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

T-Track® CMV is based on Lophius’ patented T-activated® technology. It allows the reliable and sensitive assessment of the functionality of CMV-specific cell-mediated immunity, by measuring the number of IFN-γ-secreting CMV-reactive immune effector cells.

To guide your antiviral therapy decision-making, results of 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

- Stimulation of PBMC with T-activated® proteins (IE-1, pp65) results in high assay sensitivity (Table 1).
- T-Track® CMV is able to assess the functionality of a broad network of CMV-reactive immune cells (CD8+, CD4+, NK, NKT-like) [1].
- T-Track® CMV allows a HLA antigen-independent application [1].
- The ELISpot assay shows a high linearity range between $6 \times 10^4$ and $2 \times 10^5$ PBMC per well, and performs with high precision [1].
- The one-strip, 2-replicate-based T-Track® CMV assay requires a low blood volume (7.5 ml) per test.

References:

T-Track® CMV in transplantation


The response to pp65 was significantly (MWU; p<0.001) higher at the visit preceding the first detection of CMV in blood, in intermediate-risk (D-/R+, D+/R+) kidney transplant recipients with subsequent self-limiting CMV [3].

T-Track® CMV could predict recurrence of CMV reactivation in hematopoietic stem cell transplant recipients when measured after the end of antiviral treatment for a first CMV reactivation, as well as around day 100 post-transplantation (Figs. 3 and 4) [4].

T-Track® CMV in hematopoietic stem cell transplantation (HSCT)

A prospective multicenter study was conducted in 175 intermediate-risk (D+/R+, D+/R-) and high-risk (D-/R+) HSCT patients [4]. 61 patients experienced one CMV reactivation post-HSCT, while 40 developed two or three recurrent CMV reactivations thereafter. T-Track® CMV tests were performed after the end of antiviral treatment for a first CMV reactivation (Fig. 2A).

SFC counts were significantly lower in patients with a subsequent recurrent CMV reactivation, both in response to IE-1 (MWU; p<0.001) and to pp65 (MWU; p<0.001), compared to patients free of CMV recurrence (Fig. 2B).

CMV recurrence occurred mainly in D-/R+ patients (37/40: 93%). Kaplan-Meier analyses in these patients revealed a higher probability of recurrent CMV reactivation when T-Track® CMV was negative:

- after the end of the first CMV reactivation (hazard ratio [HR] 2.7; p=0.007; Fig. 3)
- at day 100 post-HSCT, a highly relevant time point for outpatient care (HR 4.8; p=0.005; Fig. 4).

Figure 2. T-Track® CMV in HSCT patients (D+/R+, D+/R-, D-/R+) experiencing one or more CMV reactivation episodes. IFN-γ ELISpot were interpreted according to Instructions for Use (version EN 10.00), adapted to 4-replicate-based tests. In B, negative tests are depicted in red and positive tests in blue [4].

Figure 3. T-Track® CMV (IE-1 and pp65) measured after the end of treatment for a first CMV reactivation could predict subsequent CMV recurrence in D-/R+ HSCT patients. The PPV in this population was 84% [4].

Results are based on an observational study, with a special focus on high-risk HSCT patients, and have yet to be validated in an interventional setting.

T-Track® CMV is a valuable immune monitoring tool to identify transplant recipients at increased risk for CMV-related clinical complications.
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 5.** 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
- Low blood volume required per test

### 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
- Delivered with the T-Track® CMV Calculator software