# Evaluation of the QBC Star centrifugal three-part differential haematology system

O. ERHABOR, G. RICHARDSON, I. MOHAMMED, C. THORNTON, J. BARK, M. HURST, D. HAMER and P. KINSELLA Blood Sciences, Department of Laboratory Medicine, Royal Bolton Hospital

Accepted: 22 March 2013

# Introduction

Point-of-care (POC) testing is becoming an important adjunct to haematology laboratory practice, particularly in allowing more rapid and informed clinical decisions to be made. The QBC Star is a POC haematology analyser that measures nine important complete blood count (CBC) haematological parameters from venous or capillary blood samples: haematocrit, haemoglobin, mean corpuscular haemoglobin concentration (MCHC), platelet count, white cell count, absolute and percentage granulocyte and lymphocyte/monocyte count.

The Sysmex XE-2100 is an automated discrete haematology analyser designed for high-volume clinical laboratory testing (maximum throughput: 150 samples/hour). It provides a 14-parameter haemogram, a five-part leucocyte differential, reticulocyte analysis including immature reticulocyte fraction, and a nucleated red blood cell (NRBC) count. White cell differential parameters (DIFF), reticulocyte analysis, and NRBC counts are determined using flow cytometry, a semiconductor laser and fluorescent dyes. The Sysmex XE-2100 also measures and charts 16 other detector control parameters. Samples may either be run in the automated aspiration (closed) sampling mode using a sample volume of 200  $\mu$ L or in the manual (open) sampling mode using a 130  $\mu$ L sample volume.<sup>1,2</sup> The combination of side scatter (inner complexity of the cell), forward scatter (volume) and fluorescence intensity of nucleated cells, gives a concise but precise image of each cell detected in the peripheral blood. A well-defined physical description of the different leucocyte populations (clusters) is obtained. Abnormal and immature cells, with their larger nuclear volume, show much higher fluorescence intensity than normal cells, and are easily distinguished in the DIFF scattergram. Haemoglobin determination is achieved using the sodium lauryl sulphate (SLS) method. Red blood cells and platelets are enumerated in the red cell/platelet channel using the sheath flow direct current detection method.3 Haematocrit is determined simultaneously using the pulse height detection method.4

The aim of this study is to evaluate the full blood count

Correspondence to: Erhabor Osaro Blood Sciences, Department of Laboratory Medicine, Royal Bolton Hospital, Bolton NHS Foundation Trust, Bolton UK Email: n\_osaro@yahoo.com

# ABSTRACT

The QBC Star haematology system includes the QBC Star centrifugal analytical analyser and the QBC Star tube system. Together, they are capable of producing a haematology profile on venous or capillary whole blood. The aim of this study is to compare full blood count (FBC) including differential white cell count performance between the QBC Star analyser and a gold standard Sysmex XE-2100 haematology analyser. The FBC performance was evaluated according to the National Committee for Clinical Laboratory Standards (NCCLS) document H20-A. Imprecision, correlation and linearity studies all showed excellent results. Overall, the haemoglobin, haematocrit, white cell count (WCC) and platelet count parameters showed excellent correlation. Mean corpuscular haemoglobin concentration (MCHC) results showed poor comparability. The white cell differential parameters showed good correlation within certain clinically significant limits. Imprecision for haemoglobin, haematocrit, WCC, MCHC and platelet count was considered acceptable. The re-read function was found to be stable over the fivehour testing period under the authors' laboratory environmental conditions. The subjective assessment by biomedical scientist staff demonstrated that the system was user friendly, required little maintenance, and no user calibration was required. Staff considered the user manual to be excellent. Overall, the QBC Star appears to be an excellent point-of-care (POC) dry haematology analyser that delivers clinically significant nine-parameter complete blood count and will make a good POC analyser for use in field hospitals, research, screening programmes, GP surgeries as well as in emergency and intensive care units. It is a health and safetyfriendly analyser considering the fact that it uses dry haematology reagents instead of the bulky wet reagents that are often associated with liquid biohazard waste.

KEY WORDS: Evaluation. Hematology. Three-part differential. Near-patient testing. Analysis.

(FBC) and white cell differential performance of the QBC Star in comparison to the XE-2100 (Sysmex) according to guidance in the National Committee for Clinical Laboratory Standards (NCCLS) documents.<sup>56</sup> Previous reports indicate that the NCCLS documents are a useful tool for performance evaluation of hematology analysers.<sup>78</sup>

# Materials and methods

# QBC Star centrifugal haematology analyser

The QBC Star haematology system includes the QBC Star centrifugal analytical analyser and the QBC Star tube

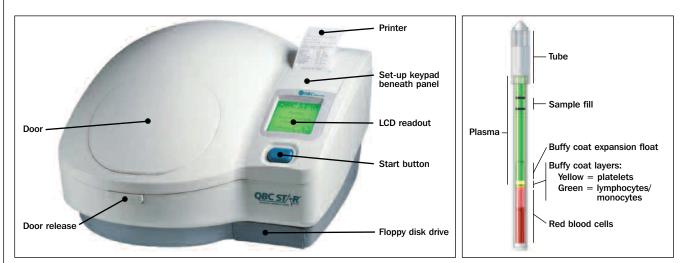


Fig. 1. (Left) QBC Star haematology centrifugal analyser. Fig. 2. (Right) Diagram of the QBC Star tube.

system. Together, they are capable of producing a haematology profile on venous or capillary whole blood. The parameters produced are:

- Haematocrit (Hct, %).
- Haemoglobin (Hb, g/dL).
- Mean corpuscular haemoglobin concentration (MCHC, g/dL).
- Platelet count (Plt, x10<sup>9</sup>/L).
- White cell count (WBC, x10<sup>9</sup>/L.)
- Granulocyte count (Gran, x10<sup>9</sup>/L)
- Lymphocyte/monocyte count (Lymph/mono, x10<sup>9</sup>/L).

#### Instrument description

The instrument consists of one main unit capable of centrifuging the sample tubes, taking appropriate measurements and deriving the result parameters (which it displays and prints out via the integrated printer). Table 1 shows the reportable range of the QBC Star analyser. There are five external connection points:

- AC power input
- serial port for connection to LIS
- barcode scanner
- parallel port for connection to full-size printer
- keyboard port.

## Principle of the test

The instrument uses centrifugation to separate cells and plasma in a whole blood sample contained in a special QBC Star haematocrit tube system.

Venous ethylenediaminetetraacetic acid (EDTA)anticoagulated or capillary whole blood may be used. For each test, a QBC Star sample tube is filled with either capillary or EDTA sampled whole blood and mixed as outlined in the system user manual. The tube is then capped and placed in the instrument, which centrifuges the tube and measures/derives the result parameters above.

# QBC Star tube system

The QBC Star tube comprises a three-inch glass haematocrit tube enclosed in a plastic sleeve. Contained within the tube is an expansion float that permits expansion of the buffy coat layer during centrifugation. The internal bore of the tube is coated with a dry layer of acridine orange and also contains the anticoagulants potassium oxalate, sodium heparin, dipotassium EDTA and monoclonal antibody. It is filled by capillary action and requires 65–75  $\mu L$  blood.

Once filled (with whole blood or liquid quality control material), the tube is capped and placed in the instrument. When the start button is pressed, centrifugation begins and results in separation of the plasma and cell components. The white cells and platelets usually separate to a position between the plasma and red cells. Within the QBC Star tube they attach to the buffy coat expansion float system, which enhances their separation (by a factor of 10). The acridine orange stains the expanded buffy coat cell layers such that platelets are yellow, granulocytes are orange and the lymphocyte/monocyte fraction stains green. This permits quantification of the buffy coat components.

Analysis of the sample within the tube occurs during centrifugation and is accomplished by the illumination/read station that consists of a dual light source and an optical detector system. The haematocrit, WCC and platelet count are measured directly from the cell layers. The haemoglobin measurement is directly related to the density of the red cells, and its determination is achieved by reference to the depth of penetration of the buffy float into the red blood cell layer. The MCHC is calculated electronically from haemoglobin and haematocrit (MCHC = haemoglobin/haematocrit x 100 g/dL).

## Evaluation

This comparative study of the QBC Star haematology analyser and the Sysmex XE-2100 was carried out at in the blood sciences laboratory of the Royal Bolton Hospital,

#### Table 1. QBC Star reportable ranges.

Parameter	Units	Lower range	Upper range
Haemoglobin	g/dL	5.0	20.0
Haematocrit	%	15	65
MCHC	g/dL	25.0	37.3
Total white cell count	x10º/L	1.6	99.9
Platelet	x10º/L	20.0	999
Granulocytes	x10 <sup>9</sup> /L	0.8	70.0
Lymphocytes + Monocytes	x10º/L	0.8	99.9

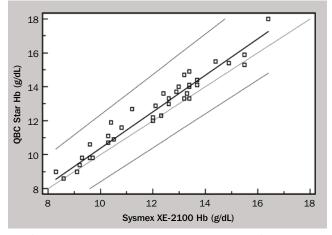


Fig. 3. Passing and Bablok regression analysis for the Sysmex and QBC Star analysers for haemoglobin.

Bolton NHS Foundation Trust. The hospital is a district general hospital and a centre of excellence in the application of Lean principles as a quality and continuing service improvement tool in the healthcare setting.

Overall, 40 venous blood samples collected in EDTAanticoagulated tubes were tested on the main laboratory analyser (Sysmex XE-2100) and the QBC Star centrifugal haematology system within four hours of sample collection over several days.<sup>9,10</sup> The samples were tested daily over a two-week period. Comparability was assessed by Passing and Bablok regression analysis. The regression equations were then used to calculate the actual differences in results at the top and bottom of the QBC quoted range extremes for each parameter. Those values were then compared with the biological database<sup>10</sup> values for total allowable error (TEa). A difference between method results within the TEa was considered not significant. Two-level QBC commercial control material was used to assess and compare precision. The method used complied with the CLSI EP15-A2 guidelines.<sup>11</sup>

The two-level controls were tested three times per day over a five-day period. Within-run and within-laboratory (total) imprecision was calculated. The observed imprecision was compared with the whole blood total imprecision claimed in the QBC Star user manual, in which 10 whole blood samples were tested in replicates of 10.

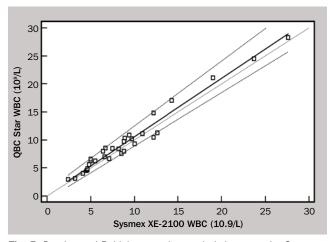


Fig. 5. Passing and Bablok regression analysis between the Sysmex and QBC Star analysers for total white cell count.

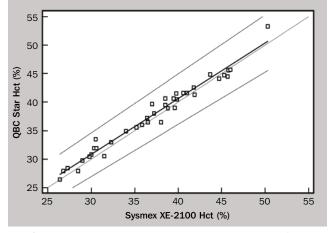


Fig. 4. Passing and Bablok regression analysis between the Sysmex and QBC Star analysers for haematocrit.

Observed coefficients of variation (CVs) were compared with previous claims of attainable CVs and with the specifications for imprecision given in the Ricos Biological Variation database<sup>12</sup> using a method described by Douglas<sup>13</sup> and using the calculator available on the Australian Association of Clinical Biochemists' website.<sup>14</sup> The observed (calculated) imprecision was compared with the whole blood total imprecision data found in the Ricos Biological Variation database.<sup>12</sup>

The re-read functionality of the instrument was checked for stability (precision) by repeat reading (eight replicates) of previously tested control sample (one at each level). The results were compared statistically using Passing and Bablok regression analysis.<sup>12</sup> Analyser re-read function was investigated by running one of each level of the two-level QC control materials on the QBC Star analyser. The same tubes were then re-read on the analyser eight times during a period of five hours from first readings. The results were recorded and CVs calculated in order to assess significance of results variation.

#### Statistical analysis

The results were recorded on an Excel spreadsheet and later subjected to statistical analysis using MedCalc statistical software. Haemoglobin, haematocrit, WCC, platelets,

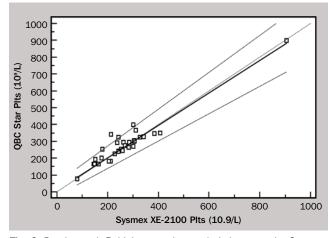


Fig. 6. Passing and Bablok regression analysis between the Sysmex and QBC Star analysers for platelet count.

Parameter	Intercept	Slope	QBC mean	Sysmex mean	QBC result range	Sysmex result range
Haemoglobin (g/dL)	-0.4000	1.0769X	12.5842	11.9974	8.6–18.0	8.3–16.4
Haematocrit (L/L)	1.4516	0.9785X	37.5605	36.9605	26.4–53.3	26.4–50.3
WBC (x10 <sup>9</sup> /L)	0.0971	1.0441X	9.7065	9.1226	3.0–28.3	2.4–27.6
Platelets (x10 <sup>°</sup> /L)	8.1220	0.9651X	282.6875	271.0625	78–897	80–906
Granulocytes (x10 <sup>9</sup> /L)	0.4325	0.9881X	7.2194	6.8084	1.6-24.4	1.07-24.33
Lymphocytes + Monocytes (10 <sup>9</sup> /L)	-0.3877	1.2270X	2.4871	2.3116	0.9–5.1	0.84-4.51

Table 2. Results of Passing and Bablok regression analysis.

Y = Intercept + Slope \* X (Y=QBC, X=Sysmex XE-2100).

MCHC, granulocytes and lymphocyte/monocyte results produced by both instruments were subjected to Passing and Bablok regression analysis. The MCHC data were also visualised by means of a bias plot (Bland Altman).  $P \leq 0.05$  was considered significant in all statistical comparisons.

# **Results**

#### Haemoglobin and haematocrit

The Passing and Bablok regression plot for haemoglobin and haematocrit indicated that the regression line was above the line of equality, indicating that the QBC Star results were marginally higher than the Sysmex XE-2100 results. However the regression line showed a proportional difference, which increases at higher haemoglobin and haematocrit levels. Statistically, the slope and intercept of the regression line showed no significant differences from the line of equality. The regression plot indicated a proportional difference between line of regression and line of equality and showed that there were no significant differences between the haemoglobin and haematocrit results of 9.7–20.3 g/dL and 28–61%, respectively. Table 2 shows the Passing and Bablok regression results for haemoglobin, haematocrit WCC, platelets, granulocytes and lymphocytes/monocytes. Figures 3 and 4 show the correlation between the reference analyser and the QBC Star for haemoglobin and haematocrit.

## Total white cell count

Visual inspection of the regression plot (Fig. 5) indicates a slight proportional difference between line of regression and line of equality. Calculation of the difference from the regression equation demonstrated that at the  $4.3 \times 10^{\circ}$ /L level there was a 6.7% difference in instrument results, and at a  $38.0 \times 10^{\circ}$ /L level there would be a 4.7% result difference (QBC

Table 3. Precision data from the QBC Star showing the degree of variation of complete haematology parameters.

Date	L2-Hct (%)	L2-Hb (g/dL)	L2-MCHC (g/dL)	L2-WBC (x10 <sup>9</sup> /L)	L2-Gran (x10º/L)	L2-Lym/Mono (x10º/L)	L1-Plts (x10º/L)
07/03/2011	36.0	12.0	33.3	20.3	9.3	11.0	172
07/03/2011	34.6	11.8	34.1	20.1	7.0	13.1	205
07/03/2011	35.8	12.0	33.5	17.2	7.3	9.9	166
14/03/2011	34.5	11.7	33.9	16.5	7.1	9.4	181
14/03/2011	35.2	11.8	33.5	19.9	8.9	11.0	187
14/03/2011	34.8	11.7	33.6	18.0	7.8	10.2	166
15/03/2011	34.4	11.7	34	17.3	6.9	10.4	175
15/03/2011	35.1	11.8	33.6	17.7	8.9	8.8	160
15/03/2011	35.0	11.8	33.7	18.8	7.8	11.0	180
16/03/2011	34.7	11.7	33.7	15.7	6.7	9.0	148
16/03/2011	36.5	12.1	33.2	20.7	9.0	11.7	219
16/03/2011	34.5	11.7	33.9	17.0	6.5	10.5	171
17/03/2011	36.5	12.1	33.2	20.0	8.5	11.5	224
17/03/2011	33.9	11.6	34.2	15.2	6.5	8.7	204
17/03/2011	35.4	12.0	33.9	23.1	9.4	13.7	218
21/03/2011	34.7	11.7	33.7	17.5	7.3	10.2	166
22/03/2011	34.5	11.7	33.9	18.5	6.7	11.8	176
Expected ranges	34–38.6	11.3–12.9	None quoted	15.0–29.0	6.3–11.9	8.7–17.1	130–252
Replicate number	17	17	17	17	17	17	17
Average result	35.065	11.818	33.70	18.44	7.74	10.70	183.41
CV (%)	2.14	1.35	0.88	11.02	13.45	13.08	12.31

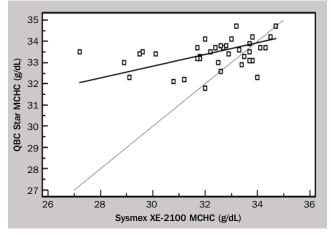


Fig. 7. Passing and Bablok regression analysis between the Sysmex and QBC Star analysers for MCHC.

results being higher). The Ricos Biological Variation database<sup>12</sup> gives a total allowable analytical error for WCC as 14.6%. Calculated differences between results at both levels were within the total allowable analytical error (P=0.05).

#### Platelet count

Visual inspection of the regression plot indicated a slight proportional difference between the line of regression and line of equality. Statistically, this difference was not significant. Calculated TEa at platelet levels of 140–600x10<sup>°</sup>/L were 8.9% and 4.8%. Differences in results between analysers at both platelet levels were less than the total allowable analytical errors quoted in the Ricos Biological Variation database for platelet count (13.4%).

#### Mean corpuscular haemoglobin concentration

Passing and Bablok regression analysis of MCHC results showed that the results from both analysers were not comparable (P=0.10). Bland Altman bias plot of the data demonstrated a visible and significant proportional difference in results. At lower levels (<31.5 g/dL) the QBC Star system gave higher results. Between approximately 31.5 g/dL and 33 g/dL, results were similar, and above 33 g/dL the QBC Star system results tended to be lower than the Sysmex XE-2100.

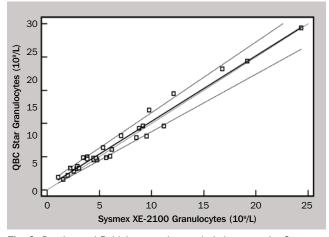


Fig. 9. Passing and Bablok regression analysis between the Sysmex and QBC Star analysers for granulocyte count.

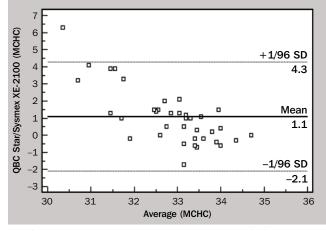


Fig. 8. Bland and Altman Bias plot comparison of MCHC values between the Sysmex and QBC Star analysers.

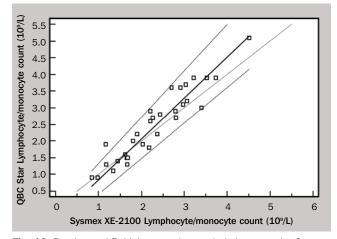
#### Granulocyte count

Visual examination of the regression plot indicated a proportional difference between the regression line and the line of equality. Statistically, there was no significant difference between the slope of the regression line and line of equality. There was a statistically significant difference for the intercept (P=0.10). Calculated differences in results at a lower and higher level for granulocytes (1.5x10°/L and 15.0x10°/L) were 27.6% and 1.7%. The difference at low granulocyte level was probably significant; however, the Ricos Biological Variation database has no information on white cell population parameters.

#### Lymphocyte and monocyte count

Visual examination of the regression plot indicated a proportional difference between results obtained by the QBC Star and Sysmex XE-2100. The regression line crossed the line of equality at an approximate level of  $1.5 \times 10^{\circ}/L$  lymphocytes/monocytes. Sysmex results were higher below a level of  $1.5 \times 10^{\circ}/L$ , while the QBC Star results were higher above that level. Statistically, there was a significant difference in both the slope and intercept of the regression line.

Regression equation for the lymphocyte/monocyte count was Y=0.3877 + 1.2270 X. Calculation of comparable results



**Fig. 10.** Passing and Bablok regression analysis between the Sysmex and QBC Star analysers for Lymphocyte + Monocyte count.

Reading	L1-Hct	L1-Hb	L1-MCHC	L1-WBC	L1-Gran	L1-L/M	L1-Plts
1	30.4	10.2	33.6	8.8	4.6	4.2	423
2	30.5	10.2	33.4	9.0	4.7	4.3	415
3	30.5	10.2	33.4	9.4	4.9	4.5	395
4	30.4	10.2	33.6	9.4	4.9	4.5	380
5	30.5	10.2	33.4	9.4	4.9	4.5	364
6	30.5	10.3	33.8	9.4	4.9	4.5	351
7	30.4	10.2	33.6	9.5	4.9	4.6	342
8	30.5	10.3	33.8	9.3	4.8	4.5	328
Distribution	Normal	Normal	Normal	Normal	Normal	Normal	Normal
Average value	30.463	10.225	33.575	9.275	4.825	4.45	374.75
CV%	0.17	0.45	2.63	0.5	2.1	2.94	9.2
Significance	None	None	None	None	None	None	None

 Table 4. Analyser re-read results of control level 1.

(using the regression equation) at three levels according to the Sysmex counts were :

- 0.84 x10<sup>9</sup>/L on Sysmex would be 0.64 x10<sup>9</sup>/L on QBC (23.5% lower)
- 1.9 x10<sup>9</sup>/L on Sysmex would be 1.94 x10<sup>9</sup>/L on QBC (2.3% higher)
- 4.5 x10<sup>9</sup>/L on Sysmex would be 5.13x10<sup>9</sup>/L on QBC (14.1% higher)

No biological variation data were available for comparison.

#### Imprecision results

The observed imprecision for haemoglobin at both control levels was within those claimed for total imprecision (1.9%). Desirable specification for haemoglobin imprecision, according to the Ricos Biological Variation database specifications is 1.8%. Observed imprecision for haematocrit at both control levels was within those claimed for total imprecision (2.0%). Desirable specification for haematocrit imprecision according to the Ricos Biological Variation database specifications is 1.7%. For control level 1, the observed imprecision exceeded the claimed levels. A within-run imprecision claim of 9.2% and a total imprecision claim of 9.0% would have been accepted with the observed data (actual calculated as 13% and 11.4%).

Desirable specification for WBC imprecision according to the Ricos Biological Variation database specifications is 5.5%. For control level 1, the observed imprecision was within claims. For level 2, the observed imprecision exceeded the claimed levels. A within-run imprecision claim of 7.8% and total imprecision claim of 9.6% would have been accepted with the observed data (actual calculated as 11% and 13%).

Desirable specification for platelet imprecision according to the Ricos Biological Variation database specifications is 4.6%. No values were given for imprecision of MCHC. The observed imprecision was between 0.9% and 1.3% CV, which is in agreement with the Ricos Biological Variation database specification of 0.9%. No claimed imprecision data were given for granulocytes. For level I control, the observed within-run and total imprecision were 13.7% and 12.3%. For level 2 control, the observed within-run and total imprecision were 15.6% and 13.2%. No claimed imprecision data were given for lymphocyte/monocyte fraction. For level 1 control, observed within-run and total imprecision were 4.8% and 4.3%. For level 2 control, the observed within-run and total imprecision were 14.9% and 13.5%. Table 3 shows the precision data from the QBC Star analyser.

#### Sample tube re-read function

The results of the spun sample (control) tubes were re-read eight times over a five-hour period and results are shown in Tables 4 and 5. The variation in results is shown as a calculated CV, which would be representative of errors associated with the reading system, and stability of the tube/reagent system. Results indicated that there was no significant difference in results under controlled laboratory temperature conditions.

# Discussion

This evaluation shows that the QBC Star and XE-2100 analysers have excellent correlation on the FBC parameters of haemoglobin, haematocrit, platelet and differential counts. However, poor correlation was observed between the MCHC values obtained. The granulocytes and lymphocyte/monocytes counts showed good correlation over certain therapeutic ranges. The differences between the MCHC and the granulocytes and lymphocyte/monocyte values observed between both analysers may be due to the method of derivation. QBC Star measures true MCHC using measured haemoglobin and haematocrit (MCHC = Hb [g/dL]/PCV [L/L] x 100), while the Sysmex XE2100 uses derived haematocrit parameters. White cell differential parameters on the Sysmex XE-2100 are determined using flow cytometry, a semi-conductor laser and fluorescent dyes, while in the QBC Star the white cells and platelets usually separate to a position between the plasma and red cells. Within the QBC Star tube they attach to the buffy coat expansion float system, which enhances their separation. The acridine orange stains the expanded buffy coat cell layers such that platelets are yellow, granulocytes are orange and the lymphocyte/monocyte fraction stains green. This permits quantification of the buffy coat components.

Reading	L2-Hct	L2-Hb	L2-MCHC	L2-WBC	L2-Gran	L2-L/M	L2-Plts
1	34.80	11.70	33.6	17.8	7.3	10.5	174
2	34.80	11.70	33.6	18.2	7.4	10.8	171
3	34.80	11.70	33.6	17.7	7.0	10.7	163
4	34.80	11.70	33.6	17.7	7.2	10.5	155
5	34.80	11.70	33.6	18.1	7.3	10.8	146
6	34.80	11.70	33.6	18.4	7.1	11.3	142
7	34.80	11.70	33.6	18.6	7.3	11.3	144
8	34.80	11.70	33.6	18.1	7.3	10.8	146
Distribution	-	-	-	Normal	Normal	Normal	Normal
Average value	34.8	11.7	33.6	18.075	7.237	10.8375	155.13
CV%	0	0	0	1.82	1.8	2.87	8.2
Significance	None	None	None	None	None	None	None

#### Table 5. Analyser re-read results of control level 2.

Overall, the QBC Star seems an excellent point-of-care (POC) testing dry haematology analyser that delivers a clinically significant nine-parameter complete blood count at the touch of a button. Recent advances in technology have made it possible to move laboratory tests closer to the patient and are intended to provide a more rapid service than can be achieved in the hospital laboratory.<sup>15</sup> Evidence has shown that implementation of POC testing in UK NHS trusts can result in dramatic improvements in turnaround time and contribute to meeting government waiting time targets.<sup>16</sup>

This study measured the imprecision of the QBC Star using two levels of controls and compared the results against the Ricos database.<sup>12</sup> In the QBC Star user manual, 10 whole blood samples tested in 10 replicates were used. The present results indicate that the haemoglobin, haematocrit, WCC, MCHC and platelet count were within acceptable ranges. No data were available from the user manual for comparison of the WCC differential parameters.

Diverse approaches have been used to measure imprecision and ensure the analytical quality of automated haematology analysers. These approaches encompass the reanalysis of retained patient specimens,<sup>17</sup> averaging selected consecutive patient measurements including red blood cell indices;<sup>18</sup> as well as the use of stabilised haematology control products. Averages of patient data are susceptible to changes in the population of patients being analysed;<sup>19</sup> the ambient room temperature and even the temperature of the haematology reagents can have an effect.<sup>20</sup> Stabilised commercial quality control (QC) materials are expensive but sensitive in the detection of analytical errors, despite being subject to artefactual error because of the constituents' longterm instability.<sup>21</sup>

This study showed that the re-read function of the QBC Star analyser was stable over the five-hour testing period under laboratory environmental conditions. The subjective assessment by biomedical scientists who evaluated the QBC Star analyser demonstrated that the system was userfriendly, required little maintenance, no calibration, and the user manual was excellent. It is a health and safety-friendly analyser considering the fact that it uses dry haematology reagents instead of the bulky wet reagents that are often associated with liquid biohazard waste.

The QBC Star is the only dry haematology system

available. All reagents to perform a FBC are contained in one easy-to-use safety tube. It uses venous or capillary samples and requires minimal maintenance. The QBC Star is an excellent piece of equipment and will be useful in field hospitals, research, screening programmes, emergency units, intensive care units in a variety of settings, including side laboratories, and even remote locations.

This study did not include a carryover evaluation; however, the ICSH guidelines for the evaluation of blood cell analysers, including those used for differential leucocyte and reticulocyte counting and cell marker applications, suggest that, where applicable, evaluation of carryover from high to low result specimens be carried out. It is recommended that a high result specimen be analysed three consecutive times followed by a low result specimen three consecutive times, following the protocol described in the ICSH document.<sup>22</sup> The QBC Star is a dry reagent system and uses an independent QBC tube per test, unlike other liquid reagent-based analyser, and as such may not experience problems associated with carryover.

## Conclusions

The haemoglobin, haematocrit, total WCC and platelet parameters between the Sysmex and the QBC Star were comparable. The MCHC results were not comparable. The QBC technology uses the World Health Organization (WHO) reference method for haematocrit, hence the MCHC is a calculated index using two measured parameters and is not derived from a calculated haematocrit, as is the case with impedance counters. This may explain the noncomparability of MCHC results.

The QBC technology gives a clinically useful result and is not inferior compared to impedance counters. Imprecision was considered acceptable for haemoglobin, haematocrit, WCC, MCHC and platelet count. No data were available for comparison of the granulocyte and lymphocyte/monocyte imprecision calculations. The lack of mean cell volume and/or mean cell haemoglobin indices may affect its utility in the diagnosis of iron deficiency anaemia and thalassaemia, and there may be the need to do further tests when indicated to differentiate between these conditions. Overall, the QBC Star system is an excellent POC analyser for use in field hospitals, research, GP surgeries and screening programmes.

The authors are grateful to QBC UK for providing the QBC centrifugal haematology analyser, an adequate quantity of consumables and the opportunity to evaluate the QBC Star analyser. Thanks are due also to the staff of the haematology unit at the Royal Bolton Hospital for their cooperation.

# References

- Briggs C, Harrison P, Grant D, Staves J, Chavada N, Machin S. Performance evaluation of the Sysmex XE-2100 automated haematology analyser. *Sysmex Journal International* 1999; 9 (2): 113–9.
- 2 Walters J, Garrity P. Performance evaluation of the Sysmex XE-2100 haematology analyzer. *Lab Hematol* 2000; **6**: 83–92.
- 3 Thom R, Hampe A, Sauerbrey G. Electronic determination of the volume of blood corpuscles and its sources of errors (in German). *Z Gesamte Exp Med* 1969; **151** (4): 331–49.
- 4 Jones AR. Counting and sizing of blood cells using apertureimpedance systems. In: van Assendelft OW, England J eds. *Advances in haematological methods: the blood count*. Boca Raton: CRC Press, 1982: 59–63.
- 5 National Committee for Clinical Laboratory Standards. *Method* comparison and bias estimation using patient samples; approved guideline 2nd edn. Wayne, PA: NCCLS, 2002.
- 6 National Committee for Clinical Laboratory Standards. Preliminary evaluation of quantitative clinical laboratory methods; approved guideline. Wayne, PA: NCCLS, 1998.
- 7 Field D, Taube E, Heumann S. Performance evaluation of the immature granulocyte parameter on the Sysmex XE-2100 automated haematology analyzer. *Lab Hematol* 2006; **12** (1): 11–4.
- 8 Langford K, Luchtman-Jones L, Miller R, Walck D. Performance evaluation of the Sysmex XT-2000i automated haematology analyzer. *Lab Hematol* 2003; 9 (1): 29–37.
- 9 National Committee for Clinical Laboratory Standards. Procedures for the collection of diagnostic blood specimens by skin puncture; approved standard 4th edn. Wayne, PA: NCCLS, 1999.

- 10 Recommendations of the International Council for Standardization in Haematology for ethylene diamine tetraacetic acid anticoagulation of blood for blood cell counting and sizing. International Council for Standardization in Haematology: Expert Panel on Cytometry. *Am J Clin Path* 1993; 100 (4): 371–2.
- 11 Clinical and Laboratory Standards Institute. User verification of performance for precision and trueness; approved guidelines 2nd edn. Wayne, PA: CLSI, 2005.
- 12 Ricos C, Alvarez V, Cava F *et al*. Current databases on biological variation: pros, cons and progress. *Scand J Clin Lab Invest* 1999; 59 (7): 491–500.
- Chesher D. Evaluating assay precision. *Clin Biochem Rev* 2008; 29 (Suppl 1): S23–6.
- 14 Australian Association of Clinical Biochemists' website Tools (www.aacb.asn.au).
- 15 Wieringa G. High street testing. Greater Manchester Strategic Health Authority, Manchester, UK, 2005.
- 16 Leman P, Guthrie D, Simpson R, Little F. Improving access to diagnostics: an evaluation of a satellite laboratory service in the emergency department. *Emerg Med J* 2004; **21** (4): 452–6.
- 17 Hackney JR, Cembrowski GS. The use of retained patient specimens for haematology quality control. *Clin Lab Haematol* 1990; **12** (Suppl 1): 83–9.
- 18 Levy WC, Hay KL, Bull BS. Preserved blood versus patient data for quality control – Bull's algorithm revisited. *Am J Clin Pathol* 1986; 85 (6): 719–21.
- 19 Cembrowski GS, Westgard JO. Quality control of multichannel hematology analyzers: evaluation of Bull's algorithm. *Am J Clin Pathol* 1985; 83 (3): 337–45.
- 20 Cembrowski GS, Hodgson DL, Etches WS. Strict use of moving averages for quality control of multichannel hematology analyzers requires optimal control of ambient temperature. *Lab Hematol* 2002; **8**: 200–3.
- 21 Gulati GL, Hyun BH. Quality control in hematology. *Clin Lab Med* 1986; 6 (4): 675–88.
- 22 Guidelines for the evaluation of blood cell analyzers including those used for differential leucocyte and reticulocyte counting and cell marker applications. International Council for Standardization in Haematology: prepared by the ICSH Expert Panel on Cytometry. *Clin Lab Haematol* 1994; **16** (2): 157–74.