A home-based portable instrument to monitor wellness and disease

In the past decade, a number of methods have been made available for health-conscious people designed with the purpose of monitoring wellness and disease information that may be obtained without visiting a conventional and centralized clinical laboratory. In response, some facilities have been opened in pharmacies or other public outlets to provide home diagnostic tests and/or to collect biological fluid samples, followed by the transport of the biosamples to an accredited laboratory facility for testing.

Unfortunately, a number of techniques performed using commercial kits or carried out in reputable clinical laboratories, which are based on mono-dimensional techniques, can result in incomplete or inaccurate information and, in turn, lead to an erroneous diagnosis and therapy. Therefore, in order to avoid inaccurate results it is of the utmost importance to use more than one technique (bi-dimensional protocols) to yield greater error-free diagnostic information.

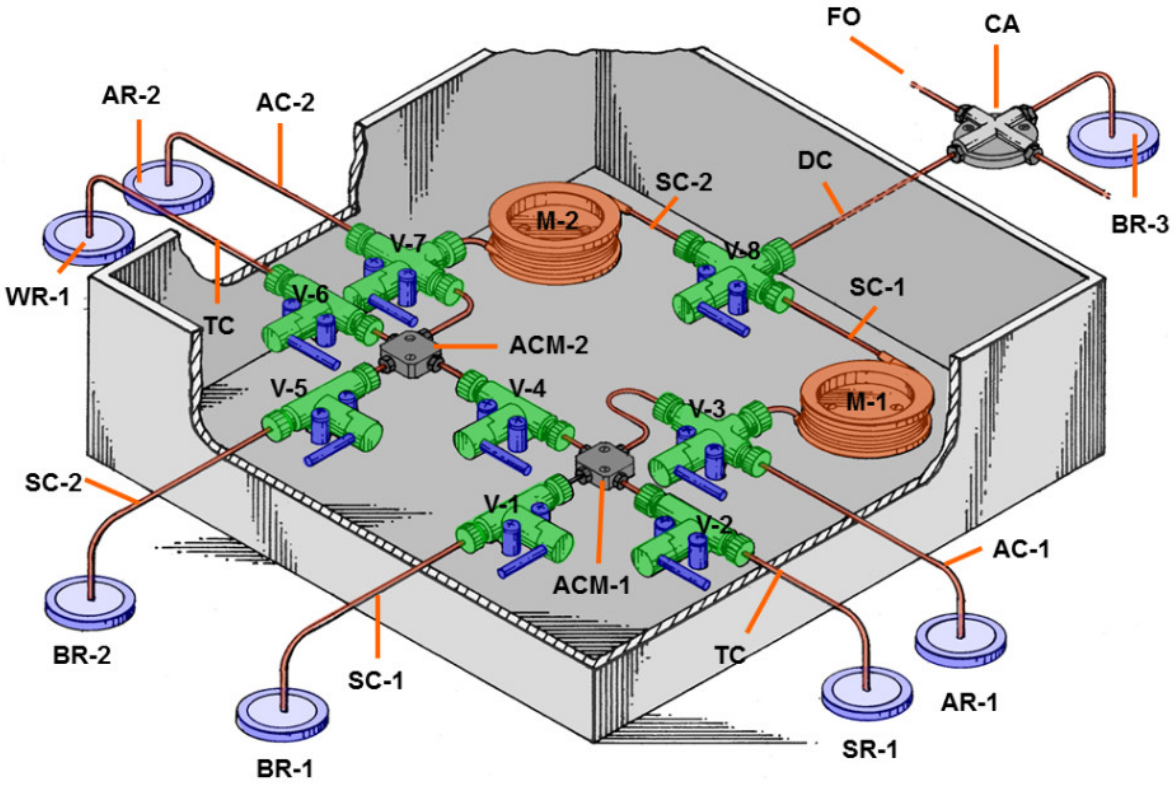

Fig. 1. Schematic representation of a multi-capillary, multi-dimensional, multi-task, immunoaffinity capillary electrophoresis. This instrument can be manufactured as a small portable design using a conventional capillary electrophoresis format or a microchip-microfluidic capillary electrophoresis

format. The principle of immunoaffinity capillary electrophoresis is based on capturing and isolating a substance of interest present in a complex mixture, in one dimension, by an affinity compound (e.g., an antibody) immobilized on the surface of a device named analyte concentrator-microreactor (ACM), and separate in a second dimension the one or more substances captured by and released from the immobilized antibody by a high-resolution technology named capillary electrophoresis.

What alternatives exist to manufacture an “error-free” point-of-care instrument capable of providing an accurate diagnosis of a disease in its early stage of formation, before a symptom is manifested? How can a panel of biomarkers (chemical or biologial indicators used to assess a particular health condition), capable of providing well-rounded information of wellness or disease, be cost-effective and accessible to everybody? How can a portable point-of-care instrument compliment the new models of healthcare systems; specifically, precision medicine and P4 medicine (predictive, preventive, personalized, and participatory)? Instituting a standard of these models propose the customization of healthcare, with medical decisions, practices, and/or products being tailored to the individual patient. Ideally, a disease should be diagnose before symptoms are manifested (predictive), in order to avoid the progression or stop the disease (preventive) through an appropriate treatment tailored to the patient (personalized), with the help of a large segment of the population (participatory) to create a large data bank of panels of biomarkers or indicators of wellness-disease.

Advancement in technology is facilitating the manufacturing of small portable point-of-care instruments, to provide easy access to check our health, and when used in conjunction with telemedicine can yield comprehensive information of the status of our health.

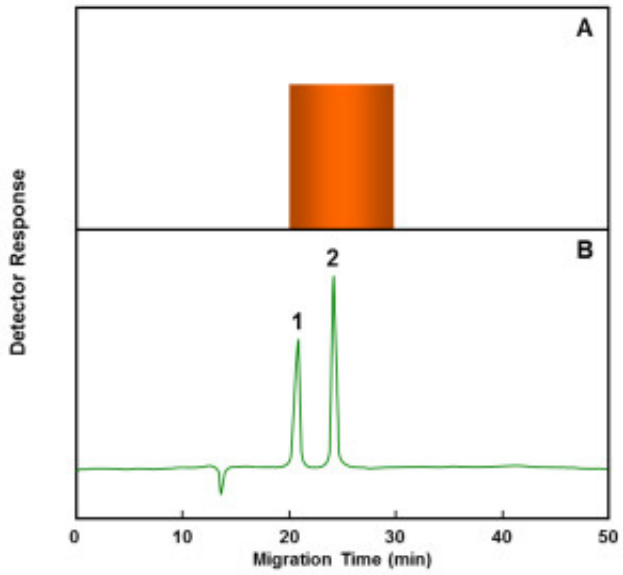

Fig. 2. Comparative information obtained when using a monodimensional technology, represented

by an immunoassay known as enzyme-linked immunosorbent assay (ELISA), versus a two-dimensional technology represented by immunoaffinity capillary electrophoresis (IACE). Panel A depicts arbitrary quantitative ELISA values of the determination of two immunoreactive milk-derived bioactive peptides, ?-casomorphin-5 and ?-casomorphin-7, in a urine sample. Panel B depicts qualitative and quantitative information of the two related ?-casomorphins, ?-casomorphin-5 (peak-1) and ?-casomorphin-7 (peak-2) assayed by IACE.

Here we present an advanced technology-driven diagnostic instrument, which is easy to operate by an individual with a minimal expertise of using a laptop computer. The purpose of this portable instrument is to be used in doctor's offices, remote clinics, or in the privacy of a patient's home. The assay consists of a panel of crucial biomarkers analyzed by the point-of-care instrument that can be cost effective, facilitating the frequency of tests to be performed in a patient. Furthermore, the resulting diagnosis information can be analyzed by a built-in-computer network system designed to accept and interpret the data against a stored data bank. The preliminary diagnosis information would be sent to a central laboratory system that maintains a large diagnostic data bank and is capable of corroborating the preliminary information generated by the point-of-care instrument. The data could further be evaluated by an appropriate team of experts and sent as a report to the family practice physician who would verify a diagnosis or may request addition information if necessary.

As demonstrated in Figure 2, two-dimensional IACE provides a high degree of specificity for the determination of peptide biomarkers that may have structural similarities with compounds present in the matrix or biological fluid. The technology of IACE is capable to separate each individual compound captured by specific antibodies immobilized to a solid support, providing qualitative and quantitative values. This is a key feature that is not possible to obtain when using ELISA, which provides only total information of the captured compounds, some of which may not be even related to the target biomarker of interest. Furthermore, only IACE is capable to be coupled to powerful detectors, such as a mass spectrometer, to obtain addition structural information of the captured and separated compounds, confirming the identity of the target biomarker of interest and thus resulting in error-free diagnosis information.

Empowering clinicians with the precise diagnosis to make decisions at the "point-of-care" has the potential to significantly impact health care delivery and to address the challenges of health disparities.

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Publication

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