OPH 3, 5-3

PALL Pall Corporation

Scientific and Laboratory Services
25 Harbor Park Drive
Port Washington, NY 11050 USA

516.484.3600 phone
516.484.3628 fax
www.pall.com

Contact: Todd Aydelotte
(212) 905-6196

UPDATE TO STUDY: REMOVAL OF PRIONS (PRP) FROM RED CELL CONCENTRATES WITH A PROTOTYPE OF A PRION REMOVAL FILTER (PRRF)

BACKGROUND: The occurrence of a variant CJD (vCJD) in the United Kingdom, together with the recent animal data and reports, suggest the possibility of transmission of the causative agent by blood transfusion. We have evaluated the use of a prototype prion removal filter for the removal of infectious prion from red cell concentrates.

ENDOGENOUS INFECTIVITY: Whole blood samples were collected from the citrate anticoagulant of hamsters that have developed a prion disease called scrapie. The blood samples were processed into red cell concentrates in a manner similar to standard blood banking procedure. The scrapie contaminated red cell concentrates were then filtered with Pall's prion removal filter. The filtered and the unfiltered control red cell samples were injected intracerebrally into normal hamsters. Preliminary results show that after 183 days none of the hamsters that received filtered red cell concentrates developed scrapies, which suggests that the filter completely removes prion infectivity from the red cell samples. In contrast, some of the animals in the control group are beginning to show signs of scrapie disease and one has been confirmed for the disease.

CONCLUSION: The present results show that the prototype of a new prion removal filter was effective in removing infectious prion from red cell concentrates from scrapie infected hamsters. The use of this type of filter may help reduce the risk of transmitting infectious prions through blood transfusion. However, additional *in vivo* studies with red cell concentrates from scrapie infected hamsters (in the clinical and pre-clinical stage of the disease) are needed and are currently ongoing.

40 CFR 56 OPH-8