

Chempaq XBC

Summary of an evaluation under the direction of SKUP Report SKUP/2006/47



In 2005 the Danish manufacturer and supplier Chempaq AS ordered a SKUP evaluation of the Chempaq XBC (eXpress Blood Counter) device. Chempaq XBC is intended for measurements of Haemoglobin concentration, Leukocyte counts and three part differential (Lymphocytes, Monocytes and Granulocytes, concentrations and %) in the primary health care. In Chempaq XBC, each sample is analysed in a disposable cassette. Leukocytes, Lymphocytes, Monocytes and Granulocytes are counted and their size is determined in an impedance cell. Haemoglobin is measured photometrically at two wavelengths. The measuring interval for Leukocytes is 0-100 x 10⁹/L and for Hgb. 0-13 mmol/L (1 mmol/L ~ 1,62 g/dL). The same type of cassette can be used for both capillary and venous blood samples.

In the first evaluation in primary care the cassette lots used had a bias due to a technical error that was eliminated in a second evaluation. The results of the evaluations are summarized in the table below.

Results

Outpatients, hospital and primary care evaluation 2. Suggested quality goals with grey background

	Range	Type of sample	Total Error, percent fulfilling the goal	
			Hospital	Two primary care centres
Haemoglobin	(3 – 12 mmol/L)		± 5% deviation	
		Capillary	83 %	68 and 78 %
		Venous	≥ 95 %	≥ 95 %
Leukocytes	(3 – 25 x 10 ⁹ /L)		± 16% deviation	
		Capillary	≥ 95 %	83 % and 95%
		Venous	≥ 95 %	≥ 95 %
Granulocytes	(3 – 25 x 10 ⁹ /L)		± 23% deviation	
		Capillary	95 %	95 and ≥ 95 %
		Venous	89 %	≥ 95 %
Lymphocytes	(0,3 – 4 x 10 ⁹ /L)		± 21% deviation	
		Capillary	95 %	85 % and ≥ 95%
		Venous	92 %	92 %
Monocytes	(0,4 – 2,5 x 10 ⁹ /L)		± 43% deviation	
		Capillary	95 %	78 and 81 %
		Venous	≥ 95 %	94 %

No agreed Scandinavian quality goals exist for Leukocytes and 3 or 5 part differentials. During the writing of the protocol for this evaluation, SKUP proposed the quality goals above. In the evaluation ≥ 95% of the results should fulfil the goals. For haemoglobin the Danish demands¹ for bias and imprecision are ≤ 2% and ≤ 3%, respectively.

In evaluation 2 Chempaq XBC fulfils the quality goals for haemoglobin and Leukocytes in venous samples. For capillary samples the goals were almost fulfilled in hospital under optimal conditions; however they are not fulfilled in primary care which may be attributed to capillary sampling. The deviation of the 3 part differential was almost within the quality goal for granulocytes and lymphocytes. The monocytes had a positive deviation for low concentrations, and Chempaq XBC seems to measure a slightly higher concentration of monocytes than Sysmex and Coulter.

The ratings of the 'Information in Manual', 'Time factors', 'Quality control' and 'Operation' were all 'satisfactory'. Both primary care centres found the instrument very easy to use; however they both pointed out that the application of the samples, especially the capillary ones, could be difficult. A special brand of glue made the results vanish from the printer paper after two weeks. The error rate in the first evaluation was about 2%, while it had increased to 14% in the second evaluation due to an identified technical error.

Comments from Chempaq AS

There is no additional information from producer attached to the report.

The complete report is found at www.skup.nu