

BLOOD PRODUCTS ADVISORY COMMITTEE

May 15 – 16, 2012

REFERENCES

Topic I. Evaluation of the Safety and Effectiveness of the OraQuick® In-Home HIV Test, OraSure Technologies, Inc. (Device Panel)

1. Carballo-Diéguez A et. al. Will Gay and Bisexually Active Men at High Risk of Infection Use Over-the-Counter Rapid HIV Tests to Screen Sexual Partners? *J Sex Res* 2012; 0(0)1-9.
2. CDC. HIV in the United States: At A Glance. March 2012; 1-2.
3. CDC. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. *MMWR* 2006; 55(No. RR-14).
4. Katz D et. al. Acceptability and Ease of Use of Home Self-Testing for HIV among Men Who Have Sex with Men. Presented at the 19th Conference on Retroviruses and Opportunistic Infections in Seattle, Washington, March 5-8; 2012. See <http://retroconference.org/> for the updated abstract.
5. Leung C and Lee S. Rapid HIV test: From meta-analysis to field application. *Lancet Infect Dis* 2012; published on-line Jan 24. 2012; DOI:10.1016/S1473-3099(12)70003-8.
6. MacKellar D et. al. Reasons for Not HIV Testing, Testing Intentions, and Potential Use of an Over-the-Counter Rapid HIV Test in an Internet Sample of Men Who Have Sex With Men Who Have Never Tested for HIV. *Sex Transm Dis* 2011; 38(5)419-428.
7. Pant Pai N et. al. Head-to-head comparison of accuracy of a rapid point-of- care HIV test with oral versus whole-blood specimens: a systematic review and meta-analysis. *Lancet Infect Dis* 2012; published on-line Jan 24. DOI:10.1016/S1473-3099(11)70368-1.
8. Walensky R and Paltiel D. Rapid HIV Testing at Home: Does It Solve a Problem or Create One? *Ann Intern Med* 2006; 145(6):459-462.
9. Wright A and Katz I. Home Testing for HIV. *N Engl J Med*; 354:(5)437-440.

BLOOD PRODUCTS ADVISORY COMMITTEE

May 15 – 16, 2012

REFERENCES

Topic II: Evaluation of Possible New Plasma Products Frozen Following In-Process Storage at Room Temperature for up to 24 Hours

1. Alhumaidan, H et. al. Stability of coagulation factors in plasma prepared after a 24-hour room temperature hold. *Transfusion* 2010; 50:1934-1942.
2. Cardigan R et. al. Coagulation factor content of plasma produced from whole blood stored for 24 hours at ambient temperature: results from an international multicenter BEST Collaborative study. *Transfusion* 2011; 51:50S-57S.
3. Cardigan R et. al. The quality of fresh-frozen plasma produced from whole blood stored at 4°C overnight. *Transfusion* 2005; 45:1342-1348.
4. Chapman C et. al. Ten years of hemovigilance reports of transfusion-related acute lung injury in the United Kingdom and the impact of preferential use of male donor plasma. *Transfusion* 2009; 49:441-452.
5. Coignard B et. al. Intra-Operative Deaths in Liver Transplant Recipients Associated with the use of Solvent/Detergent Plasma. *Hepatology* 2002; 36(4):2, Abstract 171.
6. Flamholz R et. al. Study of Three Patients With Thrombotic Thrombocytopenic Purpura Exchanged With Solvent/Detergent-Treated Plasma: Is its Decrease Protein S Activity Clinically Related to Their Development of Deep Venous Thromboses? *J Clin Apheresis* 2000; 15:169-172.
7. Goodwin, A et. al. A Review of the Technical, Diagnostic, and Epidemiologic Considerations for Protein S Assays. *Arch Pathol Lab Med* 2002; 126:1349-1366.
8. Hellstern P. Solvent/detergent-treated plasma: composition, efficacy, and safety. *Curr Opin Hematol* 2004; 11:346-350.
9. Lijfering, W et.al. Clinical relevance of decreased free protein S levels: results from a retrospective family cohort study involving 1143 relatives. *Blood* 2009; 113:1225-1230.
10. Silliman C et. al. Transfusion-related acute lung injury. *Blood* 2005; 105:2266-2273
11. Solheim B. Universal Pathogen-Reduced Plasma in Elective Open-Heart Surgery and

Liver Resection. Clin Med Res 2006; 4(3):209-217.

12. Toy P et. al. Transfusion-related acute lung injury: incidence and risk factors. Blood 2012; 119:1757-1767.
13. Yarranton H et. al. Venous thromboembolism associated with the management of acute thrombotic thrombocytopenic purpura. Br J Haematol 2003; 121:778-785.
14. Yazer M et. al. Coagulation factor levels in plasma frozen within 24 hours of phlebotomy over 5 days of storage at 1 to 6°C. Transfusion 2008; 48:2525-2530.