Studies on the processing of plasma and patient samples

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MOLECULAR BIOTECHNOLOGY AND DIAGNOSTICS

INTRODUCTION

Radiometer Turku Oy manufactures **semi-products** used for quality control purposes for the AQT90 Flex products (Figure 1.). These semi-products consist of **plasma matrix** and either **patient sample antigen** or **recombinant antigen**. Plasma matrices and patient sample pools are filtered before use to **prevent the AQT90 Flex sample needle blocking**. This process is challenging due to filtration rigidness and slow sample flow through, resulting in sample loss and in higher manufacturing cost. Plasma used as a matrix is processed for 7 days at different temperatures before use, which is inconvenient. In addition, at least one alternative plasma vendor is needed for the plasma matrix to **secure material availability**.

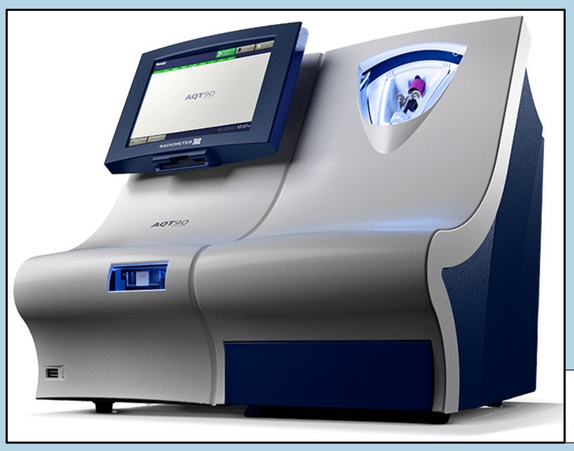

Figure 1. AQT90 Flex immunoassay analyzer.

AIM OF THE STUDY

The aim of this study was to investigate the patient sample pool filtration to remove clots without significant sample loss. Furthermore, the aim was to test shorter plasma thawing protocols and test plasma from an alternative vendor as a semi-product plasma matrix.

METHODS

- Filters from different vendors were tested for patient sample pool filtration. Plasma was used as a sample due to a lower cost.
- The necessity of the patient sample pool filtration was studied by comparing plasma matrix spiked with centrifuged or centrifuged and filtered patient sample pools (Figure 2.).
- Antigen stability was observed in plasma thawed for 24 hours at +4°C or for an hour at +37°C and compared to the plasma processed with the current protocol (6 days at +4°C, 1 day at RT).
- The stabilities of two antigens were measured in three plasma lots from an alternative plasma vendor.

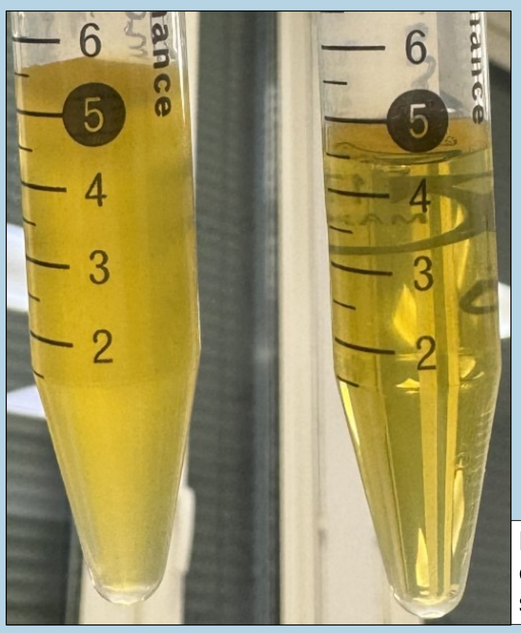

Figure 2. Centrifuged (on the left) and centrifuged and filtered (on the right) patient sample pools.

RESULTS

- **Filter testing:** Larger disc filter diameter and effective filtration area → better sample flow through.
- **The necessity of patient sample pool filtration:** ≥9% patient sample pool volume ratio to total plasma volume → clotting of the plasma matrix despite of the filtration of the patient sample pool.
- **Plasma thawing:** Plasma thawed for 24 hours at +4°C did not clot during storage at +4°C, whereas plasma thawed at +37°C did. Both antigens were stable in all plasma matrices (Figure 3.).
- **Alternative plasma vendor:** Both antigens were stable in all three plasma lots from an alternative plasma vendor (Figure 4.) → further testing is needed with different plasma lots and lot combinations.

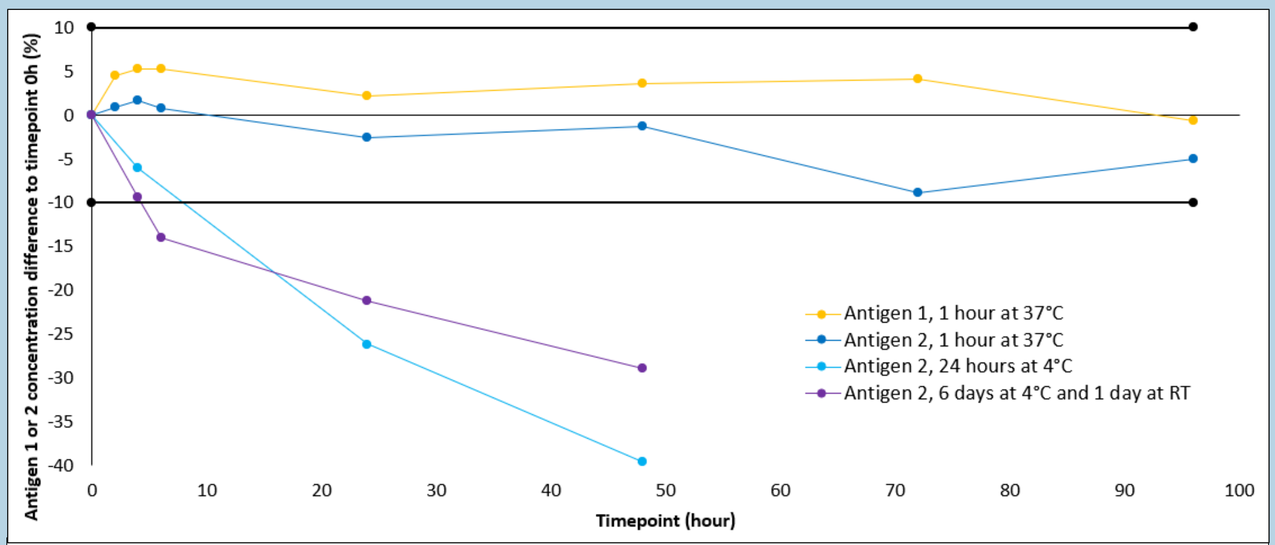

Figure 3. In-process stability of recombinant Antigen 1 and/or 2 in plasma thawed for 24 hours at +4°C, for an hour at +37°C, or for 6 days at +4°C and 1 day at RT. In-process stability requirement of recombinant Antigen 1 is 72 hours and recombinant Antigen 2 is 4 hours.

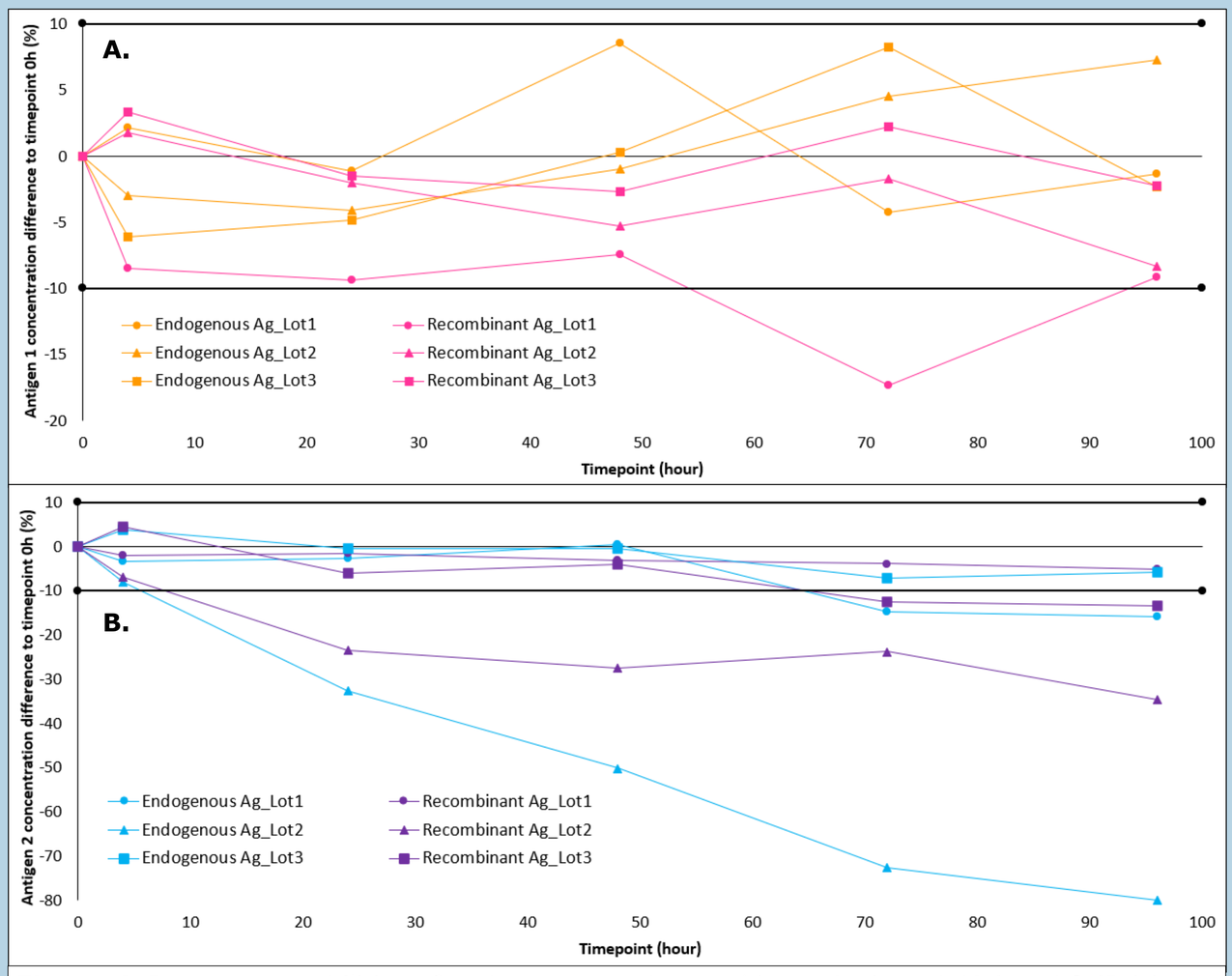

Figure 4. In-process stabilities of endogenous and recombinant Antigen 1 (A.) and 2 (B.) in three different plasma lots from an alternative plasma vendor. In-process stability requirement of endogenous and recombinant Antigen 1 is 72 hours, and endogenous and recombinant Antigen 2 is 3, and 4 hours, respectively.

CONCLUSIONS

This study has provided further information on plasma and patient sample pool processing. In addition, it was found out that **Antigen 2 stability** seems to be dependent on plasma lot. **Further testing** is still needed on the patient sample pool filtration or to introduce a new plasma thawing protocol or an alternative plasma vendor.