Quan-T-Cell SARS-CoV-2 & Quan-T-Cell ELISA

- **Interferon-gamma (IFN-γ) release assay (IGRA) for quantitative determination of the IFN-γ release by SARS-CoV-2-specific T cells**
- **Supports the detection of a past contact with SARS-CoV-2 or an immune response following COVID-19 vaccination**
- **Already well-established in research – high quality confirmed in numerous studies**
- **Fully automated processing and evaluation of the Quan-T-Cell ELISA for IFN-γ quantification**

Technical data

Coating	Stimulation tubes: (1) CoV-2 IGRA BLANK: no activating components, (2) CoV-2 IGRA TUBE: S1-based antigens, (3) CoV-2 IGRA STIM: mitogen; ELISA: monoclonal anti-IFN-γ antibody
Calibration	Quantitative, in milli-international units per milliliter (mIU/ml), 6 calibrators EUROIMMUN recommends interpreting results as follows: negative: < 100 mIU/ml borderline: 100 – 200 mIU/ml positive: > 200 mIU/ml
Sample dilution	Stimulation tubes: 500 µl human heparinised whole blood each; ELISA: 100 µl of heparinised plasma obtained by means of the Quan-T-Cell SARS-CoV-2, diluted 1 : 5 in sample buffer
Reagents	ELISA: ready for use, with the exception of the wash buffer (10x) as well as calibrators and controls (lyophilised); colour-coded solutions in most cases exchangeable with those in other EUROIMMUN ELISA kits
Test procedure	Stimulation: 20 – 24 h at +37 ± 1 °C, manual; ELISA: 120 min / 30 min / 30 min / 20 min at room temperature (sample / biotin / conjugate / substrate incubation), fully automatable
Measurement	ELISA: 450 nm, reference wavelength between 620 nm and 650 nm
Kit format	**Quan-T-Cell SARS-CoV-2:** 30 stimulation tube sets (3 tubes per set) **Quan-T-Cell ELISA:** 96 break-off wells; kit includes all necessary reagents
Order number	**ET 2606-3003 (Quan-T-Cell SARS-CoV-2)** **EQ 6841-9601 (Quan-T-Cell ELISA)** Only to be used together!

Clinical significance

SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) belongs to the coronavirus family, genus *Betacoronavirus,* and is the causative agent of COVID-19 (coronavirus disease 2019*).* SARS-CoV-2 is mainly transmitted by the respiratory uptake of virus-containing droplets and aerosols produced during speaking, breathing, coughing and sneezing. The incubation time of SARS-CoV-2 is three to seven, maximally 14 days. The infection can proceed asymptomatically or cause symptoms of a febrile disease with irregular lung infiltrates. Some patients, especially elderly or chronically ill patients, develop acute respiratory distress syndrome (ARDS).

Suitable methods for the diagnosis of SARS-CoV-2 infection are the detection of viral RNA via reverse-transcriptase polymerase chain reaction (RT-PCR) or of virus protein by means of ELISA or rapid tests. The determination of antibodies enables confirmation of SARS-CoV-2 infection in patients with typical symptoms and in suspected cases. It also contributes to monitoring and outbreak control. Around 90 % of SARS-CoV-2 patients develop specific antibodies up to day 10 after symptom onset. COVID-19 patients also often produce SARS-CoV-2-reactive IFN-γ-releasing T cells.

The cytokin IFN-γ has a central role in the defence against viruses and microorganisms. It activates, for instance, macrophages and stimulates the specific cytotoxic immunity. IFN-γ is produced early in the infection – before the occurrence of the antigen-specific adaptive immune response. The longevity of SARS-CoV-2-specific T cells has not yet been clarified. However, recent data and experiences with other human coronavirus infections show their potential to persist and their ability to control the viral replication and the infection of the host, as well as their relevance in the protection induced by vaccination.

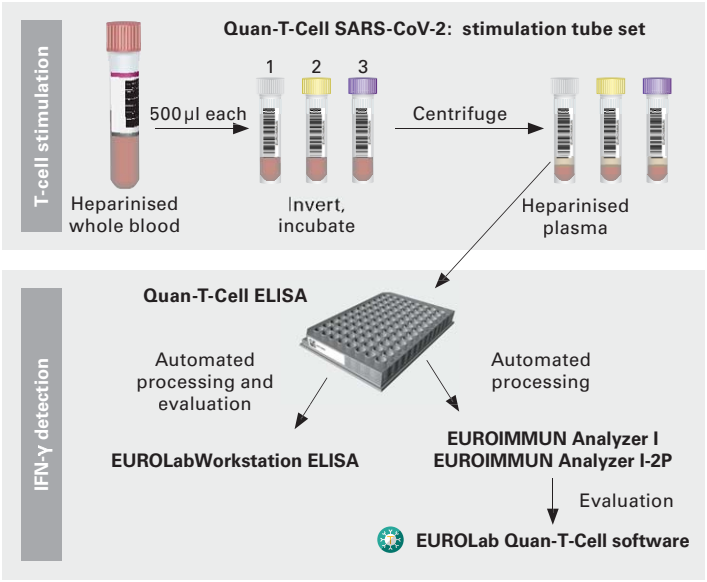
EUROIMMUN Medizinische Labordiagnostika AG · Seekamp 31 · 23560 Lübeck (Germany) · Phone: +49 451 2032-0 · info@euroimmun.de · www.euroimmun.com

Test principle

The test principle is based on the immunological test method of the interferon-gamma release assay (IGRA), which is used to quantify IFN-γ released by immune cells following pathogen-specific stimulation.

The Quan-T-Cell SARS-CoV-2 kit contains 30 stimulation tube sets each consisting of three stimulation tubes per whole-blood sample: (1) **CoV-2 IGRA BLANK:** no T-cell stimulation, for determination of the individual IFN-γ background; (2) **CoV-2 IGRA TUBE:** specific T-cell stimulation using antigens based on the SARS-CoV-2 spike protein; (3) **CoV-2 IGRA STIM:** unspecific T-cell stimulation by means of a mitogen, for control of the stimulation ability.

Fresh human whole blood from a heparin blood collection tube is pipetted into the three stimulation tubes and incubated. If stimulable immune cells are present in the sample, these are activated during the incubation to release IFN-γ. After the incubation, the tubes are centrifuged to obtain stimulated heparinised plasma, which can be used immediately for the determination of the IFN-γ concentration by means of the Quan-T-Cell ELISA or stored for analysis at a later time point.



Clinical performance

The cut-off and clinical performance of the Quan-T-Cell ELISA (EUROIMMUN order no. EQ 6841-9601) in combination with the Quan-T-Cell SARS-CoV-2 (EUROIMMUN order no. ET 2606-3003) were determined by analysing a total of 160 heparinised whole-blood samples from healthy blood donors (UKSH Lübeck, Germany, Institute of Transfusion Medicine). Following stimulation with the Quan-T-Cell SARS-CoV-2, the concentration of the released IFN-γ was determined in the obtained plasmas by means of the Quan-T-Cell ELISA. The samples were also used for determination of the anti-SARS-CoV-2 antibody status of the blood donors by means of two CE-marked antibody tests, i.e. the Anti-SARS-CoV-2 ELISA (IgA) (EUROIMMUN order no. EI 2606 A) and the Anti-SARS-CoV-2 QuantiVac ELISA (IgG) (EUROIMMUN order no. EI 2606-10 G) to detect a past contact with SARS-CoV-2 or an immune response following COVID-19 vaccination. Samples that yielded concordant positive and negative results in the two antibody tests were precharacterised as "positive" (n = 16) and "negative" (n = 144), respectively. Samples with ambiguous, borderline or invalid results were not included in the following calculation.

The recommended upper threshold of the normal value (cut-off) of the Quan-T-Cell ELISA in combination with the Quan-T-Cell SARS-CoV-2 was determined based on 114 negative samples and defined as 200 mIU/ml.

Subsequently, the positive and negative agreement of the Quan-T-Cell ELISA in combination with the Quan-T-Cell SARS-CoV-2 were determined by analysing 16 positive and 30 negative samples, respectively.

The **positive agreement was 93.8 %** (15/16) and the **negative agreement 96.7 %** (29/30).

Literature

Huzly D, et al. **Validation and performance evaluation of a novel interferon-release assay for the detection of SARS-CoV-2 specific T-cell response.** medRxiv 2021.07.17.21260316 (2021).

Schwarz T, et al. **Delayed Antibody and T-Cell Response to BNT162b2 Vaccination in the Elderly, Germany.** Emerg Infect Dis 27(8):2174-2178 (2021).

Hillus D, et al. **Safety, reactogenicity, and immunogenicity of homologous and heterologous prime-boost immunisation with ChAdOx1 nCoV-19 and BNT162b2: a prospective cohort study.** Lancet Respir Med (2021). Online ahead of print.

EUROIMMUN Medizinische Labordiagnostika AG · Seekamp 31 · 23560 Lübeck (Germany) · Phone: +49 451 2032-0 · info@euroimmun.de · www.euroimmun.com
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