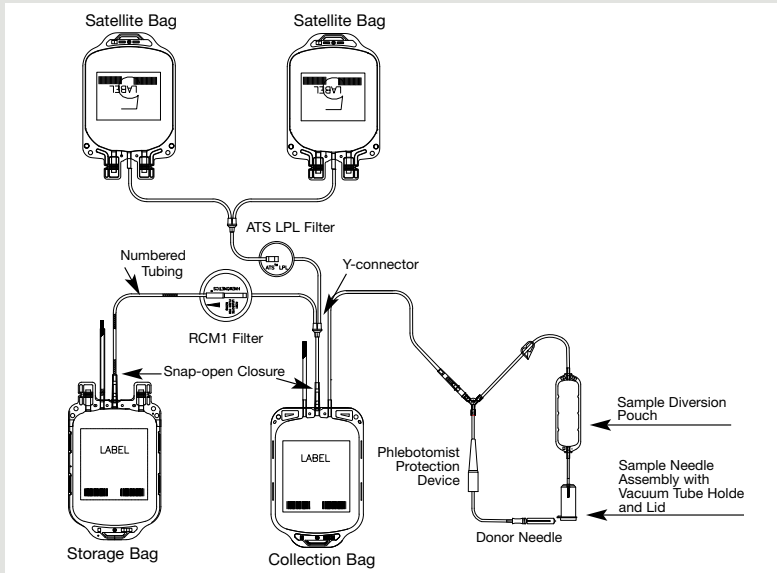


Leukotrap[®] Platelet Filtration Systems

Blood collection systems for improving the safety & availability of leukoreduced whole blood derived platelets

PLATELET IN-LINE SYSTEMS

Leukotrap RC PL System



The Leukotrap RC PL System is a closed system for the collection of one unit of whole blood, and the pre-storage leukoreduction of red blood cells, platelets, and plasma, followed by the subsequent storage of each blood component.

Indication

- Filtration must begin within 24 hours of collection.

Blood Components Produced

- Leukoreduced red blood cells
- Leukoreduced platelet concentrates
- Leukoreduced plasma

Reorder code: 123-63

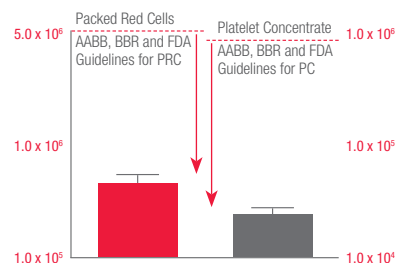
Performance

ATS LPL FILTER—A Product Innovation to Provide QC Assurance of Platelet Recovery Requirements

The ATS LPL Filter is designed for high efficiency filtration of platelet-rich plasma. Its unique design allows for semi-automatic processing and filtration of the entire platelet-rich plasma layer to provide greater QC assurance of meeting platelet recovery requirements.

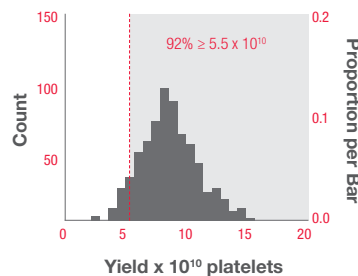
- White cell residuals for both the RCM1 and ATS LPL filters are well below industry standards and guidelines.
- RBC recovery is enhanced by auto-drainage.

Figure 1
Consistency Of Performance With RCM1 And ATS LPL Filters Using The Leukotrap RC PL System.



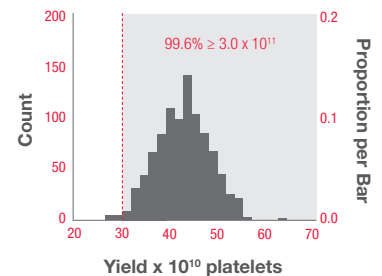
Data from actual field use.
Shown are mean residual WBC/unit and 95% confidence interval.

Figure 2
Platelet Yield Distribution Of Individual Platelet Concentrates (PC) Prepared Using The Leukotrap RC PL System.



Data from 500 mL WB (n = 700) collections processed with the Leukotrap RC PL System // Mean platelet yield = 8.87×10^{10} with a standard deviation of 2.42×10^{10} platelets // Ninety-two percent (92%) of PCs had a platelet count greater than the AABB Standards¹ for platelets prepared from whole blood ($\geq 5.5 \times 10^{10}$).

Figure 3
Platelet Yield Distribution Of A Pool Of Five (5) Individual Platelet Concentrates (PC) Prepared Using The Leukotrap RC PL System.



The distribution was obtained by computer simulation using the individual PC yield data shown in Figure 2 // Mean platelet yield with a pool of 5 = 4.3×10^{11} with a standard deviation of 5.3×10^{10} platelets // Over ninety-nine percent (99.6%) of the PC pools had a platelet yield greater than the AABB Standard for platelets prepared by cytopheresis² ($\geq 3.0 \times 10^{11}$).

Platelet In-Line System Specifications

Conditions of Use

Shelf Life:

- 3 years in unopened foil pouch.
- 30 days in an opened/resealed foil pouch.
- The set can be removed from its foil pouch and plastic outer wrap packaging and stored for up to 4 days exposure at room temperature with no compromise of product solution integrity.

Storage Conditions: Room temperature; avoid excessive heat; protect from freezing.

Single Use.

Collection

Latex Content: This product is free of natural rubber latex.

Collection Volume: 500 mL +/- 10%.

Needle Protection Device: For reducing needlestick injury.

Ultra Thin Wall 16-gauge Needle: Type 304 stainless steel siliconized for lubricity.

- 100% tested for needle sharpness for donor safety and comfort.
- User friendly, finger contoured needle hub with a “bevel-up” indicator.
- Tamper evident needle cover.

In-line Sampling System: Sample Diversion Pouch Sampling System.

- Diverts 42 mL of initial blood collected.
- Reduces donor chair time by providing test sample access while collection bag is filling.
- Efficient test sample collection process with pre-attached vacuum tube holder with lid.

Processing & Storage of Blood Products

Anticoagulant: 70 mL, Citrate Phosphate Double Dextrose (CP2D).

Additive Solution: 110 mL, AS-3 (Nutricel® Solution).

Filters:

RCM1 Leukocyte Reduction Filter:

- Filter housing hold-up volume – approximately 18 mL.
- White cell residuals consistently averaging less than 1×10^6 ; well below industry standards and guidelines.
- RBC recovery averages greater than 90%.

ATS LPL Leukocyte Reduction Filter:

- Filter housing hold-up volume – approximately 7 mL.
- White cell residuals consistently averaging less than 1×10^5 ; well below industry standards and guidelines.
- Ninety-two percent (92%) of platelets had a platelet count greater than the AABB Standards¹ for platelets prepared from whole blood (\geq to 5.5×10^{10}).

Plastic:

- Except for the CLX® Platelet Storage Container, all bags and tubing are polyvinyl chloride (PVC) with di (2-ethylhexyl) phthalate (DEHP) plasticizer.
- The CLX container is PVC with tri (2-ethylhexyl) trimellitate (TEHTM) plasticizer. This proprietary plastic is transparent, flexible and gas permeable and designed to maintain acceptable pH over the component's shelf life.

Tubing: All tubing is compatible with standard sterile tubing connection devices.

Snap-open Closures: For easy, fast opening of fluid paths between bags.

Satellite Bags: CLX Plastic Bags, plasma may be stored.

Blood Bag Labels: Enhanced paper for improved adhesion of overlabels.

Blood Product Dating:

- Up to 42 days at 1-6 °C for red blood cells, leukoreduced.
- Up to 5 days at 20-24 °C for platelet concentrates, leukoreduced in a CLX storage bag.
- Up to 1 year at < -18 °C for fresh frozen plasma, leukoreduced and cryoprecipitate.

Testing

Crossmatch Segments: 16.

QC Sampling: Plugged tubing leg on the final red cell storage bag.

¹ Standards 5.7.4.19 – Standards for Blood Banks and Transfusion Services, AABB 30th Edition, 2016.

Ordering Information

Leukotrap RC PL Systems – Case Quantity: 18 (3 sets per foil pouch, 6 pouches per case)

Reorder Code	Anticoagulant/Additive	Fill Volume (mL)	Set Configuration*	Satellite Bags
123-63	CP2D/AS-3	500	Triple	2 CLX
123-64	CP2D/AS-3	500	Quad	3 CLX

* Represents number of functional bags including final red cell storage bag.

RxOnly

For a list of worldwide office locations and contact information, visit www.haemonetics.com/officelocations

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