



Detection of Acute Promyelocytic Leukemia (APL) using CRISPR/LbCas12a system

TECHNOLOGY AVAILABLE FOR TRANSFER

UNMET NEED AND OPPORTUNITY

Acute Promyelocytic Leukemia (APL) is a medical emergency with a high risk of mortality if not treated immediately. Current diagnostic methods such as cytogenetics, immunophenotyping, real time PCR, etc. offer sensitivity and accuracy but are time-consuming, costly, infrastructure-dependent, need analytical and technical expertise, leading to critical delays in initiating life-saving therapy.

There is a strong need for rapid, reliable and affordable diagnostic tools that can be deployed at the point of care. Such solutions would enable early detection of APL, allow prompt initiation of targeted treatment and subsequently improve patient survival outcomes.

TECHNOLOGY & EXPERIMENTAL VALIDATION

This technology involves providing a rapid diagnosis of APL without the need of complex instruments for facilitating timely therapeutic intervention and minimizing the risk of early mortality.

The assay uses CRISPR-Cas technology to specifically detect the PML::RARA fusion transcript that defines APL.

A rapid amplification step (RT-LAMP) boosts the signal, and the CRISPR system then confirms the presence of the fusion transcript with precision.

The result is displayed on a simple lateral flow strip, giving a clear positive or negative readout in under three hours.

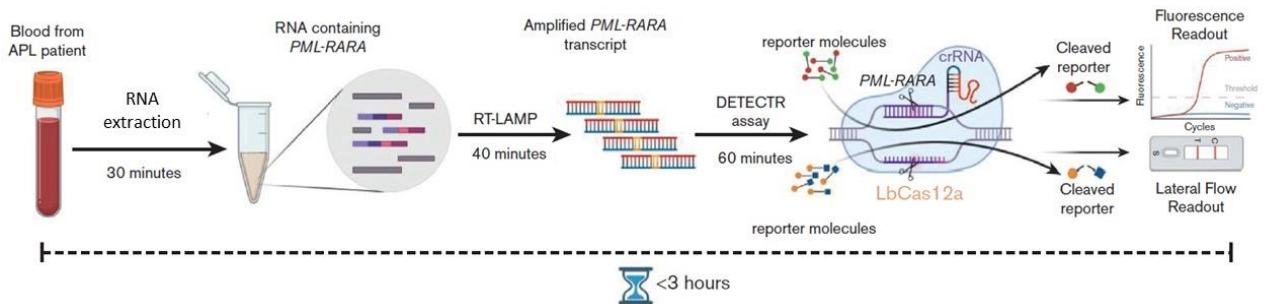


Figure showing the workflow of the assay for detection of PML::RARA fusion transcript for rapid diagnosis of APL.

STAGE OF DEVELOPMENT

The technology is currently placed at **TRL4** and has been clinically validated in more than 100 patient samples.

UNIQUE SELLING PROPOSITION

- Can serve as confirmatory test for detection of APL thus negating the need for painful bone marrow biopsies.
- High accuracy – 100% sensitivity and specificity.
- Limit of Detection – This test can detect even 1 copy of the transcript, whereas the conventional RT-PCR tests need at least 10 copies for detection.
- Rapid diagnosis – Provides results within 3 hrs.
- Cost effective – Cheaper compared to conventional RT-PCR tests.
- Shelf life – Powdered form can be stored upto 12 months at room temperature without any significant change in efficacy.
- Point-of-care capability – Suitable for on-site/outpatient usage, even at remote areas.
- Ease of use – i. Does not need advanced/ specialized instruments/infrastructure.
ii. Lateral flow strip-based simple readout allows non-specialized personnel to perform the test.

INTELLECTUAL PROPERTY

Indian patent filed.

LICENSING OPPORTUNITY

BCIL is looking for potential licensees for transfer of this technology.

CONTACT:

Dr. Purnima Sharma (Managing Director)

BIOTECH CONSORTIUM INDIA LIMITED

V Floor, Anuvrat Bhawan, 210, Deen Dayal

Upadhyaya Marg, New Delhi:110002

Phone: Tel.: +91-11-23219062,

Email: info.bcil@biotech.co.in &

tto.bcil@biotech.co.in

Website: www.biotech.co.in