



TruCulture®: Whole blood collection and culture system for clinical studies

Evaluating the pharmacodynamics (PD), dosing and safety of potential therapeutic drug candidates on the immune system during early-stage clinical trials is crucial but challenging due to the variability of isolating and culturing whole blood or peripheral blood mononuclear cells (PBMC). These samples require a specialized cell culture facility and personnel. They also exhibit low cellular viability and high variability due to delays in processing (shipment) and extensive sample manipulation.

TruCulture from Rules-Based Medicine solves these challenges by providing a closed system for whole blood collection and culturing at the collection site, requiring only a phlebotomist and a heat block. The TruCulture whole blood culture system:



Starts the instant a 1 mL blood sample is drawn directly into the TruCulture tube without delay or manipulation, substantially improving reproducibility.



Nourishes the leukocytes with 2 mL optimized media with immune stimulants or drug candidates for up to 48 hours of culture.



Uses a simple valve separator to separate the cells from the culture supernatant after incubation for downstream measurement of secreted cytokines or cell analysis.

Advantages of TruCulture	Challenges of traditional PBMC
• Closed, instant whole blood collection and culture system • Standardized for consistent performance across multiple users and clinical sites • Reliable, easy to use and reproducible, eliminating the need for cell manipulation • Retains all blood components, granulocytes, platelets, red blood cells, soluble factors and Fc receptor-expressing cells • An inexpensive heat block replaces the need for lab equipment or centrifugation steps • Has been successfully deployed in hundreds of clinical drug trials	• Separate blood collection and specialized cell culture procedures • Extensive manipulation, processing, and often freezing/shipping prior to culturing • Requires technical expertise with increased variability across users and clinical sites • Requires CO² incubator, biosafety cabinet, centrifuge, media, and cell culture plastics • Culture procedures/conditions are difficult to standardize for clinical trial applications • Open, less sterile, artificial system • Poor reproducibility

Traditional pharmacodynamic whole-blood experiments are often short in duration (2-6 hours) due to poor culture conditions and premature termination of the normal physiological immune response. TruCulture provides a longer, more robust response to enable higher sensitivity and greater relevance than short incubation times.

TruCulture benefits

- 1

Reproducible and consistent results
Reduces assay variability by eliminating the need for sample processing prior to culturing¹
- 2

Cost-effective and patient-inclusive
TruCulture eliminates the need for expensive lab equipment or specialized collection techniques. This enables broader participation from under-represented populations.
- 3

Flexibility
Send your TruCulture samples directly to RBM for Luminex- or Simoa-based testing or to your lab of choice. TruCulture is compatible with NanoString, RT-PCR and RNA sequencing platforms. Talk to our scientists for details.

In a multi-center trial coordinated by the Institut Pasteur, **TruCulture consistently demonstrated superior reproducibility and consistency** of data compared to PBMC cultures.¹

TruCulture applications

TruCulture has been utilized as a whole-blood stimulation system by researchers and drug developers in several fields to reliably measure immune response for the following applications:¹⁻⁴

1. Pharmacodynamics (including dose-response)

2. Functional immune cell analysis

3. Evaluate innate immunity

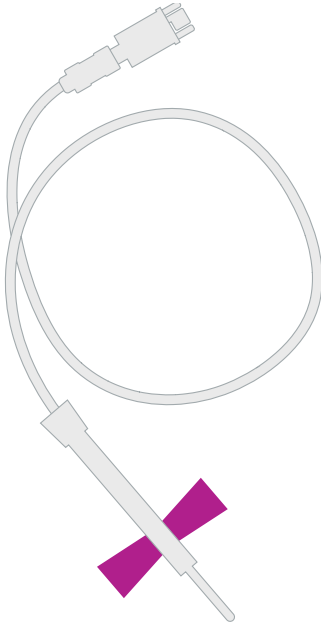
4. Disease characterization

5. Patient stratification
6. Genotype-to-phenotype association studies

7. Vaccine Development
 - Antigen recall – by segregating the response caused by your therapeutic candidate from the expected response of T cells or B cells to known stimulants
 - Early safety studies
 - Profile the functional immune status of clinical trial participants

TruCulture components

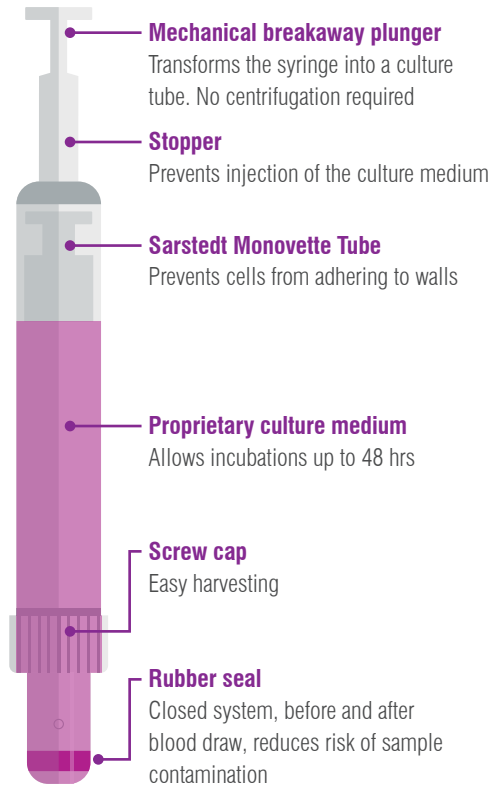
**Sarstedt Safety-Multifly®
Needle Set, 19G-21G
(Butterfly Needle)**



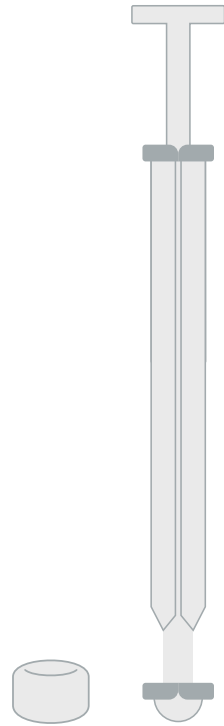
**Sarstedt S-Monovette®
(Priming Tube)**



TruCulture Tube

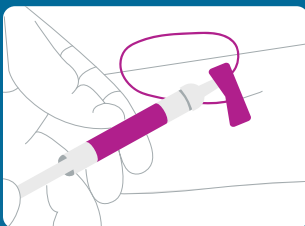


**Sarstedt Seraplas® valve
filter, V11 (Valve and Stick)**
Separates the supernatant from the cells.
No centrifugation required



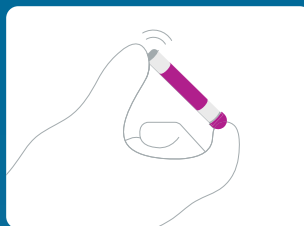
TruCulture procedure

TruCulture tubes are pre-loaded with cell culture media and immune stimulant(s) or drug candidates. Blood is drawn directly into the TruCulture tube and incubated in a dry heat block. Supernatants are collected by simply inserting a valve separator to separate cells from the culture supernatant.



1. Collect

Draw 1 mL of blood directly into the TruCulture tube and break off the plunger



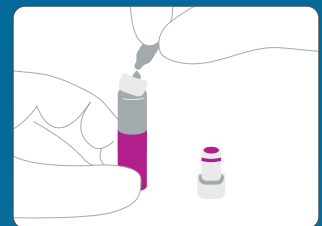
2. Mix

Gently invert the tube to mix 3 to 5 times



3. Incubate

Place tube in 37°C heat block for up to 24 or 48 hours



4. Separate

Manually insert valve to separate supernatant and cell layer for downstream analysis

A total solution for clinical research

Send your TruCulture samples to Rules-Based Medicine for multiplexed biomarker testing on the Luminex platform or ultrasensitive single-molecule array (Simoa) testing. As the specialty immunoassay lab within IQVIA Laboratories, RBM works directly with clinical trial sponsors and through central labs. The TruCulture system works seamlessly with our protein biomarker assays, offering a single-source solution for your pharmacodynamic studies.

Our TruCulture MAP profile is a cost-effective multiplex assay of 13 analytes optimized for TruCulture. TruCulture MAP analyzes the immune response to a variety of TruCulture immune stimulants. For ultrasensitive analysis, our Simoa-based assays are available.

The collected, cultured and separated TruCulture cells are also compatible with flow cytometry and gene expression (NanoString, RT-PCR and RNAseq) analysis.

Together, the *ex vivo* TruCulture system preserves physiological cellular interactions to reflect the complexities of the human immune system more accurately, bringing enhanced value to immune monitoring in clinical trials.

Custom development service

TruCulture tubes can be customized with soluble substances to target the immune pathway of choice. Our scientists are experts in developing and validating TruCulture systems with proprietary substances or biologics to support clinical studies. Our well-established process for making customized TruCulture tubes includes:

1. Solubility testing
2. Biological activity testing
3. Real-time stability testing of the custom TruCulture tube while actively used in a trial



Learn more at rbm.iqvia.com/TruCulture or email us at RBM_clientservices@iqvia.com

References

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