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INTERCEPT® Blood System for Platelets Pathogen Reduction System

Case Study: Hospital Demand, FDA Guidance Drives Pathogen Reduction Scale-Up

Versiti Blood Center of Michigan is part of Versiti Inc., a national leader in blood health innovation with a mission to improve the health of patients and enable the success of its health care partners through science, medicine, and service.

The Challenge

Having decided that pathogen reduction (PR) is its primary platelet apheresis product of choice, VM required a PR production scale-up plan that aligned with hospital demand for over 30 hospitals.

The Solution

VM developed a scale-up plan in which ~ 87% of its apheresis platelet inventory is pathogen reduced. Timing with PR ramp-up was correlated to present hospital demand and roll-out.

> "With a staggered production plan, we are able to meet the demand for pathogen reduced platelets in over 30 hospitals by FDA's deadline for bacterial compliance in Q1 2021."
>
> **– Nichole Miller, MSTM (SBB) ASCP**
> *Director – Specialized Production*
> Versiti Blood Center of Michigan

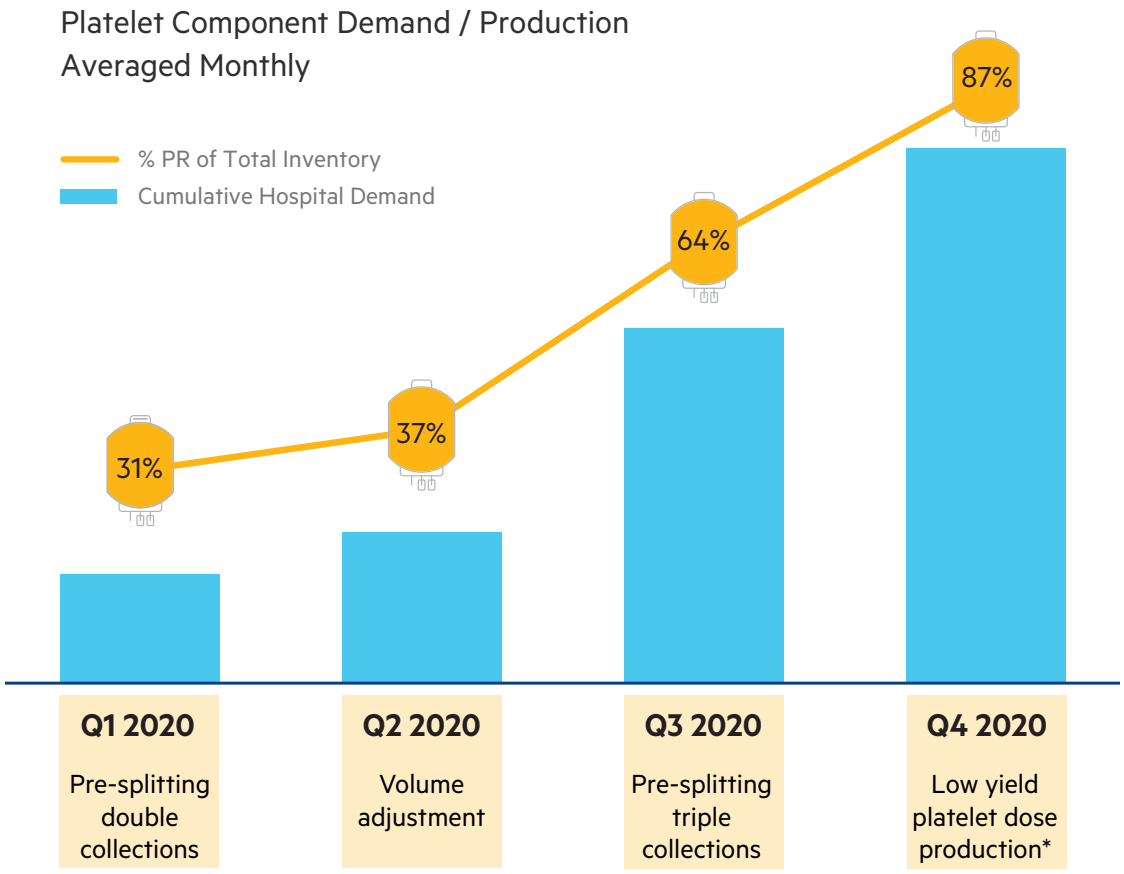
Increase in Hospital Demand for Pathogen Reduction

Five hospital systems, with over 30 hospitals expressed preference for PR platelets based on:

- **Pandemic preparedness:** the COVID-19 pandemic underscores the need for proactive blood safety, and to help ensure blood supply continuity.
- **FDA compliance:** Per FDA guidance on bacterial contamination of platelets, platelet components present the highest risk for sepsis and related fatalities; as such, FDA requires guidance implementation by March 2021.
- **Transfusion-transmission infectious (TTI) risk reduction beyond bacteria:** PR is the only FDA guidance option that reduces TTI risk beyond bacteria, with the ability to inactivate viruses, protozoans, and T-cells.
- **Operational efficiency:** PR provides hospitals with a transfusion-ready platelet unit, without the need for secondary testing, irradiation, or CMV serology.

Meeting Demand with ~87% PR Apheresis Platelet Inventory

Production optimization measures were implemented over time resulting in ~87% pathogen reduced platelets:



*Low yield (<3.0x1011) for a small portion of inventory

References: 1. The INTERCEPT Blood System for Platelets Package Insert, Cerus Corporation; September 6, 2022.

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.

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Rx only. See package insert for full prescribing information.