

Innovation with global impact

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Diagnostic for HIV management

Product of the year Bangalore-based ReaMetrix believes in innovating affordable solutions, to address the diagnostic needs of a developing nation within the challenges of the local environment.

Innovation-centered ReaMetrix has developed the 'Dry Tri-T STAT' product used in HIV management, for the global market. This is said to be the only Food and Drug Administration (FDA) cleared dried-down CD4 enumeration product available in the world today for the flow cytometry instrumentation market. The other companies that manufacture similar products are Becton Dickinson, Beckman Coulter and Guava Technologies but they all use liquid reagents. Germany's Partic has recently launched a product based on dry formula but it is not FDA approved.

The unitized, dried-down delivery format from ReaMetrix' Dry Tri-T STAT eliminates the need for refrigeration, exhibits nearly 99 percent correlation with conventional liquid format. Its pre-dispensed product tubes enable a simplified workflow, assuring highest accuracy and reliability. This test is being made available at less than one-third of the cost of the existing, imported liquid-format reagent product.

Expressing delight that a company in India has treaded a new, commendable path impacting the global medical diagnostics industry, Dr Bala Manian, CEO, ReaMetrix, says, "ReaMetrix is proud to have pioneered a revolution in global diagnostics. At

ReaMetrix, we believe in inverting the conventional thinking by solving the diagnostic needs in the developing nation and then deploying these solutions globally. The 'dried-down' innovation is a successful validation of our thinking, as this is an innovation that is set to have a global impact."

The product potential

According to National AIDS Control Organization (NACO) estimates, national adult HIV prevalence in India is approximately 0.36 percent of total population, that is nearly 2.5 million people. Currently, there are 197 government anti-retroviral therapy (ART) centers and some private ART clinics, spread across India where CD4 testing is available. Access to reliable, accurate and affordable CD4 testing solutions, is key in the clinical management of HIV patients.

Some of the predominant issues with CD4 testing in India are, the high cost of testing, poor access to testing, poorly developed cold chain for the transport, storage and use of products, complicated work flow, and a demand for skilled labor. The real challenge lies in transporting blood samples from remote areas to centralized testing centers. In most cases, this leads to 'aged' blood samples (> 48 hours), making it unusable for testing. ReaMetrix's innovative dried-down CD4 enumeration product helps address this need.

With the unitized dried down products, the cost of the CD4 enumeration test per patient will see nearly a four-fold reduction in costs, while at the same time producing accurate diagnosis. Blood can be collected, stained and fixed at the point of collection before being shipped to a central testing facility at room temperature. The stained samples can be stored for up to seven to 10 days at room temperature eliminating the issue of 'aged' blood samples.

The ReaMetrix's HIV dried-down product enables doctors to derive quality diagnostic information at an affordable price. This translates to lower cost of testing for the patient. Since there is no need for cold chain for use of these products, diagnostic laboratories will be able to access samples from far-off locations, enabling better cost-efficiencies on their centralized and capital-intensive equipments. From a public health perspective, the affordability will enable frequent testing which in turn will enable doctor to take treatment decisions based on trends rather than on just a single test result.

Key Features of Tri Dry-T STAT

1. Decentralization of sample collection: Collect samples at a remote center before shipment to a central laboratory.
2. Stability: Dried-down reagent does not require cold storage. Fixed and stained samples can be stored for up to seven days prior to analysis.
3. No cold chain: No refrigeration capabilities needed at point of blood collection.
4. Accuracy and reproducibility: Dry Tri T-STAT reagents have been evaluated at multiple laboratories in India as well as by leading international labs. Dry Tri T-STAT reagents have demonstrated robust equivalence to industry standard reagent kits.
5. Simple sample workflow: Reagents employ simple protocol of lyse/ no-wash or no-lyse/ no-wash protocol. Mix the sample and analyze.
6. One world, one quality: Dry Tri T-STAT is the only FDA cleared dried-down CD4 enumeration product available globally.
7. Affordability: At least one-third of the price of equivalent products available in the market.

What next?

The next step is to make the product accessible in all the developing and under-developed countries. Although, the product is FDA approved, ReaMetrix is not looking at marketing the product in the developed nations right now as the product Dry Tri-T STAT was developed with the aim of serving the developing and underdeveloped countries first. Shares Dr Sridhar Ramanathan, executive director, ReaMetrix, "Unless blessed in the West, a product is not well received in the local market. FDA was just an external validation for the product." ReaMetrix is aggressively focusing on South Africa where more than 2,50,000 HIV tests are done per month.

The company has set a target of six million tests per year globally from its 20,000 sq.ft. Bangalore facility and is looking at extending the drying technology to other diagnostic applications. Being a venture capital (VC) driven company, Dr Ramanathan was not willing to divulge the company's revenue and the investment value that has gone in towards developing the Dry Tri T-STAT.

ReaMetrix' product focus is to develop many such medical diagnostic solutions from a global perspective. The company intends to use the 'Indian opportunity' as an incubation center for the development of products with an international niche. Says Gokul Srinivasan, director, product development, ReaMetrix, "We have the unique capability to address local markets

with local resources and a local viewpoint. This gives us a strong competitive edge against western companies who attempt to import technology into the developing world, or simply use developing nations as sources of low cost labor. We believe that a local stake in the outcome is absolutely necessary to assure economic sustainability.”

Driven by the ‘Think Local, Act Global’ paradigm, ReaMetrix is powered by a cross disciplinary team of engineers, chemists, biologists and doctors, and offers innovative solutions in the field of medical diagnostics. The company portfolio of products currently includes products for monitoring HIV progression, stem cell enumeration, screening patients for ankylosing spondylosis and staging cancer patients.

Jahanara Parveen in Bangalore