

SOURCE PLASMA COLLECTION REPRESENTS THE FOUNDATION of the plasma protein therapeutics industry, as it has for many decades. The critical importance of this part of the industry cannot be overstated. It provides the basic material for all of the life-saving therapies that are created by the plasma protein therapeutics industry. People who come into the collection center to donate their plasma are essential to the industry and to the patients who rely on the therapies for their health and, indeed, their life.

Plasma collection has evolved. Technology has taken on a very important role in this evolution, though the central component is still the human donor.

TECHNOLOGICAL IMPROVEMENTS IN PLASMA COLLECTION

BY JOSHUA PENROD

Automated Plasmapheresis

One of the most important technological improvements that occurred within the industry is the advent and widespread adoption of the automated plasmapheresis process. This eliminates many safety concerns for donors, as the process is a contained, continuous method for removing blood from the donor, separating and harvesting the plasma, and returning the cells to the donor. This means that donors will never be at risk for unmatched cells upon the return cycles.

The automated collection devices were a significant advance as stand-alone systems, but more recent integration of these devices into the overall computerized information systems of the plasma collection facilities allows electronic capture of information that is important in the operation of the device. The adoption of increased automation helps provide a unified safety net for both the donor and the plasma. The automated collection process is the cornerstone of safety within the collection industry and represents a major contribution to the continued improvement in technology and its usage in plasma collection.

Donor Screening and Center Design: Computers and Information Technology

Evolutionary improvements have occurred in the context of center design and donor screening. These improvements have resulted in better, more efficient donor processing, while also increasing the safety of both the plasma and the donor. The screening process relies on improved technology to ensure the donor's health and the efficiency in which a donor can move through the process. Computerized donor record files track vital information and allow center staff to track and monitor not only the current donor process, but are able to view the donor's health and donation history as well.

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Improved processes in donor screening have led some companies to automate the health history questionnaires as well. The computer-assisted donor health history questionnaires allow the donor to directly communicate with the computer. This direct, computerized questioning helps ensure the donor's privacy and enables the donor to proceed at his own speed to better understand the screening process and the purpose behind it.

Testing Technology

Testing has changed over the years as well; while the screening process was discussed above, it is also important to mention the testing that is used on plasma donation. As tests to protect the plasma from pathogens were developed over the years, the initial tests were designed to detect antibodies in the plasma. The antibodies are proteins that a person's body produces in response to a foreign substance, including pathogens. It takes the human body time to recognize the foreign substance and produce antibodies against it. Relying only on antibody tests meant that there could be several weeks

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from the time of exposure to a pathogen and the test for antibodies to that pathogen to become positive. This time is called the “window period.” During the window period, a potential donor may have been exposed to the pathogen and be infectious but still have a negative test. More recent tests, using Nucleic Acid Amplification Technology (NAT) can detect the pathogen itself. Being able to detect the pathogen directly has reduced the window period to days. With today's testing methods, there is better assurance that plasma is safe and that any positive result can be communicated more quickly and with greater confidence to the donor.

Logistics and Shipping

It is as important as ever to ensure that the plasma which leaves the collection

center is transported in a way that continues the quality chain. Specialized procedures for shipping are used to ensure that the donations and test samples are kept stable and tracked throughout the process. This helps ensure the robustness of the testing of the plasma and the integrity of the plasma throughout the extensive manufacturing process. Contract partners specializing in shipping and members of the plasma industry have developed thorough systems to ensure that all of these steps are taken and meet or exceed all regulatory requirements.

Conclusion

The advancement of technology and the evolution of plasma collection have resulted in a constantly-increasing level of quality and safety of the process. This improves not only what is produced by a plasma center, but also improves the donor's safety and the donation experience. 

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