T-TRACK® CMV

CMV-specific immune monitoring tool

Experts for immune diagnostic systems
T-Track® CMV in vitro diagnostic test

The T-Track® CMV is a highly-sensitive, standardized and user-friendly CMV-specific immune monitoring tool. The in vitro diagnostic ELISpot test was developed to improve CMV management in healthy and immunocompromised individuals, such as transplant recipients.

Based on Lophius’ patented T-activation® technology, T-Track® CMV allows the sensitive assessment of the functionality of CMV-specific cell-mediated immunity (CMI), by measuring IFN-γ secretion by a broad network of clinically-relevant CMV-reactive effector cells.

To guide your antiviral therapy decision-making, results from the all-in-one ELISpot kit are available within 24 hours and can be analyzed by specialized laboratories or diagnostic departments.

T-Track® CMV performance characteristics in healthy individuals

„An optimized IFN-γ ELISpot assay for the sensitive and standardized monitoring of CMV protein-reactive effector cells of cell-mediated immunity“

Background: In this study, performance characteristics of T-Track® CMV IFN-γ ELISpot assay for the monitoring of CMV-specific CMI were validated in healthy individuals.

Results:
• Stimulation with T-activated® proteins results in improved assay sensitivity and a HLA antigen-independent application
• T-Track® CMV is able to assess the functionality of CMV-reactive CD8+ and CD4+, NK and NKT-like cells
• Robust performance in terms of assay variability (≤22%), precision and linearity

Figure 1. T-Track® CMV demonstrates high sensitivity and specificity in immunocompetent donors. IFN-γ ELISpot were performed on PBMC isolated from whole blood of 45 healthy donors (32 CMV-seropositive, 13 CMV-seronegative). Considering a test result as positive when the geometric mean for at least one of the IE-1- or pp65-stimulated approach is ≥ 10 SFC / 200,000 PBMC (grey horizontal dashed line) and when the ratio of geometric means of stimulated to unstimulated conditions is ≥ 2.5, positive agreement with CMV serology (sensitivity) was 97% (31/32) and negative agreement with CMV serology (specificity) was 85% (11/13) (Barabas et al. 2017).

T-Track® CMV is a standardized, sensitive and reliable in vitro diagnostic test for monitoring the functionality of CMV-specific cell-mediated immunity.

Reference:
Linearity of the optimized CMV ELISpot assay

The linear working range of the T-Track\textsuperscript{®} CMV ELISpot assay was determined for cell numbers between $6 \times 10^4$ and $2 \times 10^5$ PBMC per well (Figure 2). ELISpot counts were directly proportional to the number of PBMC seeded. The performant linearity of the T-Track\textsuperscript{®} CMV IFN-γ ELISpot allows the use of a reduced number of PBMC and thus reduced blood amount per assay.

Figure 2. T-Track\textsuperscript{®} CMV IFN-γ ELISpot shows great linearity within a working range of 60,000 to 200,000 PBMC per well. Results of pp65 and IE-1 stimulations of PBMC from one CMV-seropositive healthy donor (Barabas et al. 2017).

Immune monitoring prior to and following solid-organ transplantation

"Technical and clinical validation of T-Track\textsuperscript{®} CMV, a highly sensitive IFN-γ ELISpot assay monitoring CMV-specific cell-mediated immunity in hemodialysis and immunocompromised patients"

<table>
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<tr>
<th>Assay</th>
<th>Sensitivity</th>
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<tr>
<td>T-Track\textsuperscript{®} CMV (Lophius Biosciences)</td>
<td>90%</td>
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<tr>
<td>QuantiFERON\textsuperscript{®}-CMV (QIAGEN)</td>
<td>73%</td>
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<tr>
<td>iTAg\textsuperscript{™} MHC Tetramers (Beckman Coulter)</td>
<td>77%</td>
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Table 1. Blood from 67 CMV-seropositive hemodialysis patients representative of patients eligible for kidney transplantation were assayed with T-Track\textsuperscript{®} CMV IFN-γ ELISpot (n=67), and - when the amount of blood permitted - with QuantiFERON\textsuperscript{®} CMV (n=66) and iTAg\textsuperscript{™} MHC Tetramers (n=52). Assay sensitivity was 90% (60/67) for T-Track\textsuperscript{®} CMV, 73% (45/62) for QuantiFERON\textsuperscript{®} CMV (4/66 assays being indeterminate), and 77% (40/52) for iTAg\textsuperscript{™} MHC Tetramers (Banas et al. 2017).

<table>
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<tr>
<th>T-Track\textsuperscript{®} CMV</th>
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<tr>
<td>pre-Transplantation</td>
<td>95%</td>
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<tr>
<td>post-Transplantation (over 6 months)</td>
<td>88-92%</td>
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Table 2. A prospective, longitudinal, multicenter study on 96 intermediate risk (D+/R-, D+/R+) renal transplant recipients demonstrated a sensitivity for T-Track CMV\textsuperscript{®} of 95% prior to transplantation and of 88-92% over 6 months post-transplantation, under immunosuppressive treatment (Banas et al. submitted).

References:
Guiding antiviral therapy decisions

A patient risk stratification matrix and recommendations for therapy decisions is proposed based on viral load (VL) detection together with CMV-specific cell-mediated immunity measurement using T-Track® CMV (Figure 3). T-Track® CMV results should only be interpreted by the physician in combination with another CMV-specific diagnostic test (such as CMV DNAemia PCR or pp65 antigenemia) and in the context of the overall clinical picture.

Figure 3. Matrix for risk stratification of CMV-related clinical complication post-transplantation based on CMV-CMI and viral load (VL):

1) In case of intermediate or borderline viral load but stable CMV-CMI, frequent VL monitoring in parallel to T-Track® CMV might help stratify the risk for future CMV complication and guide the clinician in the decision to initiate, delay or discontinue antiviral therapy.

T-Track® CMV specifications

- CE-marked in vitro diagnostic (IVD) IFN-γ ELISpot kit
- Guiding antiviral therapy decisions
- Assessment of CMV-specific immune response and reconstitution
- Measurement of the functionality of CD8+, CD4+, NK and NKT-like cells
- Highly sensitive and standardized immune monitoring tool
- Optimized, user-friendly protocol
- HLA-antigen independent application

T-Track® CMV components

- 12 x 8-well precoated IFN-γ PVDF microtiter plate
- T-activated® pp65
- T-activated® IE-1
- PHA (positive control)
- AP-conjugated detection mAb
- Dilution and washing buffers
- Instructions for Use

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