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A cheaper, quicker swine flu test kit

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Since the pandemic after the 2009 outbreak, swine flu has been a major concern worldwide. The most devastating outbreak that year was observed in Mexico, which was caused by H1N1 strain of the influenza virus. Since then, the disease has spread in over 200 countries, causing many deaths. One of the reasons for the pandemic in emerging countries such as India was the lack of infrastructure to detect the infection in humans and controlling the spread.

Addressing the concern, a research institution in India under the Ministry of Defence's Defence Research and Development Organization, Defence Research and Development Establishment (DRDE), has come up with a swine flu diagnostic kit that can detect the H1N1 virus within an hour.

The new kit developed by the Gwalior-based laboratory and being commercialized by RAS Lifesciences uses a simple technique called real-time loop amplification (LAMP) to detect the swine flu virus. The technology has been transferred to Hyderabad-based Ras Lifesciences for manufacturing the kit commercially under a licensing agreement with DRDO that took place on March 31, 2012. The agreement was signed under the DRDO-FICCI Accelerated Technology Assessment and Commercialization program.

Unlike the new kit called NuLAMP H1N1, the method traditionally adopted for the test is the reverse transcriptase polymerase chain reaction (RT-PCR) methodology recommended by the Centre for Disease Control. This method is not only time consuming but also expensive.

As the name suggests, LAMP works at single temperature (isothermal) and does not need temperature cycling, which is required in other techniques, such as PCR, thereby eliminating the need for sophisticated equipment. "Conventional method was real time and based on PCR, which needed expensive machines and costly reagents. LAMP, however, can be performed in heating block or a water bath, thereby cutting down the cost of capital expenditure tremendously," says Mr Shesheer Kumar, MD, RAS Lifesciences.

The LAMP primers were designed and developed at the DRDE in Gwalior. Subsequently, after the technology transfer, RAS

has developed all the reagents required for the kit. Enzyme Bst polymerase was developed in-house and it proved to have three-four fold higher activity than all other commercially available enzymes. The company has already received the Drug Controller General of India's clearance for manufacturing the NuLAMP H1N1 kit.

This new kit has a number of advantages over the conventional method. For example, the kit was found to be 95 percent sensitive and 100 percent specific in 1000 samples tested. The kit drastically reduces the time required to detect swine flu from eight hours (which was required in the conventional method) to less than an hour. It is also less expensive (more than eight times) than the conventional method, which used to cost about $143 (Rs 8,000) per test.

RAS Lifesciences has approached the Indian Council of Medical Research (ICMR) for conducting trials at four different centers. "In the current facility, 400-500 kits of 100 reactions per month can be manufactured. We have been allotted a 20,000 sq mt of land in phase III biotech park of APIIC. We are also planning to build an FDA-compliant facility of 10,000 sq ft for the production of NuLAMP H1N1 kit, along with test kits for other diseases. This plant is expected to be ready in eight-to-10 months and is expected to cater up to 20,000 kits per month," says Mr Kumar.

He adds that they plan to sell the kits cheaper. "As opposed to what the real time PCR assay costs, we propose a cost of $16 (Rs 900-Rs 1,000) per test and, with the support of the government for large-scale procurement, we can bring down the cost of the kit to approximately $14 (Rs 600-Rs 800) per test. We are looking to establish distribution networks in different regions in India and outside the country as well."

The company is planning to automate extraction and LAMP procedures together so that minimal handling by people is involved. This would enable the company to install these kits at airports, railway stations and other public places for screening.