

CardioDetect[®] Data Sheet

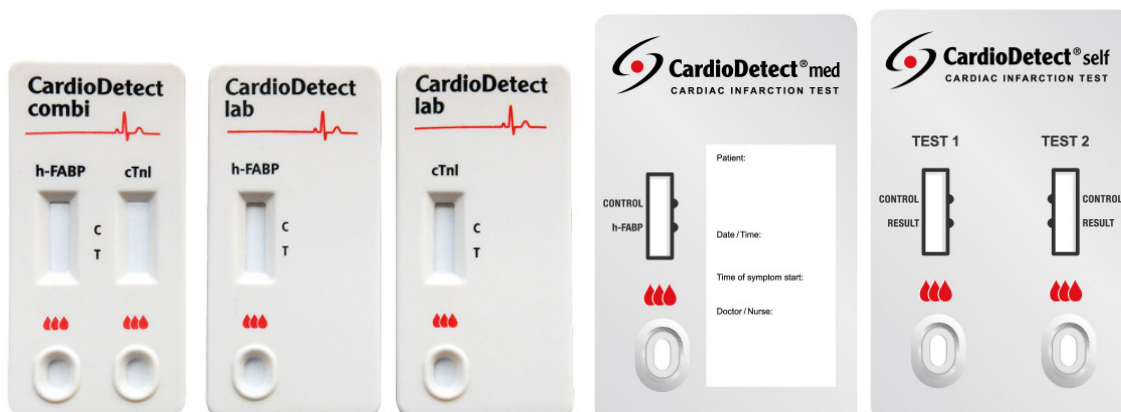
Qualitative Rapid Test for Cardiac Markers

CardioDetect is an In Vitro Diagnostic (IVD) used if the occurrence of an acute myocardial infarction (AMI) is suspected. It serves to verify or rule out an

AMI by detecting the cardiac markers heart-specific Fatty Acid-Binding Protein (h-FABP) and cardiac Troponin I (cTnI).

Product Versions

Five test versions are available corresponding to the different applications:



CardioDetect[®] combi

CardioDetect[®] lab h-FABP
CardioDetect[®] lab cTnI

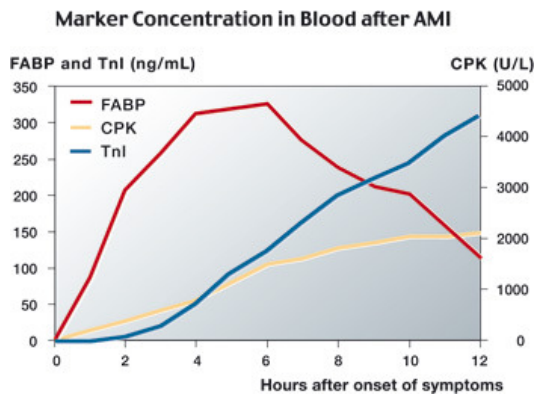
CardioDetect[®] med

CardioDetect[®] self

User	Professional	Professional	Professional	Home use
Application	Early and late testing	lab h-FABP: Early testing lab cTnI: Late testing	Early testing	Early self testing
Cardiac marker	h-FABP + cTnI	lab h-FABP: h-FABP lab cTnI: cTnI	h-FABP	h-FABP
Type of tests on each device	1 x h-FABP 1 x cTnI	lab h-FABP: 1 x h-FABP lab cTnI: 1 x cTnI	1 x h-FABP	2 x h-FABP
Threshold	h-FABP: 7ng/ml cTnI: 1.0 ng/ml	lab h-FABP: 7ng/ml lab cTnI: 1.0 ng/ml	h-FABP: 7ng/ml	h-FABP: 7ng/ml
Sample material	Full blood, serum or plasma (100µl/ marker)	Full blood, serum or plasma (100µl)	Full blood, serum or plasma (80µl)	Full blood, serum or plasma (80µl/marker)
Diagnostic window	30 min to 10 days	lab h-FABP: 30 min to 24 h lab cTnI: 4 hours to 10 days	30 min to 24 hours	30 min to 24 hours
Reading time	15 min	15 min	15 min	15 min
Size / Mass	70mm x 34mm, 6.0g	70mm x 34mm, 6.0g	85mm x 54mm, 8.0g	85mm x 54mm, 8.3g
Shelf live and Storage	12 months at 2°C-25°C or alternatively 2 months at 26°C-40°C	12 months at 2°C-25°C or alternatively 2 months at 26°C-40°C	12 months at 2°C-8°C	12 months at 2°C-8°C
Approval	CE	CE	CE	CE 0197

Functional Principle

In the myocardium heart-specific Fatty Acid-Binding Protein and the complex Troponin ITC are present. Both are released into the blood stream following damage to the myocardial cells. In the blood the Troponin complex ITC splits into its components cTnI, cTnT, and cTnC.



After application of the probe 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 test results are highly indicative of an acute myocardial infarction.

Integrated Quality Control

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

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 border 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.

Presentation

Version	Order No.	Content
CardioDetect® combi 25	11301000	25 x Disposable CardioDetect combi tests
CardioDetect® combi 10	11300000	10 x Disposable CardioDetect combi tests
CardioDetect® combi 5	11304000	5 x Disposable CardioDetect combi tests, 6 x automatic lancets
CardioDetect® combi 2	11303000	2 x Disposable CardioDetect combi tests, 2 x automatic lancets
CardioDetect® lab 25	12501000	25 x Disposable CardioDetect lab h-FABP tests
CardioDetect® lab cTnI 25	12701000	25 x Disposable CardioDetect lab cTnI tests
CardioDetect® med 10	10103000	10 x Disposable CardioDetect med tests
CardioDetect® med 5	10102000	5 x Disposable CardioDetect med tests, 6 x automatic lancets
CardioDetect® self	10101000	1 x Disposable CardioDetect self test, 2 x automatic lancets
CardioDetect® quant	10104000	1 x Reader for optional quantification of CardioDetect tests

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