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Pathogen Reduction - The Proactive Strategy in Pandemic Preparation to Secure Blood Safety

Blood Safety is Critical to Health Care Continuity

The coronavirus disease COVID-19 pandemic has highlighted concerns related to health system continuity. This includes the ability to provide critical blood components, which can become challenging on several fronts (per below). [1,2]

Blood Supply Pressure Points in a Pandemic

Safety:

Transfusion-Transmitted Infections (TTI)
Blood product contamination
Undetectable threat with asymptomatic donors
Lack of testing for emerging pathogens

Availability:

Donor "social distancing"
Blood drive cancellations
Donor deferrals
Product lookbacks and recalls
Blood and staffing shortages

The ONLY Strategy Recommended by FDA Guidance that Mitigates TTI Risk BEYOND BACTERIA

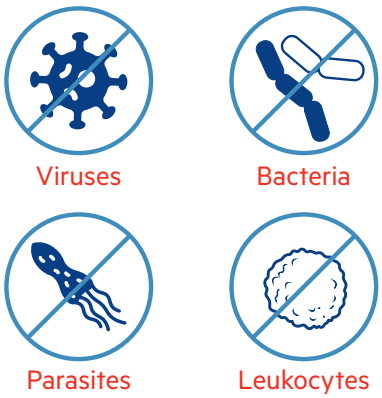
- Platelet components (PC) present the highest risk for sepsis and related fatalities; FDA's guidance requires implementation by March 2021.[3]
- The COVID-19 pandemic[4] underscores the need for additional proactive blood safety.
- Patient safety is jeopardized as TTI risk from new pathogens may not be mitigated.[4]

Major US blood centers have responded to the need and are ready to provide pathogen reduced platelets.

The INTERCEPT® Blood System for Plasma is approved and broadens the ability to safeguard the blood supply.[5]

Treat vs. Test

Broad Spectrum TTI Risk Mitigation with Pathogen Reduction[6]



Pathogen Reduction's Role in Blood Availability

Mitigation of Emerging Pathogens	• PR has sustained local platelet availability during outbreaks by maintaining an effective donor pool[7,8] • Broad spectrum PR, including coronaviruses (SARS-CoV,[9-11] MERS-CoV [10,12]) and arboviruses (Zika, Dengue, Chikungunya)[5,6]
Alternative to Tests/ Deferrals	• PR can be used in place of deferrals for malaria[13] and testing for Zika virus[14] and Babesia,[15] per FDA guidances.
Day 1 Release	• PR allows for release of product on day one. Early release provides added flexibility for managing inventory and may help hospitals get platelets sooner.
Operational Efficiency	• PR provides hospitals with a transfusion ready platelet unit, without need for secondary testing, irradiation, or CMV serology.[3,6] • Avoid false positive results and associated recalls, saving valuable time, resources and platelets for transfusion.

Cerus' Commitment to Supporting COVID-19 Convalescent Plasma Efforts

Consistent with its mission to enable blood centers to deliver safe and effective blood products to patients, Cerus has committed to supporting COVID-19 convalescent plasma (CCP) efforts.

Convalescent plasma is a promising therapy used in previous pandemics (Ebola, SARS-CoV), and has shown preliminary favorable results in improving symptoms in COVID-19 patients.[16] Pathogen reduction of plasma improves product safety through TTI risk reduction.

- With the aim of optimizing CCP therapy, Cerus formed a collaborative research group led by Dr. Laurence Corash, Cerus' Chief Scientific Officer. The research team seeks to define the key characteristics that influence the potential efficacy of CCP, including the nature of anti-COVID-19 antibodies, dosing and how these influence responses to the therapy regimen.
- In partnership with AABB, Cerus has developed tools and standardized protocols to support blood centers and hospitals to quickly implement processes for PR CCP production.

References

1) Pagano MB et al. Transfusion. 2020 Mar 21. 2) Zimrin AB et al. Transfusion. 2007 Jun;47(6):1071-9. 3) FDA, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion, Guidance for Industry, December 2020. 4) Stramer S et al. Transfusion, Vol. 49, No. S2, 2009, pp. 1S–29S. 5) The INTERCEPT Blood System for Plasma Package Insert, Cerus Corporation; September 6,2022. 6) The INTERCEPT Blood System for Platelets Package Insert, Cerus Corporation; September 6,2022. 7) Rasongles P, et al. Transfusion 2009;49:1083-91. 8) Musso D, et al.Transfusion. 2014 Nov;54(11):2924-30. 9) Perlman S. N Engl J Med 2020;382:760-762. 10) Hashem AM et al. Transfus Med 2019 Dec;29(6):434-441. 11) Pinna D et al. Transfus Med 2005;15:269-76. 12) Hindawi SI et al. Transfusion 2018 Jan;58(1):52-59. 13) Malaria FDA Guidance for Industry December 2022. 14) Zika FDA Guidance for Industry July 2018. 15) Babesiosis FDA Guidance for Industry, May 2019. 16) Duan K et al. medRxiv 2020.03.16.

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CONTRAINDICATIONS Contraindicated for preparation of platelet or plasma components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens. Contraindicated for preparation of platelet or plasma 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 are approved for use with the INTERCEPT Blood System. Use only the INTERCEPT INT100 Illuminator for UVA illumination of amotosalen-treated platelet or plasma components. No other source of UVA light may be used. Please refer to the Operator's Manual for the INT100 Illuminator. Discard any platelet or plasma 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. Amotosalen-treated plasma may cause the following adverse reaction: Cardiac Events. In a randomized controlled trial of therapeutic plasma exchange (TPE) for TTP, five patients treated with INTERCEPT Blood System processed plasma and none with conventional plasma had adverse events in the cardiac system organ class (SOC) reported. These events included angina pectoris (n=3), cardiac arrest (n=1), bradycardia (n=1), tachycardia (n=1) and sinus arrhythmia (n=1). None of these events resulted in documented myocardial infarction or death. Monitor patients for signs and symptoms of cardiac events during TPE for TTP.

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