Dry blood spot screening

Country of origin | Spain and Brazil

Health problem addressed

Early diagnosis and prevention are widely promoted by national health systems, international organizations and NGOs, because they have been shown to represent significant savings for health systems and the patients themselves. Despite this, access to these benefits by the poor is limited due to challenges in getting blood to labs for analysis.

Product description

The test analyzes specific biochemistry parameters - uric acid, cholesterol, triglycerides, glucose, creatinine - in dried blood samples, using standard laboratory equipment. Blood samples are obtained by a single-use lancet or pin prick. The system does not require special conditions for storage or transportation and it requires only minimal investment in training the personnel that handle the samples. Using the device only requires a finger-prick.

Developer’s claims of products benefits

The current blood diagnosis industry, which is based mainly on venous puncture, is oriented towards developed markets where costs of logistics (refrigeration and transportation) are expensive but do not represent the highest burden. However, in developing economies, these costs are unaffordable for the system or individuals and families. This test eliminates cold chain requirements, which results in major cost savings and makes a step towards universal lab blood service coverage. It also makes it possible to remove the key impediments to population monitoring through massive screening to inform health policies. The strategy is based on maintaining a solution at very low cost so that it can be offered to all people, including those that have very limited financial resources.

Suitability for low-resource settings

The test has been implemented in several countries. It has been used successfully in the favelas of Rio, where only 30% of the pregnant women have access to antenatal care to prevent vertical transmission. However, with the device, samples were collected in the hospital and sent to a lab, with 100% coverage of the 84,000 women in the catchment area ensuring that there was no vertical transmission from these women to their children. The system has also been tested in In Alta Verapaz, Guatemala, with coverage for 1,500 pregnant women who live in the forest.

Operating steps

A few drops of blood, are dried on filter paper at room temperature (1 - 1.30 hrs). Once dried, the sample can be transported by any means to the lab - no need for cold chain. In the lab, a 3mm sample is cut. With a single drop two to four parameters (HIV, Syphilis, Hepatitis, Cholesterol, Glucose, etc.) can be analyzed, using an appropriate solvent which extracts the biological material that is required for the test. This room-temperature extraction (stove & shaker) occurs inside a micro plate and read-out is done on an ELISA’s reader.

Regulatory status

Reagents for infectious diseases and non-communicable diseases have approval for use by authorities such as ANVISA in Brazil. It has a CE mark for its biochemistry reagents.

Future work and challenges

The business model for this product is based on high volume, high quality and affordable cost. For this reason the product needs the collaboration of governments that seek data to reduce the burden of disease. One way to obtain this data is from large-scale blood screening and analysis.

Use and maintenance

User: Self-use/patient, physician, nurse, midwife, family member
Training: One week for laboratory technicians, one hour for personnel in the field
Maintenance: None

Environment of use

Settings: Rural, urban settings, ambulatory, at home, primary (health post, health center), secondary (general hospital), tertiary (specialized hospital)
Requirements: Water. At field level: lancet and filter paper; at the local laboratory: an ELISA reader.

Product specifications

| Dimensions (mm): Not provided | Retail Price (USD): 5 |
| Weight (kg): Not provided     | List price (USD): 5   |
| Consumables: Specific reagents| Other features: Mobile, single-use |
| Life time: Not provided       | Year of commercialization: 2008 |
| Shelf life: Not provided      | Currently sold in: Brazil, Guatemala, India, Spain |

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