






TruCulture[®] Vaccine Applications

Introduction

TruCulture is a whole blood collection and culture system for immune monitoring of patients in clinical trials. Utilized in hundreds of clinical trials, TruCulture has demonstrated distinct applications in vaccine development:

-  Monitoring vaccine-induced immunity (antigen recall)
-  Effective, reproducible alternative to PBMCs for immune monitoring
-  Distinguishing between active and latent infection
-  Early safety studies of vaccines and their individual components
-  Profiling the functional immune status of clinical trial participants

TruCulture tubes are designed to capture immune cell activity at the time and place of sample collection, minimizing the bias and variability introduced by sample shipping and manipulation. The integrated whole-blood collection and leukocyte culture system is reliable and reproducible without the need for any specialized laboratory equipment. The *ex vivo* TruCulture procedure preserves physiological cellular interactions to more accurately reflect the complexities of the human immune system, bringing added value to immune monitoring in clinical trials.



An additional benefit is that IQVIA Laboratories Protein Biomarkers team can develop and manufacture custom TruCulture tubes for vaccine clinical studies, incorporating specific antigens and or adjuvants. In addition to positive and negative control tubes for T cell activation, we offer viral and microbial innate immune system stimulants.



TruCulture is a high-throughput tool for monitoring vaccine-induced immunity¹

This study demonstrated the use of TruCulture to measure antigen recall responses after seasonal influenza vaccination. Researchers collected whole blood from healthy adult volunteers before and 2 weeks after influenza immunization, then incubated 1 mL samples in TruCulture tubes pre-loaded with influenza hemagglutinin (HA) antigens. The post-vaccination samples showed a significant increase in several cytokines (IFN- γ , IL-1 β , IL-6, IL-10, IL-12, IL-17, TNF- α) when stimulated with the HA antigens matching the vaccine strains, whereas minimal cytokine changes were observed either in pre-vaccination samples or in control tubes without antigen.

TruCulture is an effective and practical alternative to PMBCs for immune monitoring in vaccine trials, without the need for labor-intensive cell isolation procedures²

TruCulture samples assessed by multiplexed immunoassay closely mirrored the results of the PBMC-based intracellular cytokine staining (ICS), detecting robust T-cell responses induced by vaccination, as well as unique responses in older adults. The authors highlight that cytokine measurements using TruCulture tubes provided a reliable, standardized, and high-throughput readout of vaccine-induced cell-mediated immunity, in agreement with traditional flow cytometry results.

TruCulture can distinguish between active and latent tuberculosis³

This study applied TruCulture to a critical vaccine-related diagnostic challenge — distinguishing active *Mycobacterium Tuberculosis* (TB) disease from latent TB infection. Standard blood tests measuring IFN- γ release in response to TB antigens cannot reliably differentiate active TB disease from asymptomatic latent infection. In response to *M tuberculosis* antigens, TruCulture produced a much stronger IFN- γ signal in active TB patients than in latent carriers, achieving an area-under-the-curve (AUC) of ~0.81–0.89 for diagnosing active disease, compared to an AUC of only ~0.56 with a diagnostic assay. These results indicate that TruCulture's integrated immunostimulation can unveil immune response patterns (e.g. higher antigen-specific IFN- γ release) that are unique to active TB and missed by other assays.

Summary

These diverse studies collectively illustrate the utility of the TruCulture whole-blood assay in vaccine research and development. By enabling ex vivo stimulation of fresh blood with vaccine antigens or immune agonists in a closed, standardized system, TruCulture allows researchers to measure functional immune responses in conditions that closely mimic the human physiological environment. The findings above highlight several advantages of this approach:



Standardization and reproducibility

The pre-filled tubes capture all circulating immune cells and don't require additional sample manipulation.



Reduced need for on-site lab equipment

TruCulture tubes are collected, incubated and frozen. No centrifuge is needed, enabling wider integration of cell-mediated immunity measures in vaccine trials that labor-intensive assays.



Discrimination between disease states

TruCulture can be used to identify the differences in immune signatures between active and latent disease, which can aid in vaccine development and monitoring adverse responses in a clinical study.



Applications across testing platforms

These studies tested TruCulture samples by immunoassay (Luminex) and gene expression analysis (Nanostring). TruCulture has also demonstrated utility when analyzed by flow cytometry.

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TRUCULTURE CUSTOM TUBE DEVELOPMENT — AN IDEAL SOLUTION FOR EARLY SAFETY STUDIES OF VACCINES AND THEIR INDIVIDUAL COMPONENTS

IQVIA Laboratories has a well-established process to develop custom TruCulture products, including a healthy donor pool that can be further tailored according to client needs. The general development process includes testing for: 1) solubility, 2) biological activity, and 3) stability.

References

1. Hwang SA, Eisinger D, LaBrie S. A TruCulture whole blood assay to evaluate annual flu vaccine recall responses. *J Immunology*, Volume 204, Issue 1_Supplement, May 2020, Page 245.14, <https://doi.org/10.4049/jimmunol.204.Supp.245.14>
2. De Rosa SC, Cohen KW, Bonaparte M, Fu B, Garg S, Gerard C, Goepfert PA, Huang Y, Larocque D, McElrath MJ, Morris D, Van der Most R, de Bruyn G., and Pagnon A. (2022). Whole-blood cytokine secretion assay as a high-throughput alternative for assessing the cell-mediated immunity profile after two doses of an adjuvanted SARS-CoV-2 recombinant protein vaccine candidate. *Clin and Transl Immunology* 11(1), e1360. <https://doi.org/10.1002/cti2.1360>
3. Duffy D, Nemes E, Llibre A, Rouilly V, Musvosvi M, Smith N, Filander E, Africa H, Mabwe S, Jaxa L, Charbit B, Mulenga H, Tameris M, Walzl G, Malherbe S, Thomas S, Hatherill M, Bilek N, Scriba TJ, Albert ML, Milieu Intérieur Consortium (2021). Immune profiling enables stratification of patients With active tuberculosis disease or mycobacterium tuberculosis *Infection*. *Clinical infectious diseases: an official publication of the Infectious Diseases Society of America*, 73(9), e3398-e3408. <https://doi.org/10.1093/cid/ciaa1562>