Development of a colorimetric isothermal assay for detection of Corynebacterium diphtheria

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About the Technology: This assay could enable point-of-care testing outside of the diagnostic laboratory and can be applied for contact tracing and diagnosis in field conditions. This assay is also able to differentiate between toxigenic and nontoxigenic species of C. diphtheriae, Laboratory demonstration of presence of C. diphtheriae in the throat swab samples require culture and isolation or PCR based tests that require time. It is also expensive, requires expertise and can be performed only in high-end laboratories.

Technology ID: PM-TT-IM-2026-Mar-35
Lead Inventor: Dr. Shyam Sundar Nandi
Institute: ICMR- National Institute of Virology and ICMR-National Institute of Epidemiology
Technology Domain: Other
Disease Area (Broad): Others
EoI Start Date: 14/05/2026
EoI End Date : 20/05/2026

Need and utility of the Technology from Public health perspective: Laboratory demonstration of presence of C. diphtheriae in the throat swab samples require culture and isolation or PCR based tests that require time. It is also expensive, requires expertise and can be performed only in high-end laboratories.

Technology Readiness level (TRL):

TRL 5: External validation of the assay was done via WHO, Delhi office, in Diphtheria testing laboratory KGMU, Lucknow which come under network for Diphtheria surveillance.

Competitive Advantage:

This assay could enable point-of-care testing outside of the diagnostic laboratory and can be applied for contact tracing and diagnosis in field conditions. This assay is also able to differentiate between toxigenic and nontoxigenic species of C. diphtheriae.

Validation Status and Study Outcome:

- Inhouse Validation –Complete
- Efficacy Outcome: External validation of the assay was done via WHO, Delhi office, in Diphtheria testing laboratory KGMU, Lucknow which come under network for Diphtheria surveillance.

Market Potential: Diphtheria is re-emerging globally, with India contributing a disproportionate share of global cases due to gaps in booster immunization and delayed diagnosis. India alone accounted for ~78% of global diphtheria cases as of 2020, with **continued outbreaks reported through 2024–2026.**

Publication: NA

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