

MACS® GMP Cytokines

# Cytokine stability studies

## Background

Recombinant human MACS® GMP Cytokines are provided as lyophilized (freeze-dried) products, ensuring a high level of stability as shown in these long-term stability studies. Here we present examples of data for selected cytokines indicating that shipment or short-term storage at room temperature do not alter the performance, i.e., biological activity. We also tested the activity after reconstituting and storing the cytokines under various temperature conditions, although it is recommended to use the reconstituted product directly in order to minimize the risk of contamination.

## Methods

### Stability testing of lyophilized cytokines

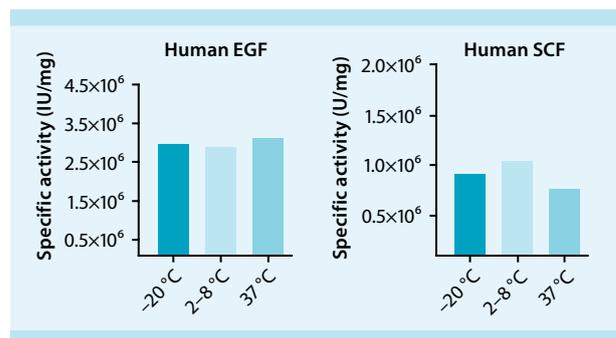
Lyophilized recombinant human MACS GMP Cytokines were stored at  $-20^{\circ}\text{C}$ ,  $2-8^{\circ}\text{C}$ , and  $37^{\circ}\text{C}$  for up to 4 weeks. Cytokines were then reconstituted with deionized sterile-filtered water, and the functionality was tested using the standard activity assays indicated in the package inserts for the respective cytokines. Package inserts are also available on the individual product pages at [www.miltenyibiotec.com/MACSGMPCytokines](http://www.miltenyibiotec.com/MACSGMPCytokines)

### Stability testing of reconstituted cytokines

In this stability study, we reconstituted different MACS GMP Cytokines with deionized sterile-filtered water for storage at  $2-8^{\circ}\text{C}$  (4 weeks) or  $-20^{\circ}\text{C}$  (14 and 28 weeks) or with TexMACS™ Medium (# 130-097-196) for storage at  $2-8^{\circ}\text{C}$  (1 and 4 weeks). All cytokines have been reconstituted to a concentration of  $25-100\ \mu\text{g}/\text{mL}$  without the addition of any protein stabilizer such as recombinant human albumin. The functionality was tested using the standard activity assay for the respective cytokine. Cytokines freshly reconstituted according to the instructions provided in the package insert served as a control, and their activity was defined as 100%.

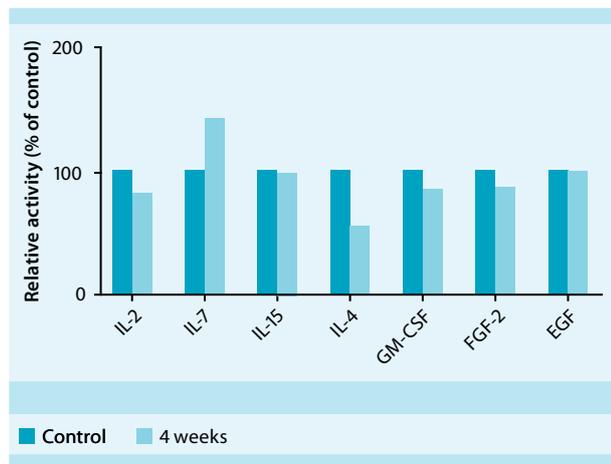
## Results

Figure 1 illustrates the stability of lyophilized recombinant human EGF and SCF at different temperatures, by way of example. Equivalent activity data are available for other cytokines such as IL-2, IL-3, IL-4, IL-6, IL-7, IL-15, IL-21, GM-CSF, FGF-2, TNF- $\alpha$ , TPO, Flt3-L, and TGF- $\beta$ 1.

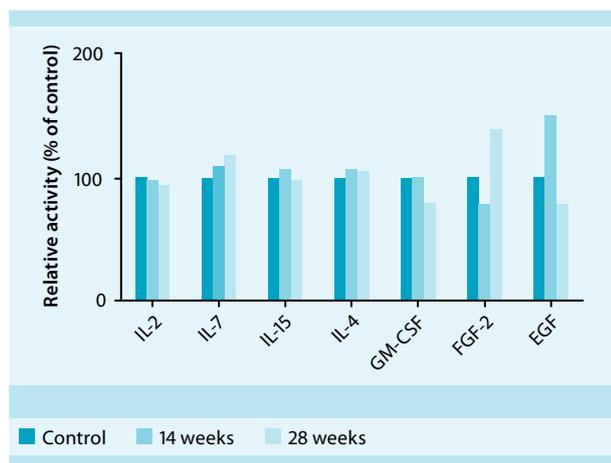


**Figure 1: Stability of lyophilized EGF and SCF.** Recombinant human MACS GMP Cytokines were stored at  $-20^{\circ}\text{C}$ ,  $2-8^{\circ}\text{C}$ , and  $37^{\circ}\text{C}$  for up to 4 weeks. Standard activity assays were performed to determine the stability immediately after reconstitution.

We also tested the stability of cytokines that were reconstituted with water and stored at 2–8 °C (fig. 2) or –20 °C (fig. 3) for several weeks.

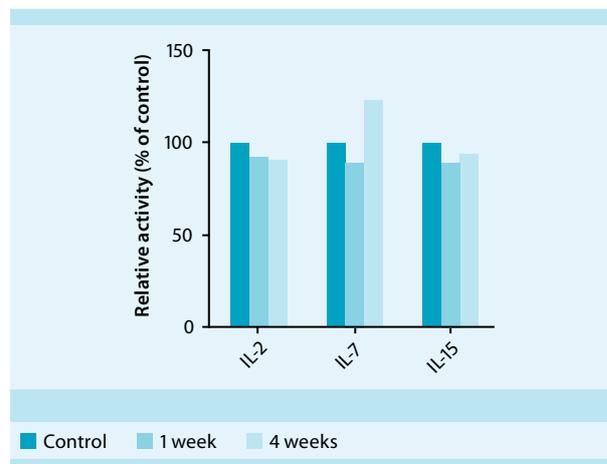


**Figure 2: Stability of cytokines reconstituted with water and stored at 2–8 °C.** Recombinant human MACS GMP Cytokines were dissolved in water to reach a concentration of 25 µg/mL (EGF: 100 µg/mL). The solutions were stored in the original glass vials and kept at 2–8 °C for 4 weeks. Standard activity assays were performed to determine the stability.



**Figure 3: Stability of cytokines reconstituted with water and stored at –20 °C.** Recombinant human MACS GMP Cytokines were dissolved in water to reach a concentration of 100 µg/mL. The solutions were stored in polypropylene vials (25 µL per vial) and kept at –20 °C for 14 weeks and 28 weeks. Standard activity assays were performed to determine the stability.

In some cases it might be necessary to reconstitute cytokines in medium instead of water. Therefore, we also tested the stability of cytokines reconstituted in TexMACS™ Medium and stored at 2–8 °C. (fig. 4).



**Figure 4: Stability of cytokines reconstituted with medium.** Recombinant human MACS GMP Cytokines were dissolved in TexMACS Medium to reach a concentration of 25 µg/mL. The solutions were stored in the original glass vials and kept at 2–8 °C for 1 week and 4 weeks. Standard activity assays were performed to determine the stability.

## Conclusion

- The lyophilized MACS® GMP Cytokines analyzed in this study are stable for at least 4 weeks when stored at 37 °C.
- MACS GMP Cytokines show a high level of stability also after reconstitution in deionized sterile-filtered water or TexMACS Medium.
- Reconstituted cytokines stored at 2–8 °C in the original glass container are stable for at least 4 weeks after reconstitution.
- Reconstituted cytokines stored at –20 °C in aliquots (in polypropylene cryogenic vials) are stable for at least 7 months after reconstitution.
- MACS GMP Cytokines and MACS Premium-Grade Cytokines share major characteristics, such as high biological activity. Therefore, performance under the tested conditions should be similar.

For more information on MACS Cytokines visit [www.miltenyibiotec.com/MACSGMPcytokines](http://www.miltenyibiotec.com/MACSGMPcytokines)



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