1.1 Plasma Testing Solutions

Using our years of expertise in plasma manufacturing and donor screening, Grifols has developed innovative solutions to streamline the workflow of plasma-screening laboratories. Our products reduce learning curves and improve ~~workflow~~ efficiency, ensuring reliable results while ~~containing~~reducing costs~~. Grifols delivers customizable processes,~~ for a broad array of ~~sample~~ pool sizes and assay configurations.

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Benefits of Using Grifols Plasma Testing Solutions

Plasma Safety

An Efficient Workflow

Contain Cost ~~Management~~

Portfolio

View our comprehensive portfolio of products and services for plasma donation screening and donor typing. Grifols offers fully automated, flexible solutions for nucleic acid technology (NAT) and irregular antibody screening. Regulatory agencies require screening of plasma for five pathogens—HIV, HBV, HCV, HAV, and ParvoB19—before fractionation. Plasma should also be free of irregular antibodies and have acceptable Anti-A and Anti-B titers to prevent hemolytic events in patients infused with IVIGs. Grifols instruments help plasma-screening laboratories effectively ~~screen~~prevent these donations from entering manufacturing pools.

MISSING NEWS SEGMENT

1.2 Plasma Safety

The safety of plasma-derived medicinal products (PDMP) is the top priority of the fractionation industry and has been a key focus at Grifols for 100 years. Detection of infected donations is paramount. Procleix assays have the sensitivity to detect pathogens even at early stages of infection, reducing the probability of a contaminated donation entering the manufacturing pool. Donations with ~~even a low titer of~~clinically significant irregular antibodies must be identified and removed as well. Grifols typing solutions based on DG Gel technology address this concern with proven and sensitive assays.

Plasma Industry Requirements

Inventory Management

Challenges Faced by Screening Laboratories

Infectious plasma donations.

To reduce the risk of viruses entering manufacturing pools, laboratories screen donations for five viruses: HIV, HBV, HCV, Parvo, and HAV. Procleix assays are proven to be highly specific and sensitive in the early detection of such pathogens.

Challenges Faced by Screening Laboratories

(1) Infectious donations. Procleix reagents were designed to reduce the possibility of viruses entering manufacturing pools.
(2) Compliance with international standards and regulations. Laboratories must comply with ~~regulatory~~the following:

- Regulatory agencies ~~such as the~~
  - U.S. Food and Drug Administration (FDA~~),~~)
  - European Medicines Agency (EMA~~), and China Food and Drug~~)
  - China's National Medical Products Administration (~~CFDA~~)~~, as well as good~~NMPA)
- Good manufacturing practices (GMP~~),~~)
- EMA's plasma master file (PMF) submissions~~, and industry benchmarks~~ ~~such as the~~
- Plasma Protein Therapeutics Association's (PPTA) Quality Standards of Excellence, Assurance, and Leadership (QSEAL~~),~~), an industry benchmark

(3) Removal of donations with irregular Ab. Grifols assays effectively block these donations from manufacturing pools.

Plasma Industry Requirements

The quality of plasma used in plasma-derived medical products (PDMPs) is of paramount importance to fractionators. Both plasma collectors and manufacturers must follow regulations and GMP. Plasma testing for fractionation is regulated by the U.S. FDA, the EMA, and other national regulatory authorities. EMA also requires the submission of a PMF attached to all PDMPs marketed in the European Union. In addition, many fractionators have adopted voluntary standards, such as PPTA's QSEAL program, which has certified laboratories since 2000.

For more information about plasma screening requirements, please watch the videos below.

Overview of the Plasma Master File Requirement

The process of plasma screening is much easier to understand if you know a few industry terms:

Plasma Master File (PMF): A regulatory document fractionators submit to the EMA containing data on the quality and safety of plasma used to manufacture PDMPs. Some of the parameters include albumin, IVIG, and coagulation factors.

PMF Holder: A company that fractionates plasma and submits the relevant PMFs. A list of PMF holders can be found here.

Manufacturing Pool: A ~~collection~~large number of donations~~—as many as 4,500~~up to several thousand—ready for fractionation.

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Plasma Minipool: A pool of plasma donations, most often 96 and sometimes up to 512 ~~donations~~samples. The EMA's Committee for Medicinal Products for Human Use (CHMP) recommends pretesting a smaller pool to avoid loss of a complete manufacturing pool through contamination—and facilitate donor tracing—in the event of a positive test result.

Plasma Pool: Also called an "in process" pool, a sample of the first homogeneous pool of plasma (after removal of cryoprecipitate, for example) ready for manufacturing. It can include thousands of donations and must be tested for viral markers to meet EMA requirements.

Validation (Directives 2004/33/EC and 2005/62/EC): The establishment of documented, objective evidence that requirements for a specific intended use can be consistently fulfilled. Validation is required, even if the assay or instrument has a CE mark—meaning it conforms to European standards of safety.

A PMF is a stand-alone document detailing the quality management procedures that were followed to obtain high-quality plasma. The first step of the PMF certification procedure includes a submission for approval to EMA. Following a satisfactory evaluation, the CHMP issues a PMF certificate of compliance with European legislation to the fractionator—not the lab. This certificate is valid throughout the European Union. It is the responsibility of the PMF holder to incorporate the PMF into the marketing materials for its PDMPs.

Plasma fractionators or PMF holders perform regular audits of plasma collection centers to verify that collection and screening are carried out in compliance with contractual obligations. As authorized manufacturers of products made from collected plasma, they are legally responsible (directly if they collect the plasma themselves, or indirectly if they obtain it from another entity) for compliance with the collection and quality standards specified in their contract.

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1.3 An Efficient Workflow

Automated NAT solutions help laboratories reduce learning curves and improve workflow efficiency. They are flexible and can be adapted to a wide range of sample pool sizes and assay configurations.

Compact, High- Throughput ~~Instruments~~

Minimal Operator Intervention

Remote Control of Overall Lab Process

Workflow Challenges

Inefficient workflow makes it more difficult to deliver a timely, quality product and can increase overall costs. Here are a few common—and avoidable—challenges labs face.

Challenge 1: ~~Inefficient equipment~~ Limited laboratory space

The solution: Compact, high-throughput instruments

The compact size of Grifols instruments helps laboratories make the best use of space. One lab operator can screen 800 donations in one eight-hour shift using less than [TK] square meters of space.

Challenge 2: High operational costs

The solution: Automated processes and remote control

Thousands of plasma donations might be screened daily by a laboratory, and an efficient workflow is critical to avoid backlogs. Choosing equipment that can process high volumes with a minimum of operator involvement is a key step in designing the ideal pathway from receiving plasma to delivering test results in a timely manner.

Challenge 3: Delayed release of donations

The solution: Streamlined workflow

~~The compact size of Grifols instruments help laboratories make the best use of space. One lab operator can screen 800 donations in one eight-hour shift using less than [TK] square meters.~~

Increased staff hours, underestimating sample storage requirements, and inefficient use of instrumentation lead to lower productivity, mechanical failures, and higher overall operating costs. All of these can be resolved with a more streamlined workflow, which means workers spend more of their time on higher-value tasks that require their expertise.

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Minimal Operator Intervention

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Procleix instruments require minimal operator intervention for maintenance and analytical operations. The Panther ART's daily maintenance routines can be scheduled to occur during off hours, so it's ready to go when the first shift begins, and it requires no more than two interventions—to load additional samples and consumables—during an eight-hour shift.

It has the flexibility ~~and high waste capacity~~ to manage reagents, consumables, and waste at any time without interrupting operations~~, and it~~. It can dispose of liquid waste products into the laboratory drain, further reducing hands-on operation.

~~Connecting to a track system optimizes worker efficiency even more. Panther ART is track-ready.~~

PDF LINK: Panther ART Specification Sheet

Remote Control of Overall Lab Process

No need to be in the lab all the time monitoring equipment—the Procleix remote dashboard is an intuitive tool that uses color coding to show the operator at a glance which instruments need attention.

Users can access the dashboard to view the status of all connected instruments remotely with a fixed touch screen or a tablet at any time, from anywhere. The Procleix ~~dashboard uses~~ NAT Manager middleware ~~to centralize~~centralizes and ~~integrate~~integrates all NAT processes and ~~control~~controls the status of the samples. NAT Manager and the remote dashboard allow efficient organization of laboratory activities and optimal use of operator time without compromising process security.

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1.4 Cost ~~Containment~~Efficiency

Instruments and ~~reagents~~duplications are the ~~most obvious~~biggest line items in a lab's budget, but inefficiencies in staffing, maintenance, consumables, waste ~~management,~~and inventory management, and use of space can drastically affect your overall operating costs. Grifols offers ways to ~~contain~~avoid runaway costs without ~~sacrificing~~compromising productivity or safety.

Reducing ~~TAT~~Turnaround Time

Increasing Productivity

Challenge 1: Reduce ~~TAT~~turnaround time

Challenge 2: ~~Provide safe, affordable services to fractionators without cutting into profits~~Maintain profitability

Challenge 3: ~~Tackle waste while remaining competitive~~ Staff training

Solution: A user-friendly platform

Staying competitive in the plasma-screening sector gets more challenging all the time. There are numerous hidden costs that reduce the profitability of a screening laboratory. Some examples are

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overtime due to long turnaround times ~~(TAT),~~ test duplication caused by false reactive results, and higher facility costs for instruments that require a lot of space, electricity, and waste management. Sometimes the solution involves upgrading your equipment.

Automated instruments help to decrease staffing costs. Highly skilled operators can spend their time on more valuable tasks when they don't have to conduct instrument maintenance several times during a shift. Compact, efficient machines also save on space, power, and waste management. These cost savings can make your ~~TAT~~turnaround time more attractive to fractionators and more profitable to you, thereby opening up opportunities for expansion.

Reduce Turnaround Time

TAB 1: ~~Run parallel assay testing of~~Test different-sized pools in parallel

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The Procleix Panther ART system gives operators the capability to load subpools or individual donations while it tests large pools ~~for up to four different assays~~, without interruption or recalibration.

The Procleix NAT Manager middleware ~~can identify~~identifies a reactive result in a pool, subpool, or donation, depending on the algorithm and initial pool size. This allows a lab to release all negative donations in the reactive pool on the same day. Better ~~TAT~~turnaround time means more billed donations processed per shift. Procleix systems can handle increases in laboratory activity with minimal adjustments.

TAB 2: Reduce unnecessary pool deconstruction

Plasma screening for fractionation is performed in large pools. Any reactive pool must be deconstructed to identify the contaminated donation and prevent it from entering a manufacturing pool. False reactive results lead to unnecessary, time-consuming, and costly deconstructions and delay the results of the rest of the donations in the pool. Procleix assays are highly specific, minimizing the need for retesting and ensuring faster release of donations.

TAB 3: Upgrade to track-ready instruments

Connecting instruments to a track system has compound benefits. It optimizes staff hours, minimizes errors, and streamlines instrument and reagent processes. By lowering ~~TAT~~turnaround time, a track system provides a rapid return on investment in reduced overall operating costs.

Panther ART (Automation Ready Technology) is track-ready.

Improve Productivity while Minimizing Costs

TAB 1: Reduce operating costs with Procleix systems

High throughput means fewer instruments can handle equal or greater volume (one Panther can process one million donations per year). Fewer instruments use less energy, take up less space, and cost less to maintain. The Panther ART also generates limited waste since it uses only two types of consumables.

TAB 2: Increase billable donations per shift and optimize staff resources

~~TAB 3: Optimize staff resources~~

Rapid turnaround time allows for more billed donations processes per shift. Procleix systems require minimal operator intervention, which means a single operator can manage several instruments with extended walk-away time. This one operator can then allocate time to additional tasks to increase productivity. Panther ART is particularly well suited for labs that have implemented LEAN workflow.

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2.1 Portfolio

MISSING TEXT

NAT Screening

Irregular Antibody Screening

CTA: Learn more about Grifols Workflow Consultancy

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NAT Screening

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Irregular Antibody Screening

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2.2 Screening Plasma with NAT

Innovation that empowers. The Procleix Panther system features Automation Ready Technology (ART) for next-level workflow automation. The Panther ART is designed to allow donor-screening labs to optimize variable workflow needs by offering superior customization with easy, scalable options that help transform the way you work as your lab needs evolve.

NAT Screening Product Line

INFOGRAPHIC

A Lab Workflow

INFOGRAPHIC

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Innovation That Empowers

Procleix systems combine full automation with versatility and smart operations for efficient NAT processing of plasma samples. The entire set of instruments has a compact footprint, fitting into even small laboratories with ease.

The Procleix Xpress is a pooling-and-archiving system that transfers plasma from individual samples to pool tubes for further testing, archiving on deep well plates, or both.

Procleix assays use Isothermal TMA, a proven, reproducible technology. Grifols has received FDA, EMA, and ~~cFDA~~NMPA clearance for screening pools of plasma samples. Assays target HIV, HBV, HCV, HAV, and ParvoB19 in pools of up to 96 plasma samples for Ultrio Elite and 256 plasma samples for Parvo/HAV. Our assays are tested using a single tube, which means less solid waste~~,~~ and maintenance and fewer moving parts~~, and less maintenance~~.

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The Procleix Panther ART features software and hardware innovations that provide the flexibility needed by laboratories implementing screening automation. It allows the lab to test plasma samples for multiple assays in succession to ensure a full set of reported results in less time. Procleix NAT Manager software compiles all results from pooling and NAT screening to simplify reporting and reduce operator intervention.

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2.3 Irregular Antibody Screening

Plasma used to produce IVIG should be free of clinically significant irregular antibodies and have acceptable Anti-A and Anti-B antibody titers to prevent hemolytic events in patients. Grifols fully automated, high- and medium-capacity instruments help laboratories efficiently screen these irregular donations from manufacturing pools.

A Lab Workflow

INFOGRAPHIC

The DG Gel System

DG Gel instruments and reagents use a proprietary card technology to help labs streamline typing and tailor an extended phenotype profile for each testing need. The instruments use a simultaneous perforation-and-dispensing technique that allows full use of the card wells while avoiding cross-contamination. For enhanced flexibility, DG Gel reagents are compatible with all

DG Gel instruments and include comprehensive DG Gel card profiles, reagent red blood cell options, and complete liquid antisera.

The Erytra Automated System is a fully automated, high-~~capacity~~throughput desktop analyzer designed to perform pretransfusion compatibility tests using DG Gel card technology.

The Erytra Eflexis Automated System is our floor-based, fully automated analyzer for performing irregular antibody tests using DG Gel technology. It is the next step in Grifols scalable blood-typing solutions.

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