expired or if the pouch is damaged.
- Always consider the sample as potentially infectious and take the appropriate precautions.

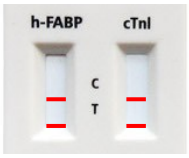
Evaluation
A positive result of one or both markers indicates that the concentration of the corresponding marker in the sample is above the threshold of the test. This indicates a high probability of acute myocardial cellular damage.
A negative result implies that the concentration of the corresponding marker in the sample is below the test threshold. Acute myocardial damage is not likely.



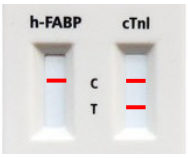
No infarction or infarction outside the diagnostic window



Infarction since 30 minutes to 1 day*



Infarction since 30 minutes to 10 days*



Infarction since 1 day to 10 days*

* *The actual values may differ*

Result of the h-FABP test	Interpretation	Marker value
2 clear lines (at "C" and at "T")	Positive	> 7ng/ml
Clear line at "C" but "T" line faint	Intermediate	~ 7ng/ml
Only 1 line at "C"	Negative	< 7ng/ml
No line or only one line at "T"	Invalid	
Result of the cTnI test	**Interpretation**	**Marker value**
2 lines (at "C" and at "T")	Positive	> 1ng/ml
Only 1 line at "C"	Negative	< 1ng/ml
No line or only one line at "T"	Invalid	

Please Note:
- If the T-line of the h-FABP test is faint than the concentration of h-FABP is close to the threshold. In this case it is recommended to repeat the test after 2 hours to exclude side effects (see "Limitations and Interferences"). An infarction is likely if the new T-line is identical or darker than the one of the first testing.
- In case of excessive sample volume the lower part of the window on the card may turn reddish. This is the effect of the passing of erythrocytes and does not affect the test result.
- The runtime of the test is 15 minutes. Do not read the result later than after 20 minutes, because the lines grow darker by time.
- For the same reason the lines of consecutive measurements cannot be compared directly.
- If required, the measurement may be quantified using a reader from RENESA.

Limitations and Interferences
- A false negative result can never be completely ruled out, especially if the test is performed at the time limit of the diagnostic window (see "Diagnostic window"). A negative test result does not rule out the possibility that a myocardial infarction has occurred! No drugs are known which affect the test when dispensed in therapeutic doses.
- h-FABP can be elevated in patients with renal insufficiency or angina pectoris. In low amounts h-FABP is also present in skeletal muscle. Therefore, it can be elevated in individuals that did sport prior to the testing and in professional athletes. In these cases a false positive result is possible.
- cTnI concentration can be elevated in patients who have a coronary bypass. Samples that contain an unusually high concentration of heterophil antibodies or rheumatic factors (RF) can influence the test result.

Test Principle
h-FABP is a protein almost exclusively found in the myocardium. It is released when the myocardial cells are damaged.
Troponin ITC is present in the myocardium as a complex. Following a myocardial infarction this complex is released into the blood stream where it splits into its components TnI, TnT and TnC.
- h-FABP: The test contains two different monoclonal antibodies specific for cardiac FABP, one of which is gold- labelled. The sample liquid releases the gold-labelled anti-FABP-antibody from its matrix. This antibody forms an intermediary complex with the h-FABP present in the sample. This complex spreads across the test strip up to the position marked by a "T" where a second antibody is located. The intermediary complex and the second antibody form a sandwich complex showing up as a red line. A sample without h-FABP does not form a sandwich complex and, therefore, forms no red line.
- cTnI: If the sample contains cTnI, it interacts with anti-cTnI-antibodies and particles coated with biotinylised anti-cTnI-antibodies. This complex passes over the test strip up to the position marked with a "T" where a line is coated with Streptavidin. The complex reacts with the Streptavidin showing up as a red line. A sample without cTnI forms no red line.

Integrated Function Control
The functioning of the test is indicated by the red control line at the position of the 'C' mark, because the excessive gold-labelled antibodies gather here. This control line is formed if the sample has properly passed across the test field. This occurs irrespective of the concentration of the analyte in the sample. The test result is only valid if this line appears.

Reactive Components
- Each test for h-FABP contains:
  Monoclonal anti-h-FABP-antibodies
  Monoclonal anti-h-FABP-antibodies conjugated to colloidal gold
  goat-anti-mouse IgG
- Each test of Troponin I contains:
  Anti-cTnI particles,
  Biotinylated anti-cTnI antibodies
  Streptavidin

Performance Characteristics

h-FABP	<3h	3-6h	6-12h
Sensitivity	90.5%	93.2%	94.6%
Specificity	64.6%	95.2%	99.4%
cTnI	99% positive and negative correlation to a CE approved test from another manufacturer		

Storage and Stability
The test can be used until the date printed on the pouch and on the box if stored at room temperature (2-25°C). Do not use the test beyond the expiration date. Alternatively it can be stored at 26-40°C for two months. Differing storing conditions can render the test unusable. The test must remain in the sealed pouch until use.

Presentation

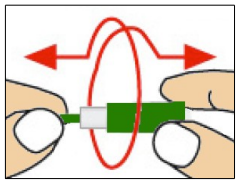
Combi 2	11303000	2 Disposable tests, automatic lancets
Combi 5	11304000	5 Disposable tests, automatic lancets
Combi 10	11300000	10 Disposable tests
Combi 25	11301000	25 Disposable tests

Required Material not included
- Lancets if peripheral blood is used (included in small packages)
- Syringes and cannulae if venous blood is used
- Chronometer

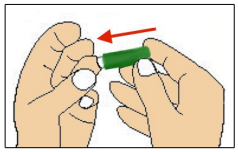
Disposal
Spent tests may be discarded as regular domestic waste. Observe the applicable local regulations. The components are non hazardous under EU regulations. They may also be safely incinerated.

Handling of Automatic Lancets
The small packaging sizes contain automatic lancets. Their needle is protected by a green pin.

1. Turn the green pin.
2. Pull it out.
   (Caution: The lancet will be damaged if you did not turn the pin previously).



3. Press the lancet against the tip of a finger until the spring is activated (preferably against a side of the tip to facilitate proper formation of blood drops).



References

- Figiel L, Kasprazek JD, Peruga J, Lipiec P, Drozdz P, Krzeminska-Pakula M, Smigielski J. Heart-type fatty acid binding protein – a reliable marker of myocardial necrosis in a eterogeneous group of patients with acute coronary syndrome without persistent ST elevation. Kardiol Pol (2008) 66: 253-259
- Ecollan P, Collet JP, Boon G, Tanguy ML, Fievet ML, Haas R, Bertho N, Siami S, Hubert JC, Coriat P, Montalescot G. Pre-hospital detection of acute myocardial infarction with ultra-rapid human fatty acid-binding protein (H-FABP) immunoassay. Int J of Card 119 (2007) 349–354
- Alhashemi JA. Diagnostic accuracy of a bedside qualitative immunochromatographic test for acute myocardial infarction. American J of Emergency Medicine (2006) 24, 149–155

IN VITRO DIAGNOSTICS (IVD)
For professional use only. Private consumers should not use the test, but inform an emergency physician about their symptoms.

Manufacturer:
RENESA UG
(haftungsbeschraenkt)
Hauptstr. 30
D-10817 Berlin

Tel: +49 (0)30 7871 0911
Email: info@renesa.de
Web: www.renesa.de

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