



December 2010

**Re: INTERCEPT Blood System™ for Platelets & Plasma**  
**Product Codes INT21, 22, 25 and 31**  
**Label Claim Expansion: INTERCEPT approved as an alternate to CMV testing and leukoreduction for the prevention of transfusion-transmitted CMV infection**

Dear Valued Customer:

CERUS is committed to continuously improving our products and services. This letter is to advise you of the most recent improvement: an expansion to our label claims for platelets and plasma.

**INTERCEPT as an Alternate to CMV Testing and Leukoreduction for Prevention of Transfusion-Transmitted CMV Infection**

The INTERCEPT Blood System for platelets and plasma has received CE Mark approval as an alternate to cytomegalovirus (CMV) testing and leukoreduction for the prevention of transfusion-transmitted CMV infection. This label claim expansion has been approved by our Notified Body, TÜV SÜD Product Service, based on robust CMV and pseudorabies virus (PRV) inactivation data and clinical experience with INTERCEPT.

Despite improving the safety of blood relative to the risk of transmission of CMV infection, the traditional methods of serology testing and leukoreduction remain a reactive and not fully effective approach to blood safety. The residual risk of CMV infection when either leukoreduction or CMV seronegative blood products are transfused to CMV seronegative recipients is between 1% and 2.5% (Bowden et al. 1995). These observations were confirmed in a more recent study of the risk of CMV transmission from leukoreduced blood products in which Wu, et al (2009) found that the residual calculated risk after leukoreduction is up to 6.5%.

In contrast, INTERCEPT is a proactive approach to blood safety. Customers can be confident that their INTERCEPT-treated products do not contain infectious CMV, thus providing the following benefits:

- Reduced administrative burden to maintain a separate CMV seronegative or leukoreduced inventory of platelets and plasma
- Reduced platelet wastage resulting from expired product due to dual inventory
- Reduced risk of transmitting infectious CMV to an immune-compromised patient
- Ability to reduce or eliminate consumables and labor costs for CMV testing and/or leukofiltration

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## Implementation

The INTERCEPT Platelet and Plasma Technical Data Sheets are in the process of being updated to reflect this new claim; upon completion, the updated documents can be downloaded from:

[www.INTERCEPTBloodSystem.com/technical\\_data\\_sheets](http://www.INTERCEPTBloodSystem.com/technical_data_sheets). There is no impact on product design, performance, or instructions for use.

We understand that blood centers are under ever increasing pressure to reduce costs and increase efficiency, all while continuing to improve the safety of the blood supply. To this end, we continue to pursue product improvements and label claims which ensure our customers realize maximum value from the implementation of INTERCEPT. We hope that you find this improvement useful.

## Contact information

If you have any questions concerning this change, please contact Cerus BV Customer Services:

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With Kind Regards,

*Cerus Europe BV*

1. Bowden RA, Slichter SJ, Sayers M, et al. 1995. A comparison of filtered leukocyte-reduced and cytomegalovirus (CMV) seronegative blood products for the prevention of transfusion-associated CMV infection after marrow transplant. *Blood*; 86:3598-603.
2. Wu Y. et al. 2009. Direct assessment of cytomegalovirus transfusion-transmitted risks after universal leukoreduction. *Transfusion*, doi: 10.1111/j.1537-2995.2009.02486.