

BioSpect

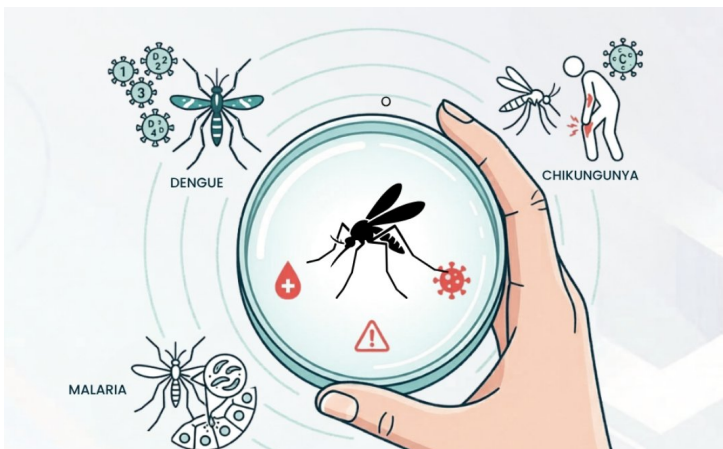
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Ameliorate Biotech's multi-diagnostic test receives CDSCO manufacturing approval

16 May 2026 | News

Simultaneously detects dengue, malaria (including vivax and falciparum differentiation), chikungunya and their co-infections using a single blood sample



India Health Fund (IHF)-supported rapid multi-diagnostic test, ASSURED, developed by Bengaluru-based Ameliorate Biotech, has received approval for manufacturing and marketing from the Central Drugs Standard Control Organisation (CDSCO).

The first-of-its-kind “Made in India” test can swiftly and simultaneously detect dengue, malaria (including vivax and falciparum differentiation), chikungunya and their co-infections using a single blood sample in under 15 minutes and can be easily used by a minimally trained workforce at the primary care level. This approval now paves the way for large-scale product manufacturing and launch in the market.

India Health Fund supported Ameliorate Biotech to conduct an open label, multicentric, performance and cost-effectiveness evaluation of the rapid antigen-based diagnostic kit. This multicentric evaluation was completed across three CDSCO-approved centres, namely RMRIMS (Patna), Rajiv Gandhi Institute (Srikakulam), and KLES's Dr. Prabhakar Kore Hospital (Belagavi).

With sensitivity and specificity being 99.34% and 100% respectively, ASSURED is now gearing up for manufacturing scale-up, setting up stringent quality control processes, distribution pipelines, and supply chain logistics. It also addresses critical healthcare inequities by being accessible, affordable, widely available, and acceptable, thereby optimising healthcare delivery.