### **TECHNICAL NOTE**

# FREEZING PLASMA BAGS AT THE EFS CENTER IN BESANÇON: A KEY STEP IN SAMPLE PROCESSING



[Technical note Number] / Olivier VARET, FROILABO

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INTRODUCTION

The Besançon center of the French Blood Establishment (EFS) is part of the national EFS network, a public institution responsible for ensuring self-sufficiency in labile blood products and guaranteeing their quality and safety. It encompasses activities including collection, biological qualification, preparation, and distribution of blood products intended for healthcare facilities in the Bourgogne–Franche-Comté region.

Among these activities, the preparation and freezing of plasma bags constitute a key step in the process of valorizing blood donations. The Besançon center is equipped with dedicated devices for the rapid freezing of Fresh Frozen Plasma (FFP), in compliance with current regulatory requirements and quality standards.

The majority of plasma bags are used for the production of medicines by the Laboratoire Français du Fractionnement et des Biotechnologies (LFB), whose main mission is to produce and distribute medicaments derived from human plasma, intended to treat severe and rare diseases.

The need for plasma for drug production is such that supply from the French EFS alone is not sufficient. In a report published in 2024, the LFB indicated it used 1.3 million liters of plasma for its annual production, of which 900,000 liters came from France. LFB aims to increase the available plasma to 3.4 million liters per year to support increased fractionation capacity.

Self-sufficiency in plasma-derived medicinal products (PDMPs) is a major strategic issue for the French government, often described as a matter of health sovereignty.

All these elements show that the need for plasma is therefore very high. It is within this context that the EFS in Besançon acquired a new FROILABO blast freezer. This application note describes the reasons behind the choice of this equipment, the procedures for freezing plasma bags, the critical parameters of the process, as well as the control points ensuring product quality and traceability.

INSTALLATION, COMMISSIONING, PRODUCTION

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As available space for new equipment is always limited in laboratories, it was important for the EFS in Besançon to choose a compact blast freezer with the highest possible sample-processing capacity per cycle. The FROILABO freezer allows processing of 100 bags of 300 ml, or 30 bags of 850 ml per cycle, in a compact format with a footprint of only  $900 \times 1440$  mm ( $35.5 \times 56.7$  in.).

The building where the freezer was installed is equipped with a chilled-water circuit. According to Arnaud LACROIX, Sales Manager at Froilabo, "this technology is recognized as the most efficient in the industry to guarantee same freezing performance throughout the year." The configuration of the FROILABO blast freezer enables simple and quick connection to a building's chilled-water circuit.

To achieve sufficient daily productivity, it is necessary to freeze 300 bags in less than one hour and thirty minutes. Thanks to the performance of the FROILABO blast freezer, the EFS in Besançon processes an average of 500 bags of 300 ml per day. This corresponds to 2 to 3 cycles per device each morning. The device's capacity allows for increased production if needed.

Thanks to a dedicated trolley, users can load 100 bags at once, which greatly limits door-opening time during the run, thereby ensuring maximum freezing efficiency. The freezing power of the device helps better preserve plasma protein integrity and ensures compliance of products intended for transfusion or plasma fractionation.

During the qualification procedure of the freezer, the EFS in Besançon verifies that the bags are frozen to -30°C at the core within a maximum of one hour and thirty minutes. At the end of the cycle, conservation mode allows to keep the bags at -30°C for up to 35 hours if necessary.

Traceability is ensured through the recording of temperatures throughout the cycle. These data can be exported for processing and archiving if needed. In addition to the data provided by the device, the EFS is also equipped with an additional external system to record temperatures within the freezer, providing enhanced security for data traceability.

Alain Cuche's team, within the Biomedical Unit of the Support and Assistance Department, is responsible for monitoring and recording maintenance performed on equipment. This includes coordinating preventive and corrective maintenance interventions. The team also supports manufacturers or service providers in diagnosing failures. Froilabo performed the qualification of the freezer during installation with this team and trained them in first-level maintenance.

## Conclusion

The FROILABO freezer has been operating at the EFS in Besançon for several months. With rapid and efficient freezing and high productivity, it fully meets the users' expectations.

We extend our sincere thanks to Mr. Alain Cuche for sharing this information

### Maintenance

For more information, please contact us at: