International Alliance for Biological Standardization

Animal Testing Replacement for Vaccines.
A One Health View: Global Outlook and Future Strategy
December 2-4, 2025
Bangkok, Thailand

Advancing Vaccine Quality Control through Non-Animal Testing at National Control Laboratory, Badan POM

This overview details the strategic initiatives undertaken by the National Control Laboratory (NCL) of Badan POM to transition vaccine batch release testing toward advanced, non-animal testing (NAT) methodologies. These efforts directly support the global commitment to ethical biological product quality control, aligning with forthcoming international standards such as the draft WHO Guidelines on the replacement or removal of animal tests. The NCL's program focuses on the high-priority replacement of conventional *in vivo* methods across three critical areas: pyrogenicity assessment, endotoxin detection, and the neurovirulence testing for novel polio vaccines (nOPV2).

Initial capacity building and validation trials have yielded crucial findings. For pyrogen testing, the Monocyte Activation Test (MAT) demonstrated successful implementation with superior sensitivity for both endotoxin and non-endotoxin pyrogens, paving the way for formal validation in 2026. Simultaneously, a trial for Recombinant Factor C (rFC) confirmed that existing infrastructure is an open system, strategically confirming the flexibility to adopt various quantitative reagent brands. To replace the Monkey Neurovirulence Test (MNVT), the NCL has invested in specialized training for Next-Generation Sequencing (NGS), establishing foundational technical expertise to handle complex genetic sequencing and data interpretation.

A comprehensive gap analysis identifies core hurdles to achieving full implementation, primarily stemming from the significant investment required for state-of-the-art infrastructure, the limited commercial access and high cost of specialized NAT reagents, and the continuous need to develop highly competent human resources. To mitigate these challenges, the NCL's 2026 roadmap prioritizes the formal validation of the MAT method, executing further rFC/RcR trials with partners, initiating the procurement of essential NGS supporting equipment, and hosting focused workshops to accelerate the final implementation of these modern control systems.