

## Affigenix develops companion diagnostics for diabetes management

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It won the award for developing the in-vitro diagnostic kit for diabetes management.

"We are hoping our simple, user friendly, affordable lateral flow kit will become preferred companion diagnostic kit along with the routine Glucose test and HbA1c measurement for diabetes management. The kit will enable doctors to make informed decision and prescribe personalized medicine that will be more efficacious in controlling glucose levels in ~7 million diabetic patients who depend on insulin in India alone," added Dr Arumugam Muruganandam, MD & CSO, Affigenix Biosolutions.

The India Innovation Growth Programme is a joint initiative of the Department of Science and Technology, Government of India; Lockheed Martin Corporation; Indo-US Science and Technology Forum, Federation of Indian Chambers of Commerce and Industry; Stanford Graduate School of Business and the IC2 Institute at the University of Texas.

The aim of this programme is to accelerate innovative Indian technologies into the global markets.

The India Innovation Growth Program is the only program of its kind, focusing on teaching using world-class commercialization strategies and the business development assistance provided.

### About the Innovation

#### Companion Diagnostics for Diabetes Management

**Introduction:** Type 1 Diabetics (T1D) depends on insulin injection daily for their survival and if the body develops anti-insulin antibodies and neutralize the injected insulin, the glucose control is lost. The patient develops complications and will eventually die.

The innovation offers a simple lateral flow test similar to pregnancy test to detect anti-insulin antibodies, and there by allow doctors to make informed decision to change the dose or switch the patients to other insulin analogues.

**Application:** The in-vitro diagnostic (IVD) kit will aid doctors to rapidly determine whether the loss of efficacy of insulin or its analogue in T1DM patients is due to presence of antibodies in patient's serum.

This will enable doctors prescribe personalized medicine that will be more efficacious in controlling glucose levels.

**Uniqueness:** The IVD kit for detecting insulin antibodies is an unmet medical need in India, and in major parts of the world. It is an alternative to sensitive, quantitative, time consuming and expensive radioactive and cell-based assay that are used in developed countries.

This simple, affordable, sensitive and specific qualitative kit can be used to detect the presence or absence of anti-insulin antibodies within few minutes.

This innovation can be a standalone product and also can be multiplexed as subcomponent of an existing diagnostic kit that use similar assay format.

**Current development status and IP:** The proof-of-mechanism has been established using the Guinea Pig anti-Insulin antibodies, and in the process of developing the commercial prototype kit for establishing proof-of-concept using clinical samples. Affigenix has filed the provisional patent application in May 2014 making it the owner of the IP.

**Market potential and customers:** In India 67 million patients are diagnosed with diabetes and invariably they need to test their blood at least 2-4 times a year for rest of their life for Glucose and HbA1c level to assess their diabetes control with drug and life style management.

The diagnostics market is expected to grow rapidly in the next few years as there are 30 million people in the pre-diabetes group. Nearly ~7 million diabetic patients depend on insulin injection.

The company's main market segment would be doctors at private and government hospitals, clinics, diabetic centres, government primary health centres, health camps and clinical laboratories who would prescribe to diabetic patients on testing for anti-insulin antibodies along with Glucose and HbA1c levels.

Other market segment would be insulin and analogue manufacturers and marketers who might promote the use of companion diagnostic by doctors to switch patients to interchange brands or substitute to other analogues.

**Competition:** To the best of our (Affigenix) knowledge, there is no commercially available IVD kits that are capable to detect the presence of anti-insulin and insulin analogue specific anti-drug antibodies.

Customized, validated cell-based NAb assays have been used by all Insulin manufacturing companies as part of immunogenicity assessment during their preclinical and clinical trials.