CLAIMS

1. A device for determining the likelihood that an individual has increased risk of a cardiovascular (CV) event, the device comprising:

means for retrieving data attributed to a biological sample from an individual, wherein the data comprises protein biomarker values that each correspond to one of at least N protein biomarkers selected from Table 1;

means for performing a classification ~~of each of~~with said protein biomarker values, wherein the classification indicates a CV event risk status as a function of the protein biomarker values; and

means for indicating a result of the evaluation of risk for a CV event for said individual

based upon a plurality of classifications; wherein N=3-155, and wherein the protein biomarkers selected from Table 1 comprise PSA:α-1-antichymotrypsin complex (PSA-ACT).

2. The device of claim 1, wherein N= 4-155; N=5-155; N=6-155; N=7-155; N= 8-155; N=9-155 or N=10-155.

3. The device of claim 1, further comprises an in vitro assay kit for detecting the protein biomarker values.

4. The device of claim 3, wherein said in vitro assay kit comprises at least one capture reagent corresponding to each of said protein biomarkers, wherein said at least one capture reagent is selected from the group consisting of aptamers, antibodies, and a nucleic acid probe.

5. The device of claim 1, wherein the biological sample is selected from the group consisting of whole blood, dried blood spots, plasma, serum and urine.

6. The device according to claim 1, further comprises means for evaluating risk for a CV event for said individual based upon said plurality of classifications ~~of each of~~with said protein biomarker values and at least one item of additional biomedical information corresponding to said individual, wherein said at least one item of additional biomedical information is independently selected from the group consisting of

(a) information corresponding to the presence of cardiovascular risk factors selected from the group consisting of prior myocardial infarction, angiographic evidence of greater than 50% stenosis in one or more coronary vessels, exercise-induced ischemia by treadmill or nuclear testing or prior coronary revascularization,

(b) information corresponding to physical descriptors of said individual,

(c) information corresponding to a change in weight of said individual,

(d) information corresponding to the ethnicity of said individual,

(e) information corresponding to the gender of said individual,

(f) information corresponding to said individual's smoking history,

(g) information corresponding to said individual's alcohol use history,

(h) information corresponding to said individual's occupational history,

(i) information corresponding to said individual's family history of cardiovascular disease or other circulatory system conditions,

(j) information corresponding to the presence or absence in said individual of at least one genetic marker correlating with a higher risk of cardiovascular disease in said individual or a family member of said individual,

(k) information corresponding to clinical symptoms of said individual,

(l) information corresponding to other laboratory tests,

(m) information corresponding to gene expression values of said individual, and

(n) information corresponding to said individual's consumption of known cardiovascular risk factors such as diet high in saturated fats, high salt, high cholesterol,

(o) information corresponding to the individual's imaging results obtained by techniques selected from the group consisting of electrocardiogram, echocardiography, carotid ultrasound for intima-media thickness, flow mediated dilation, pulse wave velocity, ankle-brachial index, stress echocardiography, myocardial perfusion imaging, coronary calcium by CT, high resolution CT angiography, MRI imaging, and other imaging modalities, and

(p) information regarding the individual's medications.

7. A device for evaluating the risk of a future cardiovascular (CV) event within a 5-year time period in a population, comprising:

means for retrieving data attributed to a biological sample from an individual of the population, wherein the data comprises protein biomarker values that each correspond to one of at least N protein biomarkers selected from Table 1,

means for performing a classification ~~of each of~~with said protein biomarker values, wherein the classification indicates a 5-year CV event risk status as a function of the protein biomarker values;

means for indicating a result of the evaluation of risk for a CV event for said individual based on said plurality classification of each of said protein biomarker values;

wherein N=3-155, and wherein the protein biomarkers selected from Table 1 comprise PSA-ACT.

8. The device of claim 7, wherein the population is selected on the basis of a characteristic selected from the group consisting of:

a) a population having or not having a prior history of cardiovascular disease; and

b) a population having or not having genetic risk factors comprising mutations, single nucleotide polymorphisms and/or insertion/deletions.

9. The device of claim 7, further comprises means for allowing stratification of the evaluated risk for CV event for individuals into categories selected from the group consisting of:

a) different categories for increased or decreased disease manage programs;

b) different risk categories relating to life insurance coverage;

c) different risk categories relating to health insurance coverage;

d) different categories of candidacy for partnership;

e) different categories of eligibility for entry into clinical trials of CV therapeutics;

f) different risk categories relating to cardiovascular safety for a CV therapeutic or any therapeutic.

10. The device of claim 7, further comprising an in vitro assay kit for detecting the protein biomarker values.

11. The device of claim 10, wherein said in vitro assay kit comprises at least one capture reagent corresponding to each of said protein biomarkers, wherein said at least one capture reagent from the group consisting of SOMAmers, antibodies, and a nucleic acid probe.

12. The device of claim 7, wherein the biological sample is selected from the group consisting of whole blood, dried blood spots, plasma, serum and urine.

13. A computer system for evaluating the risk of a cardiovascular CV event, the computer system comprising:

a module for retrieving on a computer protein biomarker information for an individual, wherein the protein biomarker information comprises protein biomarker values that each correspond to one of at least N protein biomarkers selected from Table 1;

a module for performing with the computer a classification ~~of each of~~with said protein biomarker values;

a module for indicating a result of the evaluation of risk for a CV event for said individual

based upon a plurality of classifications;

wherein N=3-155, and wherein the protein biomarkers selected from Table 1 comprise PSA-ACT.

14. The computer system of claim 13, wherein the module for indicating the result of the evaluation of risk of a CV event for the individual comprises a module for displaying the result on a computer display.

15. A computer program product for evaluating the risk of a CV event, the computer program product comprising:

a computer readable medium embodying program code executed by a processor of a computing device or system, the program code comprising:

code that retrieves data attributed to a biological sample from an individual, wherein the data comprises protein biomarker values that each correspond to one of at least N protein biomarkers selected from Table 1, wherein said protein biomarkers were detected in the biological sample; and code that executes a classification method that indicates a result of the evaluation of risk for a CV event of the individual as a function of said protein biomarker values; wherein N=3-155, and wherein the protein biomarkers selected from Table 1 comprise PSA-ACT.

16. The computer program product of claim 15, wherein said classification method uses a continuous measurement score or assigns to two or more classes.