# Sens*Aheart* One-step Assay

**One-step immunoassay for the rapid detection of acute myocardial infarction in humans**
**based on the qualitative detection of both cardiac biomarkers (cTnI and h-FABP) in one drop of whole capillary blood**

Catalogue number: R-**6503**-2 (2 tests)

Instruction for Use

## INTENDED USE

The Novamed **SensAheart One Step Assay** is an individual lateral flow-based immunoassay for the rapid diagnosis of an acute MI/ASC in shortest time after symptoms onset in the conditions preceding hospitalization (pharmacies, doctors' offices, clinics, ambulance services, emergency medical centers, airports, railway transport, etc.). The ***SensAheart One Step Assay*** detects both established heart attack indicators – the cardiac Troponin I (cTnI) and heart Fatty acid binding protein (hFABP) in one finger prick drop of human whole blood resulting by one detection band in positive case within 15 minutes. At an early chest pain onset of a heart attack, when the concentration of cTnI in the blood only begins to rise, a positive result of the SensAheart is provided solely **due to increased hFABP concentration**. In the interim stage, when hFABP starts to decay, but cTnI is still below the cut-off value, i.e. <0.5 ng / ml, a positive result of the SensAheart is provided by **the additive effect of low concentrations of both markers**. At the end of 24 hours after the onset of a heart attack, when the hFABP concentration reduces under the cut-off value, i.e. <5 ng/ml, a positive test result is provided solely **by increased cTnI concentration**.

## ASSAY PRINCIPLE

The *Novamed* SensAheart One-step Assay is a rapid qualitative lateral flow immunochromatographic assay for the detection of both cTnI and h-FABP in one drop of human whole blood. To perform the test, sample is loaded onto the assay sample input surface, through the sample port opening. h-FABP and cTnI in the specimen form complexes with colloidal gold-conjugated mouse-anti-h-FABP and anti-cTnI monoclonal antibodies. These complexes migrate through the membrane towards the assay test region. Then, a color line of variable intensity should be observed when the markers blood concentrations are greater than or equal to the assay sensitivity limit. The specimen-gold conjugate mixture then migrates further down the membrane through the assay control region to produce a color line.

## KIT COMPONENTS

Each kit contains everything needed to perform 2 determinations.

- 2 test-cassettes, individually wrapped with 1 plastic disposable capillary and 1 desiccant.
- 2 sterile disposable automatic finger prick lancets
- 2 alcohol pads
- 1 dropper bottle with 0.5mL of buffer
- 1 Instruction for use

## ASSAY PROCEDURE

The blood sample is collected by standard finger prick procedure using a provided sterile disposable lancet. Use the disposable automatic lancet to make a light puncture on the finger pad.

There are two methods for loading the test.

A. Attach the finger with a large protruding drop of blood to the center of the sample collection pad on the test cassette (according to the direction of the arrow).

**or**

B. Step 1: Hold the capillary horizontally and touch the drop of blood with the tip of the capillary. Capillary action will automatically draw the sample. It is crucial to fill the capillary tube up to the marked black line.
Step 2: To expel the sample, align the tip of the capillary with the blood toward the center of the sample collection pad on the test cassette (according to the direction of the arrow) and squeeze the bulb.

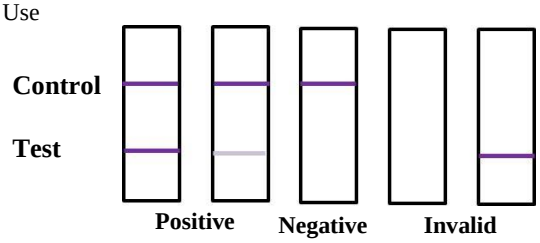
Wait for the sample to fully being absorbed (about 10 seconds), add 2 drops of buffer.

Wait 15 minutes for the colored line(s) to appear. Do not interpret results after more than 20 minutes.

**NOTE:** Filling the capillary is automatic: Never squeeze the tube while sampling.

## INTERPRETATION OF RESULTS

(Please refer to the illustration below)




**POSITIVE*: Two distinct colored lines appear.** One clear colored line is visible in the control region (**C**), and another colored line should be detected in the test region (**T**) of test cassette.

***IMPORTANT: The intensity of color in the test line region (T) is subject to variability reflecting the concentration of both cTnI and h-FABP present in the specimen. Therefore, any intensity of color in the test line region (T) should be considered positive.***

***ACTIONS TO BE DONE UPON THE POSITIVE RESULTS:*** *In case of two lines (C and T) are presented (POSITIVE RESULT) the patient is very highly suspected to be in an ACS stage and should get evaluated by a medical professional.*

**NEGATIVE: One colored line appears in the control region (C).** No colored line is visible in the test region (**T**) of test cassette.

***ACTIONS TO BE DONE UPON THE NEGATIVE RESULTS:*** *In case of only the Control line (C) is presented it indicates that no cTnI or/and hFABP are detected or their level is below the detectable and the result is negative.*

***IMPORTANT:*** ***When the test result is negative or is in conflict with other results, it is imperative to perform a new test approximately within about 3 hours later. If the second result is negative than the patient has likely not suffered from AMI***

**INVALID: Control line (C) fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the assay with a new test cassette. If the problem persists, discontinue using the kit immediately and contact your local distributor.

## TYPICAL POSITIVE RESULTS


## QUALITY CONTROL

An internal procedural control is included in the assay. A colored line in the control region (**C**) of test cassette is an internal procedural control. It confirms sufficient specimen volume, membrane integrity and correct procedural technique.

## STORAGE AND STABILITY

The *Novamed* SensAheart One-step Assay should be stored at +4+30ºC in its sealed pouch and under dry conditions. Expiration date for each assay lot is indicated on the pouch. **Do not use if foil pouch seal is not intact!**

**LIMITATIONS**

1. The Novamed SensAheart One-step Assay is a qualitative assay device capable of detecting elevations of h-FABP levels above 5ng/mL and/or cTnI levels above 1.0 ng/mL
2. A positive test result from a patient suspected of AMI requires further confirmation. To diagnose cardiac emergencies, this product should not be used as a sole diagnostic mean, but in conjunction with other data, such as clinical signs, and electrocardiogram.
3. Caution should be exercised when interpreting results obtained from samples expressing elevated level of substances known to interfere with lateral flow format tests, such as rheumatoid factor or antinuclear antibody, produced in certain diseases. These substances are generally known to impose false positive and false negative results.

**WARNINGS AND PRECAUTIONS**

1. For *in-vitro* diagnostic use only
2. The *Novamed* SensAheart One-step Assay should remain in foil pouch until ready for use. The pouch containing the test card must be completely sealed.
3. Do not use the Novamed SensAheart One-step Assay beyond the expiration date printed on foil pouch.

**PERFORMANCE CHARACTERISTICS**

Sensitivity and Specificity

In order to evaluate the diagnostic accuracy of SensAheart One-step Assay in patients with definite or possible Acute Coronary syndrome (ACS), the test was performed in 255 consecutive patients with definite or possible ACS admitted to departments of Hadassah Medical Center (Jerusalem). Initial cTnT evaluation using The Elecsys® Troponin T-high sensitive assay (Roche Diagnostics) and simultaneous SensAheart One-step Assay testing were done under the ACC/ESC (American College of Cardiology/European Society of Cardiology) consensus guidelines. The study was done under consensus guidelines.

Results

Upon this study analysis, compared to the hospital first troponin test (The Elecsys® Troponin T-high sensitive assay, Roche Diagnostics), the SensAheart One-step Assay have 16.6% higher sensitivity for ACS early at admission.

| | SensAheart One-step Assay | Elecsys® Troponin T-high sensitive (Roche Diagnostics) |
|---|---|---|
| Sensitivity | 80.4% | 63.8% |
| Specificity | 86.2% | 95.4% |
| Positive Predictive Value (PPV) | 90.2% | 95.6% |
| Negative Predictive Value (NPV) | 73.5% | 62.4% |

Among the 138 patients detected with ACS, this superior early sensitivity of SensAheart One-step Assay allowed it to detect 22.4% (31/138) of them early at admission while the high-sensitive hospital test could do that, but only a few hours later.

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Savyon Diagnostics Ltd.
3 Habosem St. Ashdod 7761003 , ISRAEL
Tel.: +972.8.8562920
Fax: +972.8.8523176
E-mail: support@savyondiagnostics.com