



International Alliance for
Biological Standardization

**Maintaining the Quality of Vaccines through the Use of Standards:
Current Challenges and Future Opportunities
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The use of reference materials in the standardization of immunological assays

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Comparing immune responses against different vaccine candidates intended for the prevention of a specific viral infection is challenging. To improve immunological assay standardization across different vaccine candidates and meaningful comparison of results, the Coalition for Epidemic Preparedness Innovations (CEPI) has created a Centralized Laboratory Network (CLN) vaccine immunogenicity testing selecting laboratories with high quality standards worldwide, picking the most advanced assays to be used across the Network and providing all the laboratories with harmonized protocols and key reagents. The Network has worked on SARS-CoV-2 assay since its creation in 2020 and is now expanding to new pathogens.

The Centralized Laboratory Network today counts 15 laboratories worldwide, is open to all vaccine developers worldwide to apply for testing samples from pre-clinical to Phase III clinical studies to facilitate rapid evaluation, approval, and dissemination of the most effective vaccine candidates and supports their pathway towards licensure.

The CLN focuses on immunological assays including antibody binding assays, neutralizations assay, and an immune cell-based assay. The assays are developed, qualified and validated in one reference laboratory and then transferred to the rest of laboratory partners for suitable use in clinical trials in accordance with the regulatory guidelines. All CLNs use the same key reagents, comparable materials and equipment, parallel protocols and procedures, and well characterized standards and panels including the WHO international antibody standards to ensure accuracy, reproducibility and harmonization of assay results. The use of standards material is useful in assay harmonization efforts but also has its challenges.