Versiti | Blood Center of Michigan
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Declaration of Urgent Medical Need
Product with Nonconforming Test Results

Affix Recipient Hospital Label or Complete

Name: _____

DOB: _____

MRN: _____

Unit ID(s) _____

Product testing from this donation indicates that the product may be at increased risk for transmission of a communicable disease agent to the recipient and/or may have low cell viability.

☐ The product cultures are incomplete. At time of infusion, cultures will have been held for fewer than 14 days. Culture results are negative at the time of infusion.

☐ The product has cultured positive for _____.

☐ Test thaw CD34 viability is <70% and there is no CFU-GM growth.

☐ Test thaw CD34 viability is <50% (regardless of CFU-GM results).

The FDA requires documentation that the transplant center physician has been notified of the results of the donor/product screening and testing.

Urgent medical need, as defined by the FDA, means that no comparable donor/product is available, and the recipient is likely to suffer death or serious morbidity without use of this product.

Based on the above documentation, I choose to:

☐ Accept this product ☐ Decline this product

_____	_____	_____
Transplant Physician print	Transplant Physician signature	Date

My physician has explained to me, in terms that I have understood, the risks and benefits to me if I proceed to receive this product that has:

☐ Incomplete culture results

☐ Positive culture results

☐ Low cell viability

I understand that if I choose to accept this product, I will be monitored for signs and symptoms of infection and engraftment. Depending on my condition, my physician may choose to give me antibiotics or other treatment as they deem appropriate. I agree to accept the product.

_____	_____	_____
Recipient or Legal Guardian signature	Relationship, if legal guardian	Date

	_____	_____
	Versiti-MI Medical Director signature	Date