



STABILITY AND STERILITY OF AUTOLOGOUS SERUM-EYE-DROPS AFTER LONG-TERM STORAGE

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Background

Autologous serum can be compounded into eye drops that are used to reduce symptoms of severe dry eye syndrome. In case of appropriate stability and sterility, frequency of blood drawings from the patients to generate eye drops might be reduced and clinical logistics also simplified.

Objectives

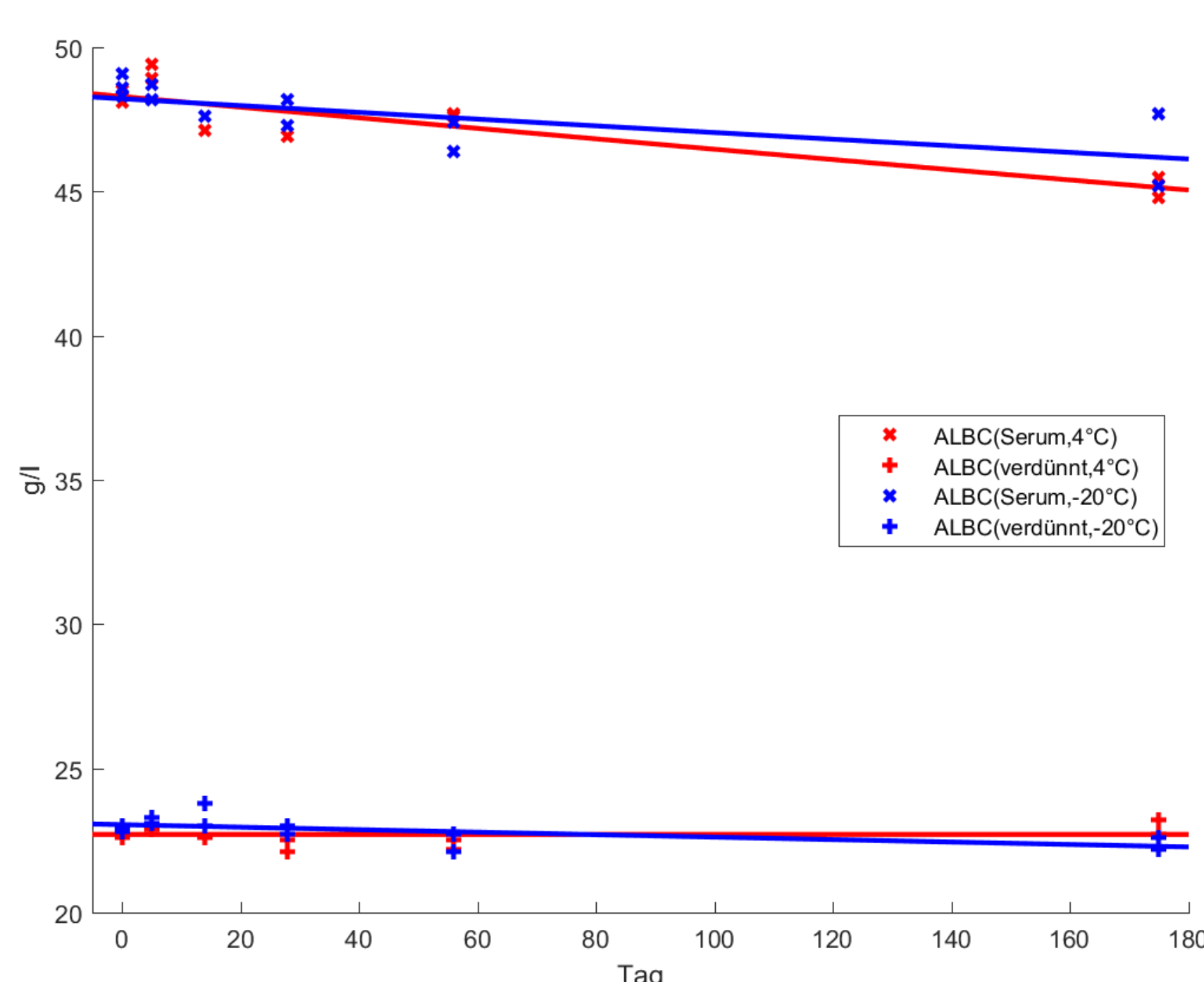
To assess the stability and sterility of serum under different storage conditions and prolonged storage time up to 6 months.

Methods

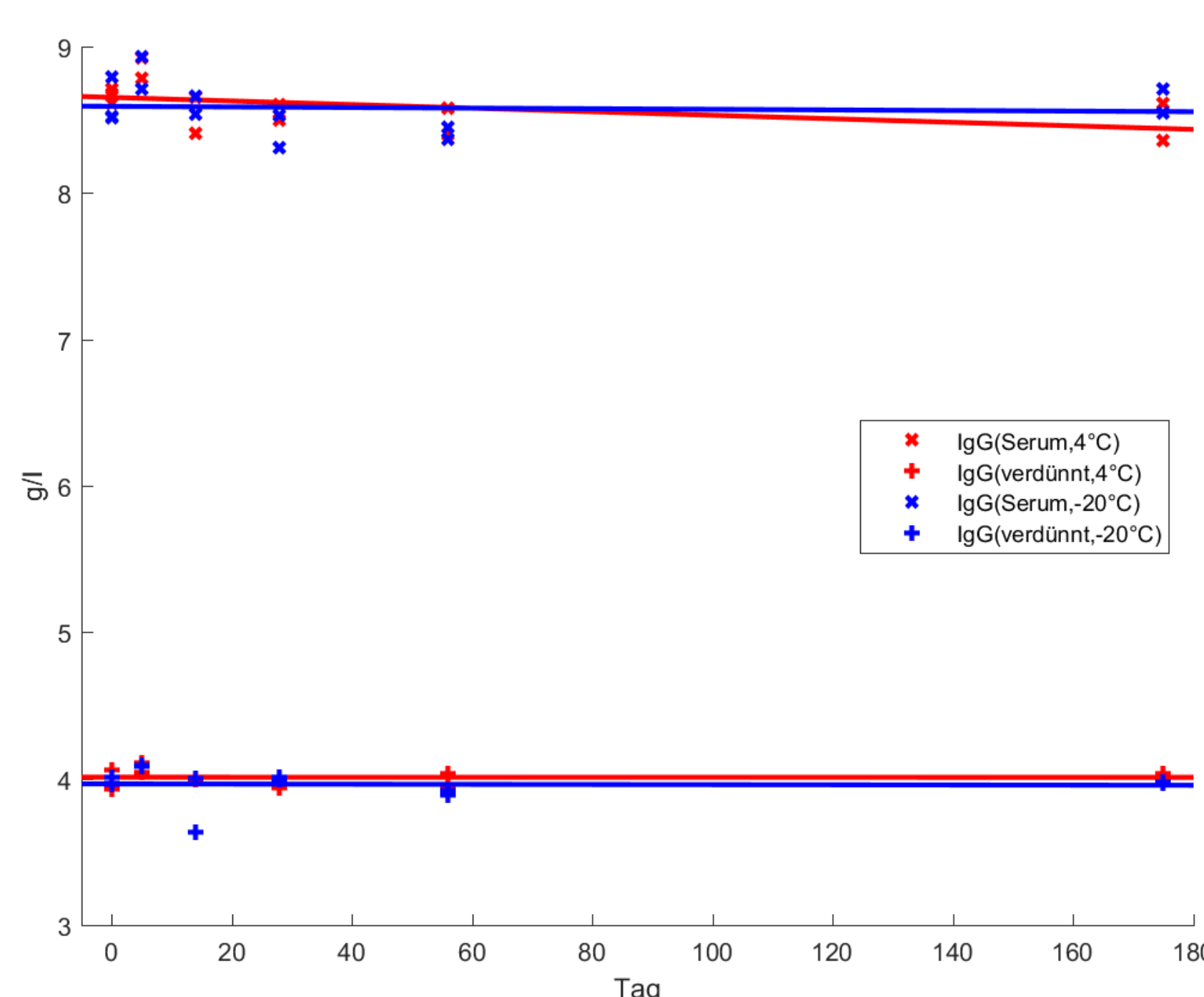
After obtaining human whole blood and preparing unit dose autologous serum-eye-drops 100% and 50% (diluted with BSS Plus®), samples were stored at 4°C and -20°C for up to 6 months. Concentrations of albumin, immunoglobulin G and C4 (C4c) were used as surrogate stability biomarkers and measured at storage days 1, 8, 15, 30, 60, 90, 180. Sterility according to European Pharmacopoeia (2.6.1) was evaluated at storage days 1, 15, 30, 60, 90, 180. C4c, IgG and albumin were measured by immunonephelometry on a BN ProSpec System (Siemens Healthcare Diagnostics, Germany).

Results

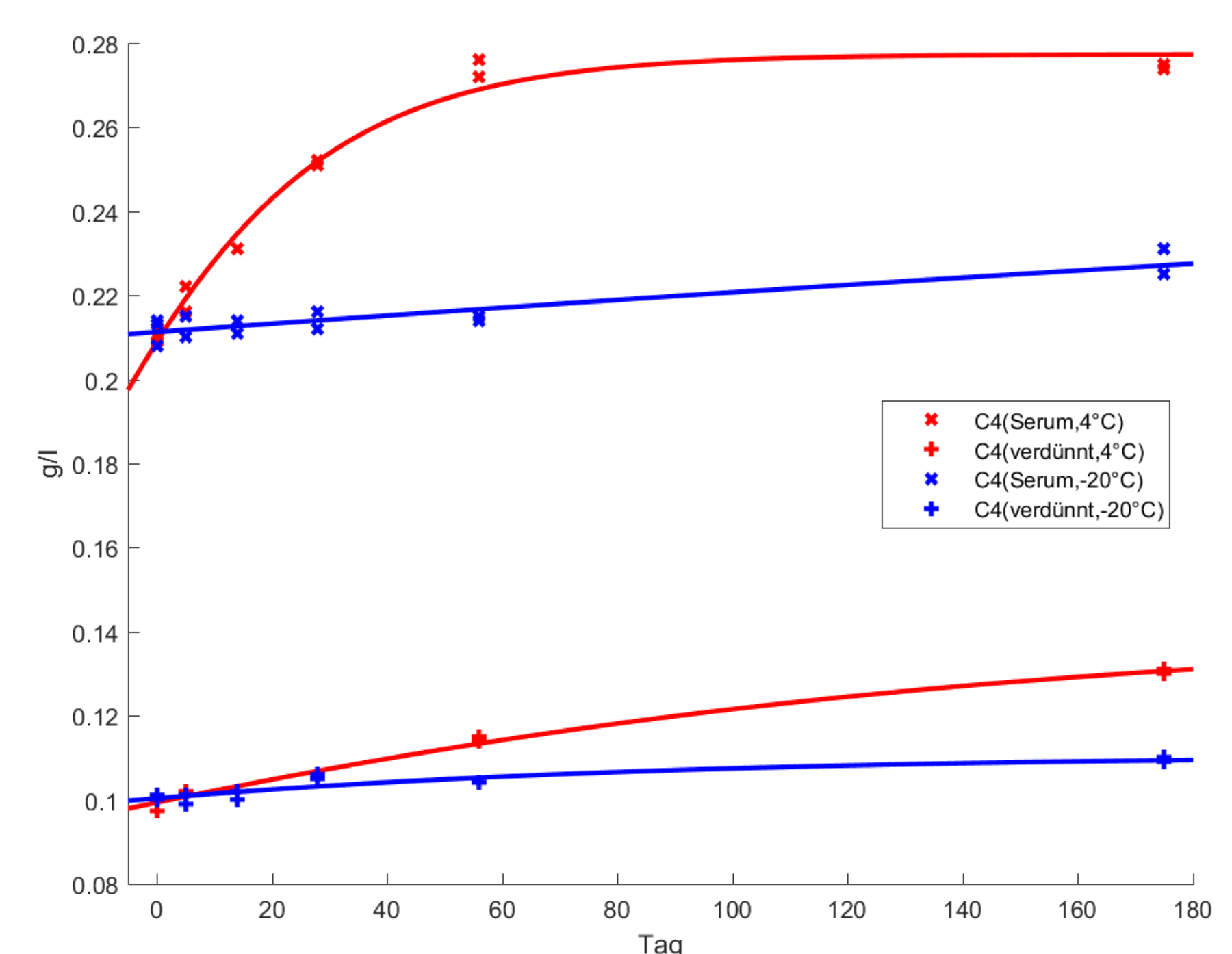
The concentrations of albumin slightly decreased in the non-diluted condition (3.8 % and 6.3% at -20°C and 4°C). Immunoglobulin G levels remained stable under both temperature conditions over the entire period of 6 months. The C4c concentration increased by about 30% at storage temperature of 4°C. This was not the case for samples stored at -20°C. No differences were seen between undiluted and diluted serum. Sterility was maintained in the 4°C and -20°C samples throughout the period tested.



Concentrations Albumin, undil., dil., (4°C, -20°C), 180 d



Concentrations IgG, undil., dil. (4°C, -20 °C), 180 d



Concentrations C4c, undil., dil. (4°C, -20 °C), 180 d

Conclusions

The present results show that the serum parameters albumin, immunoglobulin G and C4c are overall stable at -20 °C for 6 months. As C4c is a breakdown product of C4b, the increase in C4c at 4°C may be indicative for some instability of C4b. However, this increase is considered mild and values remained within normal range, hence, this change may rather be without clinical significance. At both temperatures tested, sterility of serum-eye-drops was not impacted including the longest duration tested. In summary, results support that, using aseptic preparation techniques and storage temperature at -20 °C, a 6-months supply of autologous serum-eye-drops can be offered to patients allowing better access to this therapy through a less frequent blood donation schedule.

Acknowledgements

Ines Maria Hartmann¹, Jasmin Leweke²