

# PRODUCT DESCRIPTION

## MI RISK MYOCARDIAL INFARCTION TEST

## the test

The MI RISK kit is an innovative and unique tool for the personalized predisposition detection and prevention of dangerous medical conditions.

MI RISK helps the patient to carry out preventive behaviors many years if not decades before the occurrence of a possible life threatening health condition, obtaining a considerable advantage on his/her future life quality.

The MI RISK analysis calculates the chances of incurring in a cardiovascular event over a specific time period taking into consideration both standard cardiovascular diagnostic parameters and the personalized genetic predisposition risk.

Every year cardiovascular diseases kill over 4.3 million people in Europe and cause the 48% of the total amount of deaths (54% in women, 43% in men). Those diseases are the first cause of death, the most frequent cause of admitting to hospital and one of the most important causes of invalidity.

The risk factors (the traits which, if present in a person or population, indicate the greater chances to incur in that illness) of those diseases are very well known. Epidemiological studies in the last years have shown that the risk is reversible and it is possible to reduce or postpone the risk of incurring in cardiovascular events via reducing the risk factors.



## risk factors and myocardial infarction

During the last year several exhaustive studies, both nationwide and worldwide, revealed how the genetic makeup influences cardiovascular risk. Everyone has a specific genetic asset, which is unique and not modifiable, that render him/her liable to cardiovascular diseases. The MI RISK kit can quantify this “basic genetic risk”, putting together worldwide knowledge and state-of-the-art genetic technology.

A person can take advantage of knowing if he/she has a higher cardiovascular risk, acting in order to reduce other risk factor with a healthier way of life and referring to medical help to know which strategies would be best to reduce the risk of a cardiovascular event. Examining mutations in the DNA and relating them to the lifestyle permit to compile a combined evaluation of risk and suggest the best strategies.

**Traditional risk** represents a statistic evaluation of chances to incur in cardiovascular events in the next 10 years assuming the current conditions will remain identical (cholesterol levels, blood pressure, smoke, etc.) This kind of risk is calculated with traditional parameters according with the Italian Superior Institute of Healthcare.

**Genetic risk** represents the individual predisposition to diseases depending on the information in the DNA. It is known that specific mutations in some genes in the DNA have a critical role in developing cardiovascular diseases. To realize an efficient prevention against those illnesses it is essential to identify the genetic risk factors that could improve chances to develop them.

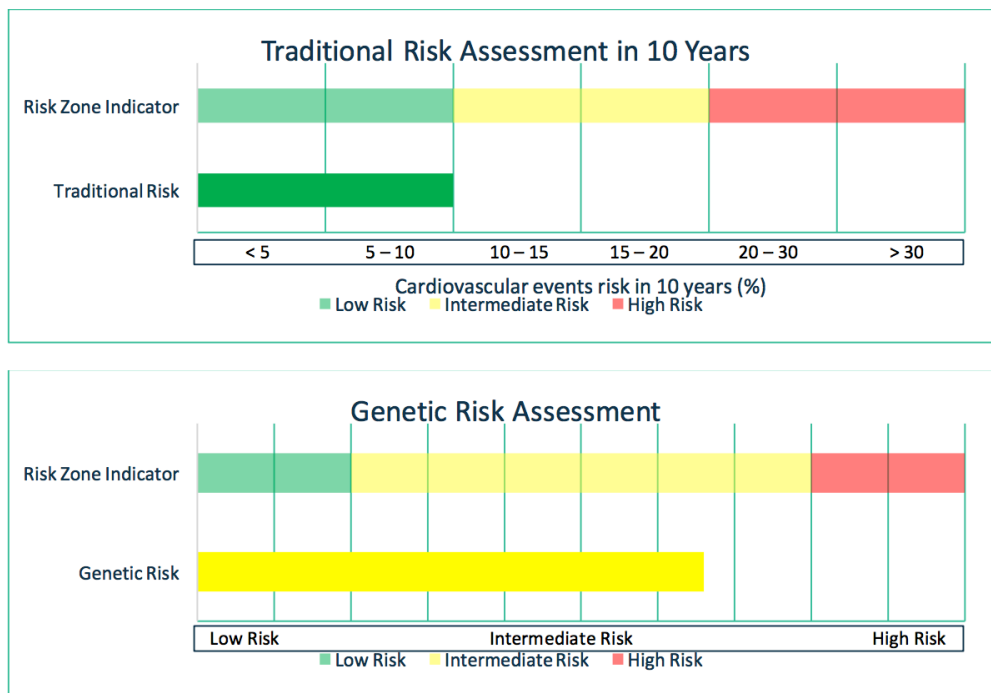
The DNA test does not set once and for all if a person will develop a disease for sure, but gives great advice about his/her genetic predisposition, so one can implement personalized precautionary measures to improve chances of good health.

The total amount of traditional and genetic risks is elaborated by Personal Genomics' medical team through a specific algorithm which allows the medical team to develop a combined risk analysis that contains all those parameters.

Cardiovascular diseases and **myocardial infarction** in particular are nowadays the first cause of death in the world. Not all those deaths are caused by common risk factors such as smoking habits, diabetes, hypertension, high cholesterol rates, obesity etc. It has been

demonstrated that the genetic predisposition has a critical role in these diseases. Recent Genome-Wide Association Studies (GWAS) allowed the identification of crucial genetic markers that greatly improve the predictive power of the test for the risk assessment of Acute Myocardial Infarction.

Predisposition genetic markers are used in combination with individual information regarding traditional risk factors for the calculation of the personalized risk. (Girelli D. et al, Seminars in Thrombosis and Hemostasis 2009; Visel A. et al., Nature 2010).









## testing procedure

MI RISK testing procedure starts with sample taking and anamnesis collection. Personal Genomic takes care of the DNA extraction prior the beginning of the SNPs analysis process. The risk level profile is assessed and reported on the final test results.



### kit usage

The kit is very simple to use: it consists of a small swab that the customer can directly use to collect a saliva sample simply passing it in his own mouth. Personal Genomics will then extract the DNA from the saliva sample provided by the customer. A simple questionnaire will be used to collect the information about the traditional risk factors that will be used to obtain an anamnesis that complements the genetic information provided with the medical report.

	<p><b>1</b></p> <p>Pull open the package from one end.</p>
	<p><b>2</b></p> <p>Remove the swab from the tube, taking care not to touch the white swab head with your fingers</p>
	<p><b>3</b></p> <p>Insert the swab into your mouth and rub firmly against the inside of your cheek or underneath lower and upper lip. For standard DNA collection rub for <b>1 minute</b> and in all cases rub for a minimum of 20 seconds. <b>Important – use reasonable, firm and solid pressure</b></p>
	<p><b>4</b></p> <p>Place the swab back into the tube. Do not touch the swab head with your fingers</p>
	<p><b>5</b></p> <p>Place your thumbnail in the small groove set in the handle, then snap the handle in two by bending to one side. Let the swab head fall into the tube.</p>
	<p><b>6</b></p> <p>Seal the tube securely with the cap provided.</p>

### SNPs analysis

The genetic analyzer evaluates the presence of a series of genetic polymorphisms (SNPs) associated with the Acute Myocardial Infarction's risk. The genetic markers considered were selected on the whole genome based on their statistical predictive value, which was demonstrated in recent scientific publications (Visel A. et al., Nature 2010 and Schunkert H. et al., Nature Genetics 2011).

### kit results

The results of the genetic analysis provide a genetic risk score specific for each individual. The test takes into account both the “damaging” and the “protective” genetic alleles for the global cardiovascular risk and their relative effect based on Genome Wide Association Studies (GWAS). The genetic information analyzed with the kit is then integrated with general medical information regarding each individual’s lifestyle and the traditional risk factors considered by cardiologists (blood pressure, cholesterol, smoking habits, weight, age, etc.)

The final result consists in a risk profile that assesses the personal probability of acute Myocardial Infarct over a specific timeframe. The test can point out possible bad habits and/or modifiable behaviors for the improvement of the person’s overall health and the cardiovascular apparatus efficiency through specific disease prevention actions. A specialized clinician and a geneticist certify the medical report provided.

The combined risk analysis of myocardial infarction gives accurate information both on the risk extent to incur in heart pathologies, and on which preventive measures adopt to reduce that risk. Anyway Personal Genomics’ business mission is to offer the most complete service to its clients; in order to do so, it instituted some Reference Centers, which are able to follow the client in order to give more support and counseling about the test results, in collaboration with cardiovascular specialists of excellence.

### testing target

MI RISK is intended for a very wide set of people and a very large age group that includes all those people aware that some of the peculiar characteristics of nowadays’ life, such a deskbound job, a non-balanced diet, stress and hypertension, can worsen a genetic system which might be potentially already prone to the development of cardiovascular diseases. Such a risk awareness helps preventing the actual development of the disease, and gives advices on which habits to change in order to improve the lifestyle or which medical prevention actions to consider.

### other characteristics

MI RISK is **noninvasive**. The DNA for the test is extracted from the saliva collected through a simple swab. It is an easy and absolutely non-invasive method.

MI RISK is **one-shot**. Results are valid for the entire life: the genetic variants analyzed are present in each person’s DNA and do not change during the lifetime unlike biochemical parameters assessed in standard medical exams. The MI Risk result defines your genetic profile and predisposition to myocardial infarction just once in your lifetime.

MI RISK is **decisive**. Once the test is performed, the risk is accurately calculated using an algorithm that combines genetic variations (SNPs) and traditional risk factors. A medical doctor evaluates the calculated risk and adjust the medical report on the individual case suggesting specific medical analysis (ECG, etc.), the evaluation of drug preventive regiments or specific behavior changes in order to lower the risk.

## the company

Personal Genomics is a spin-off of the Functional Genomics Center of the prestigious University of Verona. Our mission is to offer services, products and solutions with highly innovative technological content intended for the Precision Medicine, diagnostics and genomics fields.

It was born thanks to the extraordinary experience of three great professionals in Genetics and Cardiovascular Medicine, worldwide acknowledged: professor Massimo Delledonne, professor Oliviero Olivieri and professor Domenico Girelli.

Personal Genomics offers quite a number of products at the state of the art and several services in genetics. During the last years the latest discoveries in the genetic environment up to the complete sequencing of the human genome, have brought a great amount of information about the genetic variability between human beings; the great progress in genetic research brought a revolution in the concept itself of Medicine, bringing new perspectives in prevention, diagnosis and treatment of diseases. These discoveries and their applications have brought information unavailable before and that are now crucial in diagnosis and prevention of diseases.

Personal Genomics promotes this innovative concept of Precision Medicine, i.e. an approach in diagnosis and treatment of illnesses personalized for every single person on his/her genetic makeup basis.

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