RULES BASED MEDICINE
a Q² Solutions Company

Antigen Recall Responses to SARS-CoV-2 Spike Protein

TruCulture® is a whole blood collection and culture system for immune monitoring of subjects in clinical trials. Utilized in hundreds of clinical trials for a variety of applications, our newest off-the-shelf TruCulture stimulant, SARS-CoV-2 Spike Protein (aa 1-1208) is ideal for use in clinical studies in need of:

1. Quantifying SARS-CoV-2 vaccine-dependent T cell activation
2. Investigating the magnitude and duration of T cell response post SARS-CoV-2 infection

TruCulture is a whole blood collection and incubation system designed to stimulate discrete or complex immune responses from clinical trial subjects at the time and place of blood draw. Because it is a closed system, there is no need for specialized cell culture equipment or technical knowledge. All that is required is a phlebotomist and a 37°C heat block.

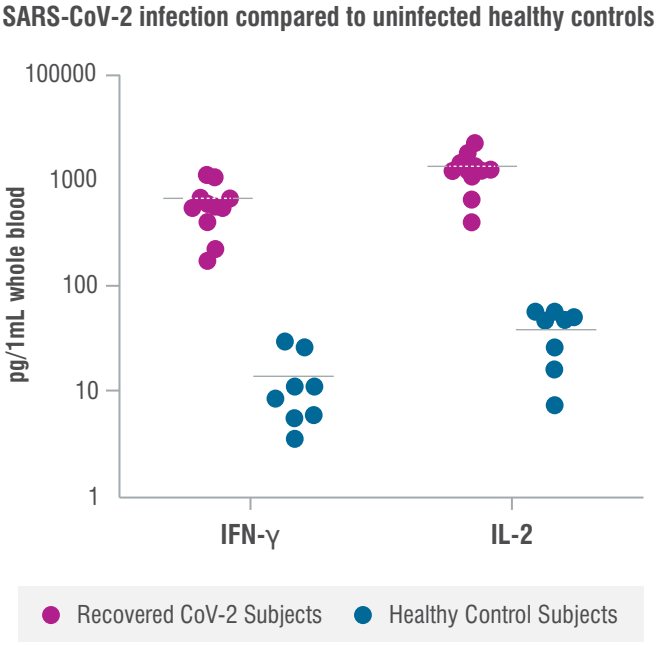
SARS-CoV-2 TruCulture tubes incorporate human cell expressed recombinant spike protein from SARS-CoV-2. *Figure 1* shows antigen-specific T cell responses (increased secretion of the T cell cytokines IFNγ and IL-2) from human subjects with documented past SARS-CoV-2 infection compared to uninfected healthy controls.

In addition to comparisons to non-infected subjects, control experiments supporting that IFNγ and IL-2 production is specific to SARS-CoV-2 spike protein includes:*

- Significant low levels of innate immune activation from healthy controls as determined by IL-6, TNFα, and IL-1β compared to SARS-CoV-2 positive subjects.
- Purified recombinant spike protein with endotoxin level <0.01EU/μg protein.

Figure 1: TruCulture SARS-CoV-2 spike protein stimulates whole blood secretion of IFNγ and IL-2 from recovered SARS-CoV-2 positive subjects

1 mL of whole blood from 11 SARS-CoV-2 PCR positive subjects (4 -5 weeks after testing positive by RT-PCR) and 8 healthy subjects with no known history of exposure were collected into SARS-CoV-2 Spike Protein TruCulture tubes (1μg/mL final concentration of spike protein). After ~44 to 48 hours incubation at 37°C in a heat block, the supernatants were collected and analyzed for IFNγ and IL-2 by Simoa ultrasensitive immunoassays from Rules-Based Medicine (RBM), a Q² Solutions Company. Data plotted for each individual subject with the mean shown.



truculture®

** Data available upon request*

Turning Hope Into Help™

- IFNγ and IL-2 induction by SARS-CoV-1 or MERS-CoV spike proteins are significantly low compared to SARS-CoV-2 spike protein in SARS-CoV-2 positive subjects.
- TruCulture tubes containing spike proteins from the common cold corona viruses (HKU1, OC43, NL63, 229E) induce T cell cytokines in both SARS-CoV-2 infected and non-infected individuals.

SARS-CoV-2 spike protein TruCulture overcomes many challenges to demonstrating T cell antigen specific activation

Generating T cell antigen response data is challenging yet vitally important to SARS-CoV-2 research and vaccine development. Existing methods such as ELISpot are extremely difficult and expensive to execute at clinical trial sites since they are laborious, require skilled personnel, PBMC isolation, and a fully equipped cell culture laboratory. Furthermore, the ability of stored blood or PBMCs to secrete IFNγ upon subsequent antigen stimulation declines by over 80% in just 1-2 hours after collection.[1] With TruCulture, antigen processing and presentation starts the instant a 1mL blood sample is drawn directly into the TruCulture tube containing 2 mL of media harboring the SARS-CoV-2 spike protein antigen.

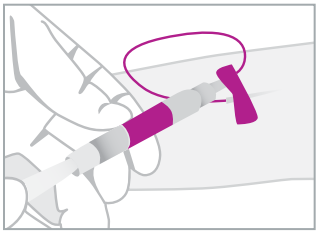
The TruCulture SARS-CoV-2 Spike Protein can be easily incorporated into clinical vaccine and research studies. In addition to measuring cytokines from TruCulture supernatants, the cell layer can be collected for downstream analyses such as gene expression[2,3] and flow cytometry.[4] TruCulture tubes containing recombinant spike proteins from other coronaviruses are also available on a made-to-order basis.

References

1. Cytokine-based human whole blood assay for the detection of antigen-reactive T cells. Petrovsky, N. & Harrison, L.C. (1995) J. of Immunol. Methods 186 37-46.
2. RNA Extraction/Purification Protocol for TruCulture Samples https://rbm.q2labsolutions.com/scientific-media/rna-extraction-purification-protocol-for-truculture-samples/
3. Gene Expression Analysis of RBM's TruCulture Samples with the Nanostring nCounter Panel https://rbm.q2labsolutions.com/scientific-media/gene-expression-analysis-of-myriad-rbms-truculture-samples-with-the-nanostring-ncounter-panel/
4. Standard Flow Cytometry Protocol for Analysis of Surface Markers https://rbm.q2labsolutions.com/scientific-media/standard-flow-cytometry-protocol-for-analysis-of-surface-markers-for-truculture/

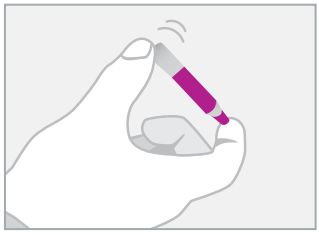
A whole blood collection and culture tube for standardized immunophenotyping procedures

TruCulture tubes are designed to capture immune cell activity at the time and place of sample collection, thereby minimizing the bias and variability introduced by sample shipping and manipulation. These revolutionary tubes consist of an integrated whole-blood collection and leukocyte culture system that is reliable, simple to use and does not require 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.



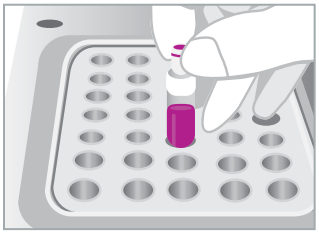
1. COLLECT

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



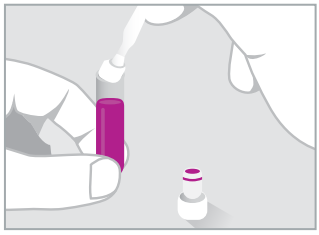
2. MIX

Gently invert 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 from the cells. Collect supernatant and cell layer for downstream analysis.

Contact us

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