# Instructions for use H-FABP True Rapid Test

**For professional use**

**In vitro diagnostic (IVD)**

**Do not re-use**

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**Qualitative rapid test for the determination of the H-FABP protein in capillary blood to support the diagnosis of an acute myocardial infarction (AMI).**

## 1. Indication for use

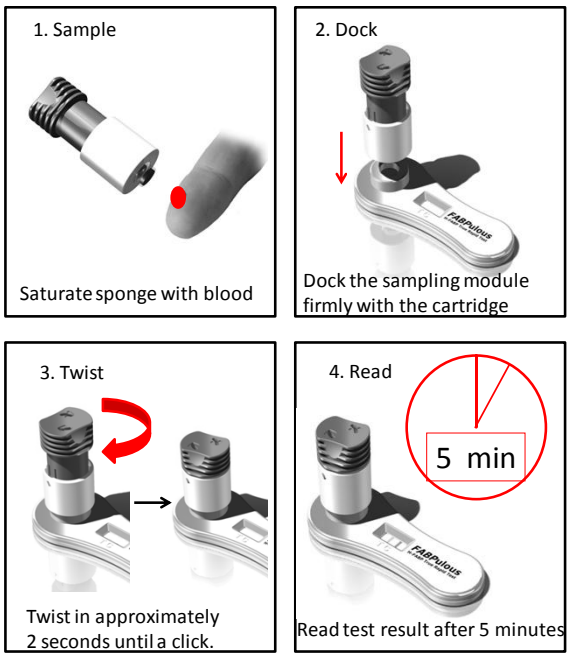
The FABPulous H-FABP True rapid Test is a fast test to support the diagnosis of a suspected acute myocardial infarction (AMI). The test is intended for professional use. The test is for single use only. The test must be used from 3 hours until 18 hours after onset of symptoms.

## 2. Sample type and sampling

The test is performed with fresh capillary blood, which is obtained by a finger prick. A full droplet of blood has to be obtained before applying to the sponge. Commercially available and approved finger prick kits must be used. Finger prick kits are not included into the package.

## 3. Execution of the test

The test can only be used with whole blood. Open the package and place the cartridge onto a table or solid surface.




## 4. Additional information for test execution

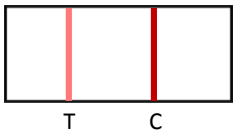
Always apply sufficient blood sample, as this is essential for the test performance. The sponge needs to be saturated with blood (dyed completely red), however, no loose droplets of blood should remain on the outside of the sponge by oversaturation.

On the back side of the package, there is space to write down information of the patient ( ID ), the start ( ) and end ( ) time of the test and the test result.

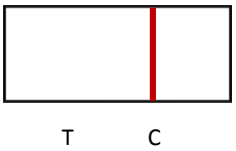
Do not use tests of which the package has already been opened or of which parts are visually damaged.

Always treat a blood sample as infectious and take appropriate measures for this.

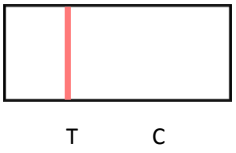
## 5. Interpretation of test results



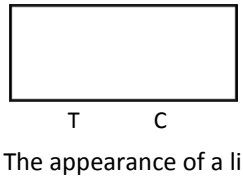

**Valid: H-FABP +**
H-FABP elevated




**Valid: H-FABP -**
H-FABP not elevated




**Invalid: H-FABP ?**
Retest advised. If not feasible, treat result as elevated H-FABP.




**Invalid: H-FABP ?**
etest advised.

The appearance of a line at the position marked with a "C", being the control line, indicates that the test has performed correctly. The test result is only valid when this control line is visible.

An elevated H-FABP concentration supports the diagnosis of an AMI.

## 6. Additional information with respect to interpretation of the test result.

In case blood samples have been collected within 3 hours after onset of symptoms or later than 18 hours after onset of symptoms, a false negative result can occur. It is important to read the test result at 5 minutes after the start of the test. When the results are read after 5 minutes of test initiation, a false positive results can occur. H-FABP values may be elevated within patients with severe renal insufficiency (eGFR<30).

## 7. Test methodoly

H-FABP (Human Heart-type fatty Acid Binding Protein) is a protein, which is present in a relatively high concentration in cardiac muscle. In case of the occurrence of an AMI the cells of the cardiac muscle are damaged and the H-FABP protein is quickly released into the circulation. This test targets the H-FABP protein in blood.

The test is based upon a so-called immunoassay technology. Inside the cartridge a strip is present, which contains an antibody that specifically binds H-FABP. The H-FABP that is present in the blood sample will bind to this antibody and this will result in the appearance of a colored line on the strip if the concentration H-FABP is elevated. Additionally, a control line is present on the strip, which is independent on the H-FABP concentration and which will always generate a visible line in case of a correctly executed test.

The included sample module serves to absorb the patient's finger prick blood and to dilute it with a proper buffer and consecutively apply it to the strip.

The reactive components are:

- Colloidal gold-particles (40nm)
- Monoclonal anti-H-FABP antibodies
- 62 mM Phosphate buffer, 2.7 mM KCl, 137 mM NaCl, detergent (0.05% Tween) and antibacterial proclin (0.05%)

## 8. Interfering substances

The following drugs have been subjected to interference testing, and for all drugs it has been demonstrated that they do not interfere in the test result at their maximum therapeutic concentrations. Acenocoumarole, acetaminophen, acetylsalicylic acid, amoxicilline,atorvastatin, diclofenac, doxycyclin, furosemide, hydrochlorothiazide, ibuprofen, metformin, metoprolole, naproxen, nitrofurantoin, omeprazole, oxazepam, simvastatin and temazepam.

Triglycerides (3000 mg/dl), hemoglobin (300 µM), bilirubin (491µM) and cholesterol(20 mM) do not interfere in the test result at the concentration mentioned. Also no cross-reactivity occurs with other FABP-subtypes that are not heart specific.

## 9. Diagnostic specifications

The diagnostic sensitivity of the test (from 3 to 18 hours after onset of symptoms) is 93.6% and the specificity 67.4%

The cutoff is 4 ng/ml (the H-FABP concentration at which 95% is detected).

## 10. Expiry and storage conditions

The test device can be used until the expiry date that is printed on the package, if the appropriate storage conditions have been applied. The test device must be stored between 2-30°C at ambient conditions. The test device shall not be stored in an environment where there is direct contact with water or other liquids.

Avoid exposure to very high or low temperatures and avoid bending or deformation of the test device. In case the date has expired, the device shall not be used anymore.

## 11. Package content

The package contains the following parts:

- one pouch with a sampling module (1) and one pouch with a cartridge ( 2);
- an instruction for use;
- a quick reference guide on the back side of the package with space to write upon.

## 12. Decommissioning

Used tests contain human blood sample that must be treated as infectious and should be decommissioned as such. The test device does not contain chemicals in such concentration that other specific guidelines have to be followed.

## 13. Miscellaneous

For other questions with respect to the use of this product you can contact the manufacturer. The contact information can be found in the header of this instruction for use. The website is www.fabpulous.com and e-mail is info@fabpulous.com. Rev1, EN.