Health problem addressed
Cancer is one of the main causes of death in the world. It is expected that death by cancer worldwide will grow to reach 13.1 million in 2030. Colon cancer is among those with the highest death rate. However, the success rate of treatment is also high when detected at early stages and properly treated.

Product description
The device enables fast qualitative detection of occult blood in feces. It consists of a sandwich type chromatographic immunoassay and makes use of a combination of monoclonal and polyclonal antibodies for the detection of human hemoglobin with a high degree of sensitivity. In five minutes, levels of human hemoglobin as small as 0.2 µg/mL can be spotted in feces and positive results are visually evident. The test is used for annual screening of colorectal cancer in people above age 50 and it is useful for the early diagnosis and follow-up treatment of gastrointestinal disorders that cause bleeding. The product is supplied in boxes of 20 cassettes and 20 collector flasks.

Developer’s claims of products benefits
The test can provide highly sensitive and rapid detection of human blood in the feces. The technology uses a detection method that is specific to human hemoglobin, so the patient does not need to stop eating meat two or three days earlier as there is no interference with animal hemoglobin.

Suitability for low-resource settings
Standard (household) refrigeration is the only requirement. It has been used successfully in Cuba.

Operating steps
A small amount of feces should be taken as a sample by using the applicator incorporated to the top of the collector flask. Afterwards, the top is wound and the flask content agitated. A diluted sample will be placed on the cassette by using the collector flask dropper. In five minutes, the result can be read from the device.

Regulatory status
The test is registered in Cuba and Peru and is GMP compliant. It has been evaluated by Cuba’s CECMED (Centro Estatal para el Control de Equipos Médicos y Medicamentos) and Peru’s DIGEMID (Dirección General de Medicamentos, Insumos y Drogas).

Future work and challenges
The strategy is to provide a stable supply of consumables (diagnostic kits), a stable after sales service, and technological renewal as soon as improved diagnostic kits are developed.

Use and maintenance
User: Physician, technician
Training: None
Maintenance: None

Environment of use
Settings: Rural, urban settings, ambulatory, primary (health post, health center), secondary (general hospital)
Requirements: Product should be stored in a standard (household) refrigerator between 2-8 °C.

Product specifications
Dimensions (mm): 160 x 115 x 80 (per box of 20 cassettes and 20 collector flasks)
Weight (kg): 0.3 (per box of 20 cassettes and 20 collector flasks)
Consumables: None
Life time: 2 years
Shelf life: 2 years
Retail Price (USD): 2 (per test)
List price (USD): 2 (per test)
Other features: Portable, single-use
Year of commercialization: 2013
Currently sold in: Cuba

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