

## CSL Bioplasma

Immunohaematology

Thursday, 24<sup>th</sup> June 2010

Dear Valued Customer,

### Re: CSL 0.8% Reagent Red Blood Cell (RRBC) Product Discolouration and Haemolysis - Update

I am writing to inform you of our findings regarding the investigation of the discolouration and haemolysis observed by some customers in affected 0.8% RRBC products as listed below.

**Table 1: Reports of Affected 0.8% Products**

Product Name	Batch No	Expiry
Abtectcell™ III 0.8%	8245035	10/07/2010
Phenocell™ C 0.8%	9653 013	9/07/2010

CSL has identified the causative agent to be a low-grade contaminant in the flush solution used during the dispensing process for these select 0.8% batches. It is important to note that not all product within the batch was affected and all other RRBC products are not affected (eg. all 3% RRBCs, all Securacell™ products, 0.8% Revercell™ products).

A root cause analysis was performed with input from our Quality Assurance (QA) department. The subsequent deployment of new equipment has allowed us to eliminate the use of flushing solutions when dispensing all RRBC products and thus the risk of this situation reoccurring has been eliminated. As a further precautionary measure, re-analysis of risk assessments of our manufacturing process are being conducted, to identify preventative actions and controls, that will be implemented to further improve our manufacturing processes.

In the management of this investigation and issue, CSL has worked closely with customers. Where possible, replacement product from existing stock has been deployed. All replacement products have now been issued. We thank you for your assistance with this.

CSL has over 25 years history in development and manufacturing RRBC products and are committed to ongoing supply of quality products to Asia. CSL genuinely apologises for any inconvenience and angst that this incident may have caused. CSL appreciates the feedback from our customers; we take these issues seriously and place the utmost importance on the quality of our products and patient safety. We are confident that we have fixed the issue and have deployed activities to prevent reoccurrence.

If you have any questions or would like further information or assistance, please contact Damien Heathcote, IH Development & Quality Manager, Doug Gray, IH Director International Sales & Marketing or myself directly.

Sincerely,



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