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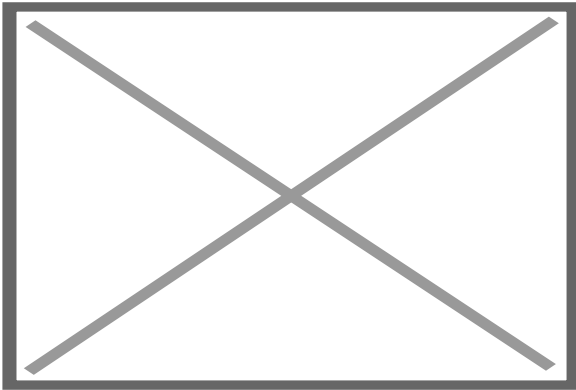
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Mission: Diagnostic kits for autoimmune diseases

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The BIPP funding helped Amar Immunodiagnostics develop cost-effective kits that are now at the final testing stage



Amar Immunodiagnostics embarked on a project to develop diagnostic kits for autoimmune diseases in India to make them affordable and to provide proper medical care to people. Mostly, the diagnostic kits available in the country for detection of autoimmune diseases are all imported, expensive and beyond the reach of the common man.

An amount of `13 lakh provided by the Biotechnology Industry Partnership Programme (BIPP) helped the company start the project. "We made an application for developing diagnostic kit for detection of all autoimmune diseases before the BIPP. The DBT requested us to work on tissue transglutaminase (Celiac disease). Recently, it called for more applications for research in understanding autoimmune diseases in India," said Dr Jayant Bhanushali, director-R&D, Amar

Immunodiagnostics.

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The project was funded in April of 2011 for a seven-month period. The company has already developed the kit, and the project is in the final quality testing stage.

Amar Immunodiagnostics, a private company, was the first to market LH, FSH and Prolactin ELISA kits in India in early 1986. Having started with importing ELISA-based diagnostic kits, the company then started manufacturing the kits. At present, the company manufactures more than 20 ELISA kits in India.

The company also diversified into developing and manufacturing GMO testing kits to detect genetically modified plants, such as Bt cotton, maize, brinjal and soybean. Some of its kits are approved by multinational corporations, and for many of these kits, it is the only manufacturer in Asia.

The company has its own monoclonal and polyclonal antibodies facilities, and has developed in-house expertise to develop kits directly from DNA sequences. The unique selling point of this expertise is that it is not necessary to have purified protein to develop antibodies or the immunoassay-based diagnostic kit. According to the company, all the kits manufactured at the company conform to US FDA guidelines on specificity, reproducibility, stability and other specifications required by regulatory agencies.

The way forward

The company has tied up with Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI), Lucknow, for testing the

autoimmune disease kits for quality. According to Dr Bhanushali, the company tied up with the SGPGI because of the latter's experience in this field and to ensure stringent quality checks.

“I think public private partnership is a very good idea but it should be time-bound. The government agencies have their own priorities and the projects at times get delayed,” said Dr Bhanushali.

He said they have developed two GMO kits - genes for them were developed by scientists in India - and the company is the only manufacturer of those kits in the world. “We have made a small beginning by exporting our kits to China,” he said.

Rahul Koul in NewDelhi