BCIL Biotech Consortium India Limited

Japanese Encephalitis Virus detection technology

TECHNOLOGY AVAILABLE FOR TRANSFER

UNMET NEED AND OPPORTUNITY

Japanese encephalitis virus (JEV) causes brain infection that spread through Mosquito bites and is the most important cause of viral encephalitis in Asia. JEV infection in humans is most commonly asymptomatic, however, the case-fatality rate among those with encephalitis can be as high as 30%. Gastrointestinal pain and vomiting may be the dominant initial symptoms. Severe disease is characterized by rapid onset of high fever, headache, neck stiffness, disorientation, coma, seizures, spastic paralysis and ultimately death.

There is no cure for the disease, however, treatment is focused on relieving severe clinical signs and supporting the patients through safe and effective vaccines. Researchers are trying to identify particular gene sequence to develop diagnostic kits for detection of JEV. There are multiple diagnostic kits in the market but their sensitivity and specificity are low. The present technology relates to an antigen based Lateral Flow Assay (LFA) for rapid and sensitive screening of JEV infection compared to other commercial assay kits.

TECHNOLOGY

The technology is based on an antigen based lateral flow assay for rapid screening of Japanese Encephalitis Virus (JEV) in clinical serum samples. It provides a recombinant Japanese Encephalitis Virus (JEV) non-structural 1 (NS1) protein and its polyclonal antibody for development of cost-effective and a simple lateral flow assay to detect the presence of JEV in humans and animals.

UNIQUE SELLING PROPOSITIONS

- The process of making recombinant JEV NS1 protein in bacterial expression system is easier, less time consuming and cost-efficient.
- The JEV NS1 polyclonal antibody can recognize multiple epitopes resulting in higher binding affinity to the target antigen which in-turn increases the sensitivity.
- The JEV NS1 polyclonal antibody can detect minute quantities of the target antigen in sample and has a higher chance of showing affinity towards mutating antigens.
- Only one set of in-house produced JEV NS1 polyclonal antibody required as both capture and detector antibodies.
- The present technology detects the JEV NS1 protein instead of IgG antibody or envelope protein which is more advantageous as the protein is found in the secretary system from the first day of infection enabling detection at an early stage.
- Rapid results with minimal sample preparation and volume.
- The technology can detect **up to 10 pg/ml Ag in serum samples** and is disposable, cost- effective, user-friendly, and most-importantly for point-of-care detection.

STAGE OF DEVELOPMENT

- Thoroughly characterized and successfully employed for fabrication of (LFA) and detection.
- The technology has been developed, tested, and validated on 70 clinically infected JEV pig serum samples consisting of 34 JEV positive and 36 JEV negative samples and third-party validation have also completed.

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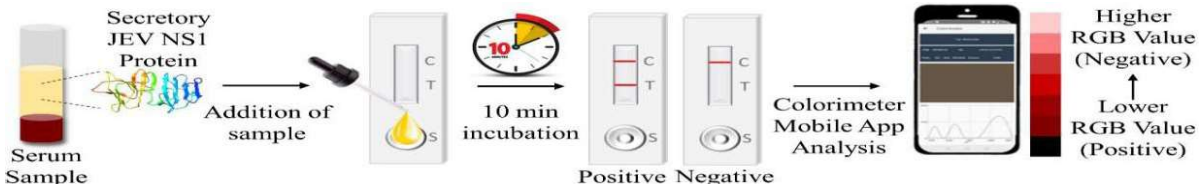

The technology has also undergone inter-lab and third-party validation for further confirmation of presence or absence of JEV in serum and CSF of patients. The sensitivity of the technology is **97.14%**

Table-1: Results of Third-party validation of JEV detection technology:

Sample No.		In-house result	Result validated by ICAR- Indian Veterinary Research Institute	Result validated by CSIR-CCMB, Hyderabad
1		Positive	Positive	Positive
2		Positive	Positive	Positive
3		Positive	Positive	Positive
4		Positive	Positive	Positive
5		Positive	Positive	Positive
6		Positive	Positive	Positive
7		Positive	Positive	Positive
8		Positive	Positive	Positive
9		Positive	Positive	Positive
10		Positive	Positive	Positive
11		Negative	Negative	Negative
12		Negative	Negative	Negative
13		Negative	Negative	Negative
14		Negative	Negative	Negative
15		Negative	Negative	Negative
16		Negative	Negative	Negative
17		Negative	Negative	Negative
18		Negative	Negative	Negative
19		Negative	Negative	Negative
20		Negative	Negative	Negative
21	(Positive control)	Positive	Positive	Positive
22	(Negative control)	Negative	Negative	Negative
23	West Nile Virus (WNV)	Negative	Negative	Negative
24	Yellow Fever Virus (YFV)	Negative	Negative	Negative
25	Dengue Virus	Negative	Negative	Negative

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INTELLECTUAL PROPERTY

Patent Application is filed in India.

LICENSING OPPORTUNITY

BCIL is looking for suitable industrial partner for commercialization of this Diagnostic technology for Japanese Encephalitis Virus detection.

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