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INTERCEPT® Blood System for Platelets Pathogen Reduction System

Case Study: Assessing Platelet Availability through Usable Shelf-Life, Time of Release and to Transfusion from Blood Center and Hospital Perspectives

A medium sized independent blood center that supplies over 10,000 platelet components per year to more than 30 hospitals utilizes both pathogen reduction (PR) and large volume delayed sampling (LVDS 48hr) to meet FDA bacterial guidance[1] criteria. These methods differentially impact platelet component availability for release, shelf-life, time to transfusion, and waste. The blood center assessed collection and distribution data to evaluate platelet availability when comparing PR (INTERCEPT® Blood System for platelets)[2] and LVDS 48 hr.

Access to platelet components was also evaluated at a large level II trauma center hospital serviced by the blood center in this study. Hospital and patient platelet access was based on time to transfusion, as well as usable shelf life.

The blood center and hospital requested to remain anonymous but reviewed the data and agreed with the results and conclusions.

Blood Center Perspective: Earlier Platelet Release and Lower Waste with PR

The blood center distributed a total of 4,793 components from October 2021 through February 2022; approximately 90% were INTERCEPT treated while the remainder were tested with the LVDS 48-hour methodology. Analysis of collection and distribution data demonstrated that INTERCEPT treated platelets were released 64 hours (2.7 days) earlier ($p<0.0001$) and provided greater remaining usable shelf life than LVDS 48-hour tested platelets ($p<0.0001$).

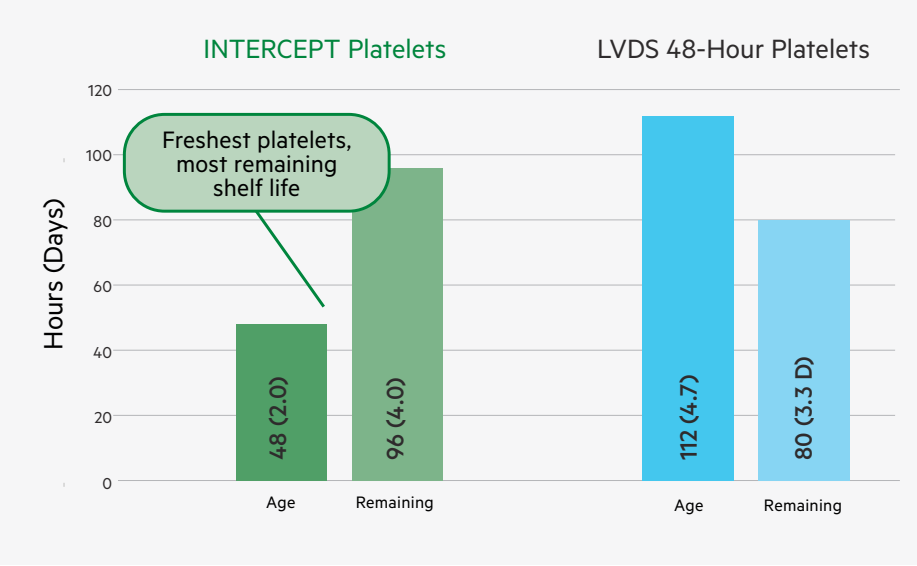


Figure 1

The earlier release of PR platelets and corresponding remaining shelf life were largely attributed to the avoidance of testing holds inherent with LVDS as well as an optimal turn-around-time for infectious disease test results.

Earlier platelet release also translated to significantly fewer wasted platelets with INTERCEPT versus LVDS 48-hour methodologies ($p<0.0001$).

Table 1

Comparison of wastage among types of platelet units.

Platelet Units	Total # of Units	# Wasted	% Wasted
INTERCEPT	4,326	341	**7.9%**
LVDS 48 Hr	467	120	**25.7%**

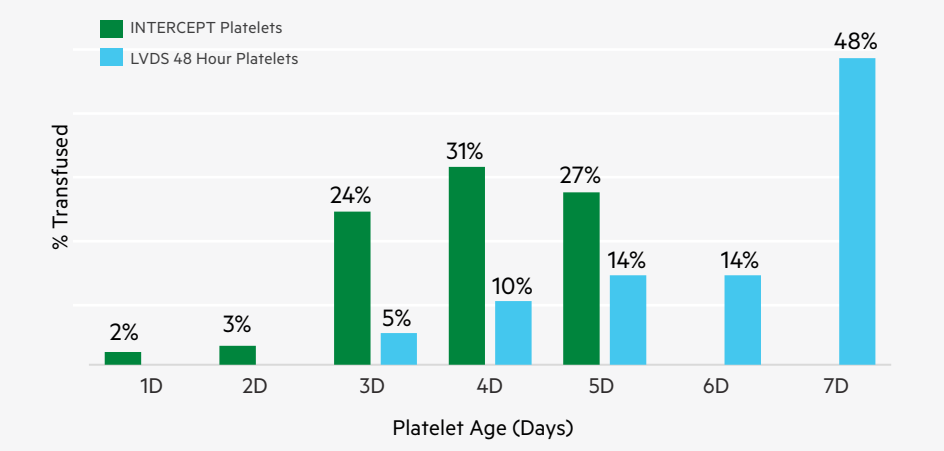
Hospital Perspective: Fresher, Faster Platelet Availability with PR

A large level II trauma center hospital provided one month of data including the date and time of transfusion for INTERCEPT treated and LVDS 48hr platelets. These data were cross-referenced with the distribution information provided by the blood center, and the platelet age at transfusion was determined.

The comparison of platelet age at transfusion demonstrated earlier availability and transfusion of fresher platelets with pathogen reduction.

Figure 2

Of note, this hospital routinely accepts short-dated platelets thus resulting in skewed distribution/transfusion toward the end of expiry for both platelet types (i.e. Day 4-5 for PR and Day 7 for LVDS).



References

1) Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion: Guidance for Industry. US FDA; December 2020.
2) The INTERCEPT Blood System for Platelets Package Insert, Cerus Corporation; May 2019.

CONTRAINDICATIONS Contraindicated for preparation of platelet components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of platelet components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen. **WARNINGS AND PRECAUTIONS** Only INTERCEPT Processing Sets for platelets are approved for use with the INTERCEPT Blood System. Use only the INTERCEPT INT100 Illuminator for UVA illumination of amotosalen-treated platelet components. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any platelet components not exposed to the complete INT100 illumination process. Tubing components and container ports of the INTERCEPT Blood System contain polyvinyl chloride (PVC). Di(2-ethylhexyl)phthalate (DEHP) is known to be released from PVC medical devices, and increased leaching can occur with extended storage or increased surface area contact. Blood components will be in contact with PVC for a brief period of time (approx.15 minutes) during processing. The risks associated with DEHP released into the blood components must be weighed against the benefits of therapeutic transfusion Pulmonary events: Acute Respiratory Distress Syndrome (ARDS). INTERCEPT processed platelets may cause the following adverse reaction: Acute Respiratory Distress Syndrome (ARDS). An increased incidence of ARDS was reported in a randomized trial for recipients of INTERCEPT processed platelets, 5/318 (1.6%), compared to recipients of conventional platelet components (0/327). Monitor patients for signs and symptoms of ARDS.

Rx only. See package insert for full prescribing information.

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