

# RENESA Cardiac Tests

## Point of Care Tests for Acute Myocardial Infarction

RENESA's In Vitro Diagnostic devices (IVD) for AMI are used when the occurrence of an acute myocardial infarction is suspected. They serve to verify or rule out an AMI by detecting the cardiac markers heart-specific Fatty Acid-Binding Protein (h-FABP) and/or cardiac Troponin I (cTnI).

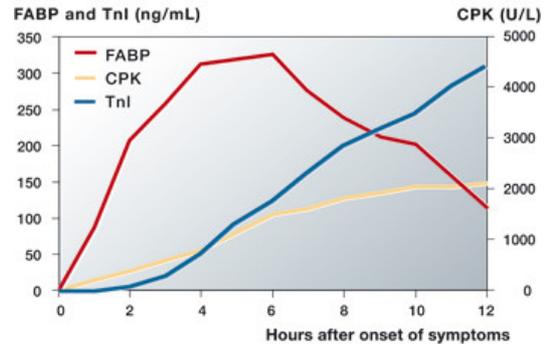
rise and fall characteristics. In contrast, the individual Troponins rise much slower, but can be detected over a long period of time.

### Functional Principle

In the myocardium the protein *heart-specific Fatty Acid-Binding Protein* (h-FABP) and the protein complex *Troponin ITC* are present. Both are released into the blood stream following myocardial necrosis. In the blood stream the Troponin complex splits into its components cTnI, cTnT, and cTnC.

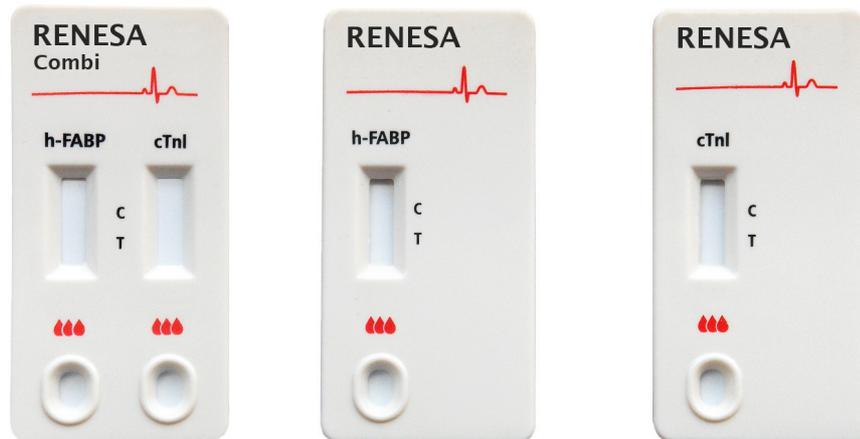
The h-FABP protein is much smaller than the Troponin complex and not structurally bound, resulting in a sharp

Marker Concentration in Blood after AMI



### Product Versions

The markers h-FABP and cTnI are provided as a combined or individual test:



	Combi	h-FABP	cTnI
<b>Cardiac marker</b>	h-FABP + cTnI	h-FABP	cTnI
<b>Application</b>	Early and late testing	Early testing	Late testing
<b>Diagnostic window</b>	30 min to 10 days	30 min to 24 h	4 hours to 10 days
<b>Sample material</b>	Full blood, serum or plasma		
<b>Sample volume</b>	h-FABP: 70µl cTnI: 100µl	70µl	100µl
<b>Sample preparation</b>	No preparation and no buffer required		
<b>Threshold</b>	h-FABP: 7.0ng/ml cTnI: 1.0ng/ml	7.0ng/ml	1.0ng/ml
<b>Run-Trough time</b>	15 min		
<b>Shelf life and Storage</b>	18 months at 2°C-25°C or alternatively 2 months at up to 40°C		
<b>Approval</b>	CE		

## Test Principle

The sample is applied to the funnel on the lower end of the cartridge. Thereafter, the sample liquid flows along the dipstick. In the result window a red line appears at the position "T" in case that the concentration of the cardiac marker is above the corresponding cut-off (positive). Positive test results are highly indicative of an acute myocardial infarction.

## 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% correlation to a leading CE approved test from another manufacturer (for positive as well as negative samples)		

## Integrated Quality Control

A red line at "C" signals proper functioning of the test.

## Presentation

Qualitative Tests	Order No.	Content
Combi 2	1001002	2 x Disposable h-FABP + cTnI tests, automatic lancets
Combi 5	1001005	5 x Disposable h-FABP + cTnI tests, automatic lancets
Combi 10	1001010	10 x Disposable h-FABP + cTnI tests
Combi 25	1001025	25 x Disposable h-FABP + cTnI tests
h-FABP 2	1002002	2 x Disposable h-FABP tests, automatic lancets
h-FABP 5	1002005	5 x Disposable h-FABP tests, automatic lancets
h-FABP 10	1002010	10 x Disposable h-FABP tests
h-FABP 25	1002025	25 x Disposable h-FABP tests
cTnI 5	1003005	5 x Disposable cTnI tests, automatic lancets
cTnI 10	1003010	10 x Disposable cTnI tests
cTnI 25	1003025	25 x Disposable cTnI tests

Quantitative Tests*	Order No.	Content
Combi-R 25	1001110	25 x Disposable quantitative h-FABP+cTnI tests
h-FABP-R 25	1002025	25 x Disposable quantitative h-FABP tests
cTnI-R 25	1003025	25 x Disposable quantitative cTnI tests
Reader R1	2001010	Reader for quantification of RENESA tests
Barcode Reader	2001011	Accessory for the Reader
Mobile Printer	2001012	Accessory for the Reader
Car Adapter	2001013	Accessory for the Reader

\*require the reader R1

## Manufacturer

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## Limitations

A negative test result does not exclude the possibility that a myocardial infarction has taken place! Especially if the testing is performed at the boarder of the diagnostic window (see table). No drugs are known at present to interfere in therapeutic concentrations.

*h-FABP*: In patients with renal insufficiency or angina pectoris a false positive result can not be excluded. In low amounts h-FABP is also present in skeletal muscle. Therefore, for individuals that performed rigorously prior to the testing and for athletes a false positive result can not be excluded.

*cTnI*: Cardiac Troponin I can be elevated in patients that underwent coronary bypass surgery. Samples that contain an unusually high concentration of heterophil antibodies or rheumatic factors (RF) can influence the test result.

## Optional Quantification

The reader system R1 in combination with reader specific test versions (-R versions) allows for quantification of the above parameters.