Hemochron® Jr. Signature Whole Blood Microcoagulation Systems

Summary of an evaluation organised by SKUP Report SKUP/2004/33

Esther Jensen, SKUP Esther.Jensen@ouh.fyns-amt.dk

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 (Denmark1)			≤ 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	7.4 (6.1 – 9.4)		
		39	7.7 (6.3 – 9.8)		
	Capillary	40	9.1 (7.5 – 11.7)		

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.

The measurement principle of the Hemochron instrument 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

(Fortsætter side 34)

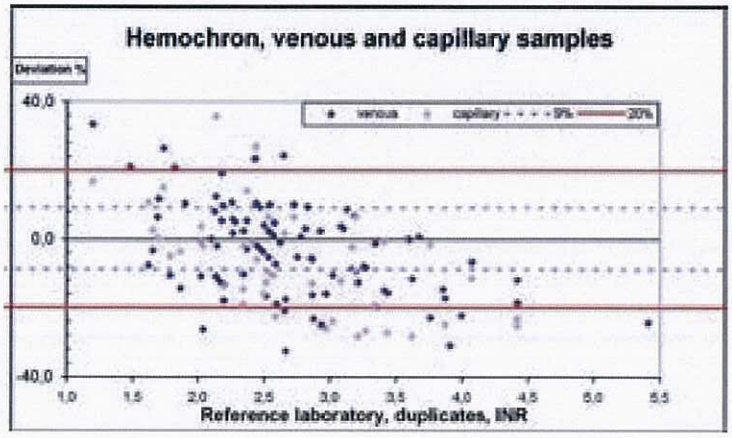

Figure 1. Total Error. Hemochron The diagram shows the deviations of the Hemochron results with venous and capillary samples. X-axis = mean of reference method duplicate results and Y-axis = ((first Hemochron result– mean of reference method, duplicate results)/ mean of reference method, duplicate results) x 100. Acceptance limits for Hemochron is ± 20 %. 95 % of the results should be within the acceptance limits. It is considered as acceptable that 1 % of the results deviate > ± 25 % from the reference laboratory. Acceptance limits for the hospital laboratory is ± 9 %. 95 % of the results should be within the acceptance limits.

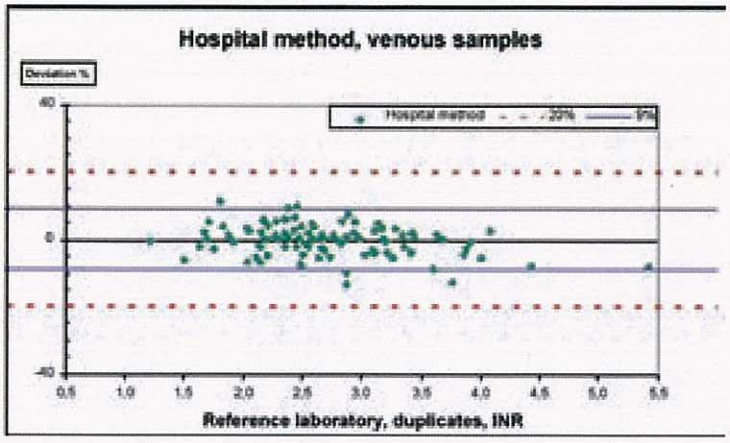

Figure 2. Total Error. Routine method in the hospital laboratory
This figure can be explained as figure 1, but this is the results of the samples with the hospital laboratory method. The hospital laboratory fulfils the goals.

(Fortsat fra side 29)

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.

The results with Hemochron using venous samples and capillary samples under optimal conditions in a hospital laboratory and in two general practices are seen in the table. Total Error are visualised for the Hemochron method and a hospital method in figure 1 and 2 respectively.

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 while 'Quality control' was not 'satisfactory'. The results of the 'low therapeutic value, INR 1,6' control had a CV of 11.8 %. This means, that it cannot be recommend as a tool for control or troubleshooting. The 'high therapeutic value, INR 4,6' control had a CV of 6.0 %, which is also too high.

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 Hemochron evaluation report inclusive comments from the manufacturer ITC is available at www.SKUP.nu or www.SKUP.dk

References

1 Laboratorieudvalget under "Faglig Udvalg vedr. Almen Praksis". Kvalitetskrav og kvalitetsvurderingssystem for hyppigt udførte klinisk biokemiske og klinisk mikrobiologiske analyser i almen praksis. November 2003.

Igelkott. Foto: Henrik Alfthan.