Dextramer® CMV Kit

IMMUDEX®
PRECISION IMMUNE MONITORING

Identify Patients at Risk of CMV Infection

60 to 80% of post-transplant patients are susceptible to high morbidity and mortality from cytomegalovirus (CMV) infection due to suppressing cell-mediated immunity.

Dextramer® CMV Kit enables reliable monitoring of CMV-specific CD8+ T cells in hematopoietic stem cell transplantation (HSCT) recipients for appropriate prophylactic treatment while avoiding potential toxicity from antiviral drugs.

- Quantify CMV-specific CD8+ T cells in blood
- Follow CMV immunity in post-transplant patients
- Predict patients at risk of CMV reactivation.

Guidance for Patient Management

A semi-quantitative assay intended for the identification and enumeration of CMV-specific CD8+ T cells that allows to:

- Measure reconstitution of CMV-specific CD8+ T cells
- Manage patient stratification: Delayed recovery of T cells, high-risk patients[1-4] (**Figure 1**).
- Guide therapeutic decision-making based on:
  - Cost-effective approach
  - Ensure the optimal treatment
  - Fewer side effects.

Features of Dextramer® CMV Kit

- **The only available IVD assay** for the enumeration of CMV-specific CD8+ T cells in blood by flow cytometry[5-7]
- **Ready-to-use kit:** Fast, robust, and reproducible assay
- **Robust monitoring** of patients' CMV immunity
- **Sensitive assessment** of the risk of CMV reactivation[5-9]
- **Regulatory Status:** For in vitro diagnostics use in US and Europe[8,9]

Patients at Risk of CMV Reactivation

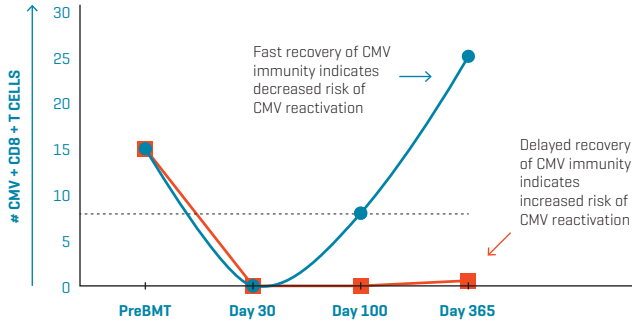

Figure 1. Model for CMV-specific T-cell immune monitoring in two post-transplant patients. The dashed line indicates the threshold for recovery of CMV T-cell immunity.

Dextramer® CMV Kit Application

- Use in conjunction with measurement of CMV viral load
- Testing is every other week starting on Day 30 post-transplant

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Use of Dextramer® CMV Kit in Clinical Data

Clinical Data Support the Use of Dextramer® CMV Kit for assessment of CMV-specific immune status and risk of CMV reactivation in HSCT patients following immunosuppression

In a prospective study, 120 allogeneic HSCT patients were followed up for CMV reactivation in the first year post-transplant[8, 9]. The absolute number of CMV-specific CD8+ T cells was monitored in whole blood using Dextramer® CMV Kit and flow cytometry.

The number of CMV-specific CD8+ T cells at day 100 post-transplant showed a significant association with the risk of developing CMV reactivation (**Table 1**)[8, 9].

No. of CMV-specific T cells	CMV Reactivation Yes	No
< 7 cells/µL	90%	10%
≥ 7 cells/µL	26%	74%

Table 1. The relative risk was 3.4 times higher (95% CI: 1.57 – 7.46) for patients with < 7 cells/µL CMV+ CD8+ T cells compared to patients with ≥ 7 cells/µL CMV+ CD8+ T cells[8,9]

Dextramer® CMV Kit - Product Description

The Dextramer® CMV Kit is for in vitro diagnostic (IVD) use in HSCT patients in the EU[10] and US[11]

Cat. No.: CX03, Europe (CE-IVD)

- CMV-specific Dextramer® Reagents
  - HLA-A*0101/VTEHDTLLY
  - HLA-A*0201/NLVPMVATV
  - HLA-B*0702/TPRVTGGGAM
  - HLA-B*0801/ELRRKMMYM
  - HLA-B*3501/IPSINVHHY
- Negative Control
- CD3/CD4/CD8 Antibodies included

Cat. No.: CX02, US (IVD)

- CMV-specific Dextramer® Reagents
  - HLA-A*0101/VTEHDTLLY
  - HLA-A*0201/NLVPMVATV
  - HLA-B*0702/TPRVTGGGAM
  - HLA-B*0801/ELRRKMMYM
  - HLA-B*3501/IPSINVHHY
- Negative Control
- CD3/CD4/CD8 Antibodies included

References

1. Cwynarski,K. *et al.* Direct visualization of cytomegalovirus-specific T cell reconstitution after allogeneic stem cell transplantation. Blood (2001) 97:1232.
2. Gratama, J.W. *et al.* Immune monitoring with iTAg MHC Tetramers for prediction of recurrent or persistent cytomegalovirus infection or disease in allogeneic hematopoietic stem cell transplant recipients: a prospective multicenter study. Blood (2010) 116:1655.
3. Gratama, J.W. *et al.* Tetramer-based quantification of cytomegalovirus (CMV)-specific CD8+ T lymphocytes in T-cell depleted stem cell grafts and after transplantation may identify patients at risk of progressive CMV infection. Blood (2001) 98: 1358.
4. Borcher,S. *et al.* Sequential anti-cytomegalovirus response monitoring may allow prediction of cytomegalovirus reactivation after allogeneic stem cell transplantation. PLoS One (2012) 7: e50248.
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7. Chen, G. L. *et al.* Low-Level Cytomegalovirus Antigenemia Promotes Protective Cytomegalovirus Antigen-Specific T Cells after Allogeneic Hematopoietic Cell Transplantation. Biol Blood Marrow Transplant (2020) 26(11):2147-2154.
8. TF1000.07 Dextramer CMV Kit Package Insert US (IVD), Immudex.
9. TF1293.01 Dextramer CMV Kit Package Insert EU (CE-IVD), Immudex.
10. CE certified in vitro diagnostic test in compliance with the General Safety and Performance requirements under the IVDR
11. K153538 510(k) premarket notification

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