Hemochron® Jr. Signature
Whole Blood Microcoagulation Systems

Summary of an evaluation under the direction of SKUP
Report SKUP/2004/33

Background
The Norwegian supplier Medimport AS ordered a SKUP evaluation of the Hemochron® Jr. Signature Whole Blood Microcoagulation Systems (Hemochron) manufactured by ITC US. Hemochron is intended for measurement of Prothrombine Time (PT) in the primary health care. The PT analysis is used for monitoring of patients in vitamin K antagonist treatment to prevent thrombosis.

Hemochron
The measurement principle is whole blood clot time measured after optical detection of the change in movement of the mixture in the cuvette. The clotting time is defined as the time from the mixing of blood and reagents until the blood movements of the mixture decreases below a predetermined rate. The system is based on the Quick method for Prothrombine Time (PT), (factor II, V, VII, X and fibrinogen). From the whole blood measurement the equivalent plasma PT is calculated based on regression analyses performed across multiple centres. The result is given in the scale INR (International Normalised Ratio). The International Sensitivity Index (ISI) is approximately 1.0. A high number in the INR-result reflects a high anticoagulation effect. Both capillary and venous blood samples can be measured, but with two different kinds of cuvettes.

Results. The analytical quality and the user friendliness are regarded equally important.

Analytical quality

	Type of sample	N	CV % (Within) (95 % CI)	Bias (%) At 3 or 2 levels	Total Error, fulfilment of goal
Quality goals (SKUP)			≤ 5 %		> 95% < ±20% deviation
Quality goals (Denmark[1])			≤ 5 %	≤ ± 6%	
Hospital laboratory	Venous	100	8.5 (7.4 - 9.8)	1.5, -2.2, -10.2	84.0 %
	Capillary	46	7.9 (6.5 – 9.9)	1.5, -14.5	73.9 %
Primary care	Venous	40 39	7.4 (6.1 – 9.4) 7.7 (6.3 – 9.8)		
	Capillary	40	9.1 (7.5 – 11.7)		

User friendliness
Evaluated with venous samples: The ratings of the 'Information in Manual', 'Time factors' and 'Operation' were all 'satisfactory' both in the hospital laboratory and in the primary care. 'Quality control' was not 'satisfactory'; see comments in the report.

Conclusion
Hemochron does not fulfil the quality goals set up by SKUP (or the Danish 'Laboratorieudvalget'[1]) for analytical imprecision (CV_{within}) and total error in this evaluation, neither with venous nor with capillary samples. The within-series imprecision was > 5 % for both venous and capillary samples. The Total Error was < 20 % for only 84 % of the results with venous samples. The user friendliness of 'Manual', 'Time factors' and 'Operation' for venous samples were regarded as satisfactory, while 'Quality control' was not.

The complete report is available at www.skup.nu