

Evaluation of the Sysmex XT-2000i, a New Automated Haematology Analyser

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The XT 2000i is a recently released automated haematology analyser that was evaluated during a three-month-period. For measurement of the haemoglobin (HGB) concentration the sodium lauryl sulphate (SLS) method is used, while red blood cells (RBC, RBC-I) and platelets (PLT, PLT-I) are counted by impedance technology. White blood cells (WBC), reticulocytes (RET), platelets (PLT, optical measurement; PLT-O) and red blood cells (RBC, optical measurement; RBC-O) are counted by flow cytometry using a polymethine fluorescence dye.

Reproducibility, carryover and linearity were analysed. The correlation study was performed with the Sysmex XE-2100 and included a comparison of sample flagging. Instrument flagging data were also checked against microscopy differentials according to the recommendations of the National Committee for Clinical Laboratory Standards (NCCLS).

The correlation coefficients for complete blood cell count (CBC) and automated differentials obtained by comparison with the XE-2100 were good, except for the reticulocyte fractions. Sensitivity, specificity and efficiency of the various flags were adequate compared to microscopy differentials.

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Key Words

Automated Hematology Analyzer, XT-2000i, Complete Blood Count, Platelets

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INTRODUCTION

Automated haematology analysers are increasingly able to process the great majority of blood cell counts including the automated white blood cell (WBC) differential. Instrument manufacturers generally invest in development of new technologies or improvements of existing approaches.

The Sysmex XT-2000i is a newly developed haematology analyser based on the same technologies as the Sysmex XE-2100, but without the counting of nucleated red blood cells (NRBC) and without the IMI-channel¹. The haemoglobin (HGB) is measured with the colorimetric sodium lauryl sulphate (SLS) method. Leukocytes are counted using multi-angle scatter separation; a WBC differential can be performed by a combination of the scatter signals and the polymethine fluorescence dye signal. Platelets (PLT) and red blood cells (RBC) are normally counted by impedance technology (PLT-I, RBC-I) but can also be counted in the reticulocyte mode using optical methods (scatter signals and fluorescence signal; PLT-O, RBC-O). Reticulocytes (RET) are counted by side fluorescence signals from the DNA/RNA content, which are stained by the fluorescent polymethine dye.

The analyser has a maximum throughput of 80 samples per hour, and uses 150 µL of blood in the closed sample mode, 85 µL in the open sample mode and 40 µL in the capillary mode. The analyser can be run in the following parameter selections: complete blood cell count (CBC), CBC + differential, CBC + RET and CBC + differential + RET.

The correlation of the CBC, automated WBC differential and RET data were performed against the Sysmex XE-2100. The instrument flagging of the WBC differential was checked microscopically.

MATERIALS AND METHODS

The XT-2000i tested was a production model and initially checked and adjusted by the manufacturer. During the evaluation period daily quality control samples were run on the XT-2000i as well as the XE-2100. All samples used for the evaluation study were anticoagulated with K₃EDTA and processed in parallel on both analysers. For reproducibility 10 consecutive analyses from a single specimen were analysed in the manual mode. The following specimens were analysed: (a) low WBC, RBC, PLT, RET, (b) normal WBC, RBC, PLT, RET, and (c) high WBC, RBC, PLT, RET.

For linearity a specimen with high blood cell counts was diluted (100%, 80%, 60%, 40%, 20%, 10%, 5%) in autologous plasma yielding the following concentrations:

| | |
|-----|---|
| RBC | 0.38 – 8.27 × 10 ¹² /L |
| WBC | 9.2 – 21.2 × 10 ⁹ /L, and 0.75 – 8.72 × 10 ⁹ /L |
| PLT | 62 – 1287 × 10 ⁹ /L, and 19 – 102 × 10 ⁹ /L |
| RET | 16 – 200 × 10 ⁹ /L |

The carryover study was performed according to the International Council for Standardization in Haematology (ICSH) protocol by using 3 specimens of low and high WBC, RBC, and PLT concentrations². For each sample the carryover can be calculated by the formulae:

$$\text{Carryover (\%)} = \frac{l3-l3}{h3-l3} \times 100$$

where l1, l2 and l3 are the first, second and third analysis of the sample with the low cell counts, and h1, h2 and h3 are the first, second and third analysis of the sample with the high cell counts.

To compare the analyser, 100 normal and 100 abnormal samples with a mixture of abnormal cell types such as immature white cells and blasts and where the analyser reports a complete 5-part WBC differential were analysed. Data were analysed using paired t-test, regression analysis by Passing-Bablok³⁾ and Bland-Altman analysis⁴⁾.

Comparison of flags produced by the XT-2000i and manual methods (400-cell differential by two technologists each performing a 200-cell count) was made by analysing 100 normal and 100 abnormal samples.

All specimens were processed within 6 hours including the preparation of a blood smear. The smears were stained using the May-Grünwald Giemsa staining method. A microscopic 400-cell differential count was performed according to the NCCLS H20-A protocol⁵⁾. Flag sensitivity, specificity and efficiency were calculated using the following formulae:

$$\text{Sensitivity: } \frac{\text{true positive}}{\text{true positive} + \text{false negative}} \times 100$$

$$\text{Specificity: } \frac{\text{true negative}}{\text{false positive} + \text{true negative}} \times 100$$

$$\text{Efficiency: } \frac{\text{true positive} + \text{true negative}}{\text{true positive} + \text{true negative} + \text{false positive} + \text{false negative}} \times 100$$

For band cells we used the criteria of the Dutch Society for Laboratory Haematology in this study, as described earlier by Lee, et al.⁶⁾: constrictions of one half to one third of the nuclear width are considered to represent the lobulation of a segmented neutrophil. The reference value for band cells in human blood is less than 7%. More than 6% band cells or more than 1% metamyelocytes or other immature granulocytes (IG) are considered positive for left shift.

RESULTS

Reproducibility

Coefficients of variation (CV) for all parameters demonstrated good results and are listed in **Table 1** for the WBC, RBC, PLT-I, PLT-O and RET.

Carryover

For the WBC the carryover was 0.12%, for the RBC 0%, and for the PLT-I and PLT-O 0% and 0.75%, respectively.

Comparison of the XE-2100 and XT-2000i

The comparability was tested by measuring 100 normal and 100 abnormal samples with a mixture of flagging.

The results are listed in **Table 2**. Furthermore Bland-Altman plots were made for the comparison of both analysers (**Fig. 1**).

Table 1 Reproducibility of the XT-2000i analyser

| Parameter | Unit | Mean | SD | CV% |
|-----------|-----------------------|--------|-------|-------|
| WBC | × 10 ⁹ /L | 1.78 | 0.03 | 1.90 |
| WBC | × 10 ⁹ /L | 6.29 | 0.09 | 1.44 |
| WBC | × 10 ⁹ /L | 17.14 | 0.36 | 2.10 |
| RBC | × 10 ¹² /L | 2.44 | 0.01 | 0.29 |
| RBC | × 10 ¹² /L | 3.78 | 0.03 | 0.75 |
| RBC | × 10 ¹² /L | 5.84 | 0.03 | 0.57 |
| PLT-I | × 10 ⁹ /L | 19.4 | 0.70 | 3.64 |
| PLT-I | × 10 ⁹ /L | 164.6 | 5.66 | 3.44 |
| PLT-I | × 10 ⁹ /L | 1109.7 | 14.83 | 1.34 |
| PLT-O | × 10 ⁹ /L | 21.2 | 0.83 | 3.90 |
| PLT-O | × 10 ⁹ /L | 189.2 | 5.66 | 2.99 |
| PLT-O | × 10 ⁹ /L | 1247.9 | 20.51 | 1.64 |
| RET | % | 0.16 | 0.08 | 53.03 |
| RET | % | 1.01 | 0.01 | 0.30 |
| RET | % | 3.97 | 0.16 | 3.92 |

Table 2 Comparison of the XE-2100 and the XT-2000i analysers for the CBC, RET, and WBC differentiation

| Parameter | Unit | Intercept | Slope | Correlation coefficient |
|-----------|-----------------------|-----------|-------|-------------------------|
| WBC | × 10 ⁹ /L | -0.0216 | 0.983 | 0.998 |
| PLT-r* | × 10 ⁹ /L | -4.38 | 1.020 | 0.992 |
| PLT-I | × 10 ⁹ /L | -1.79 | 1.013 | 0.992 |
| PLT-O | × 10 ⁹ /L | 1.36 | 0.888 | 0.996 |
| RBC | × 10 ¹² /L | -0.1515 | 1.035 | 0.998 |
| HGB | mmol/L | -0.100 | 1.000 | 0.998 |
| HCT | L/L | -0.0022 | 0.979 | 0.995 |
| MCV | fL | -2.400 | 1.000 | 0.991 |
| MCH | fmol/L | 0.0102 | 1.015 | 0.987 |
| MCHC | mmol/L | 0.0400 | 1.000 | 0.914 |
| RET | × 10 ⁹ /L | -0.0014 | 1.315 | 0.976 |
| RET-LFR | % | -17.047 | 1.176 | 0.899 |
| RET-MFR | % | -0.859 | 1.206 | 0.846 |
| RET-HFR | % | 0.00 | 1.016 | 0.829 |
| NEUT | × 10 ⁹ /L | 5.19 | 0.994 | 0.998 |
| LYMPH | × 10 ⁹ /L | 0.62 | 0.962 | 0.995 |
| MONO | × 10 ⁹ /L | -0.99 | 0.776 | 0.957 |
| EO | × 10 ⁹ /L | 0.000 | 1.000 | 0.855 |
| BASO | × 10 ⁹ /L | 0.000 | 1.000 | 0.855 |

*PLT-r is the reported count value.

PLT-r means the PLT count value reported for each sample by each analyser; This may be either the PLT-I or PLT-O value, depending on which value was considered most reliable in each case by the "switching algorithm" in the XE-2100 and the XT-2000i.

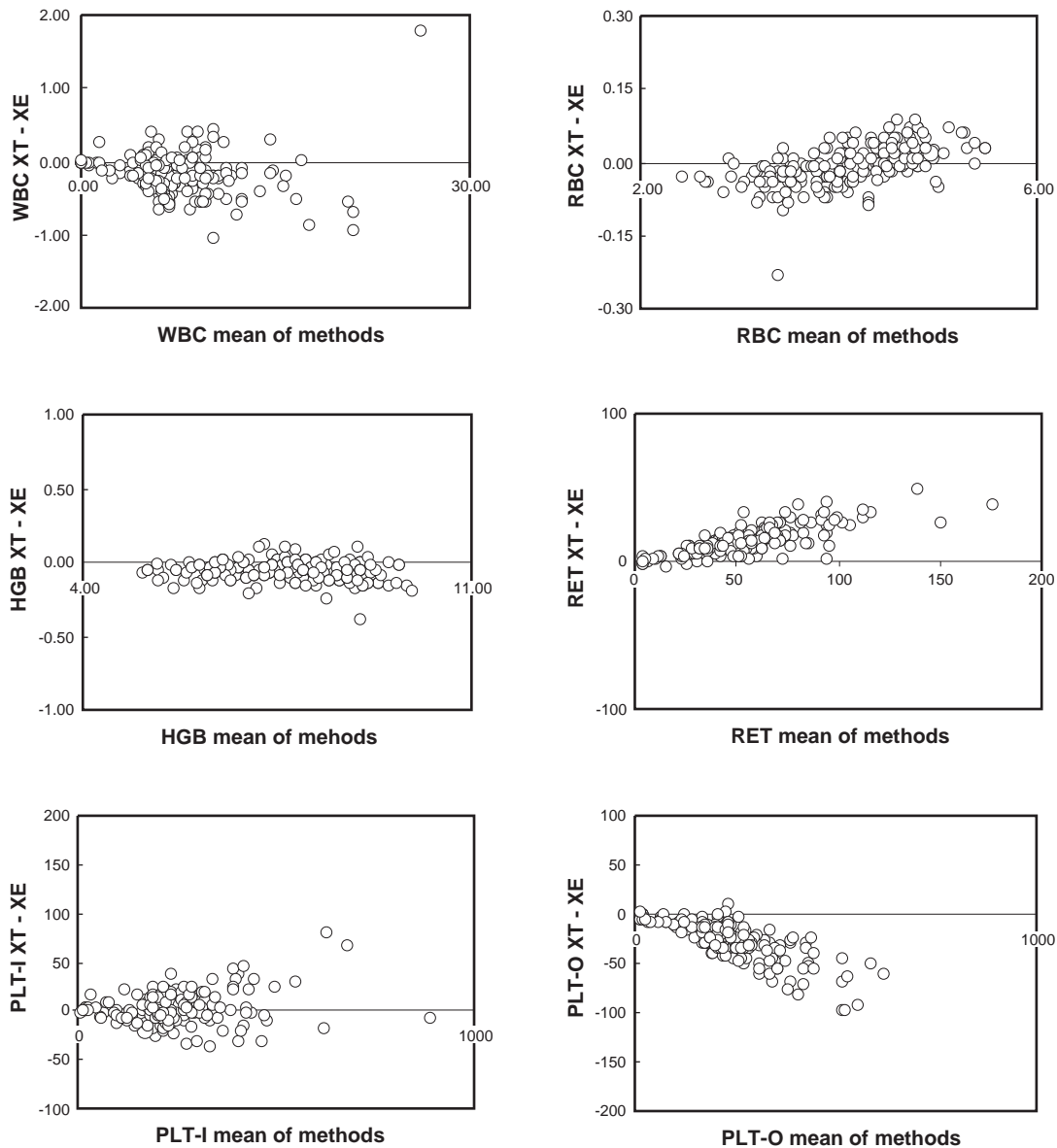


Fig. 1 Bland-Altman plots of various parameters for the comparison of the XE-2100 and XT-2000i

Linearity

Linearity data for the samples measured on the XT-2000i showed good correlation for all cells and are presented in *Table 3*.

Comparison of XE-2100 and XT-2000i abnormal flagging capabilities

The comparison of the flagging messages of both analysers is summarized in *Table 4*. The settings of the

Q-flags for the XT-2000i were performed by the manufacturer, whereas the settings for the XE-2100 were performed by the evaluating laboratory.

Specificity and sensitivity of XT flagging data

The comparison of the analyser flagging with the microscopic 400-cell differential is summarized in *Table 5*.

Table 3 Linearity of the XT-2000i analyser

| Parameter | unit | range | r ² |
|-----------------------|-----------------------|--------------|----------------|
| Open mode | | | |
| RBC-I | × 10 ¹² /L | 8.27 – 0.38 | 0.9987 |
| RBC-O | × 10 ¹² /L | 8.12 – 0.37 | 0.9995 |
| HGB | mmol/L | 15.0 – 0.7 | 0.9995 |
| PLT-I | × 10 ⁹ /L | 1,287 – 62 | 0.9954 |
| PLT-I | × 10 ⁹ /L | 102 – 19 | 0.9929 |
| PLT-O | × 10 ⁹ /L | 1,669 – 82 | 0.9954 |
| PLT-O | × 10 ⁹ /L | 101 – 13 | 0.9822 |
| WBC | × 10 ⁹ /L | 219.2 – 9.2 | 0.9993 |
| WBC | × 10 ⁹ /L | 8.72 – 0.75 | 0.9986 |
| RET | × 10 ⁹ /L | 200.0 – 15.8 | 0.9552 |
| Capillary mode | | | |
| RBC-I | × 10 ¹² /L | 6.94 – 0.36 | 0.9937 |
| RBC-O | × 10 ¹² /L | 6.86 – 0.35 | 0.9931 |
| HGB | mmol/L | 12.8 – 0.7 | 0.9939 |
| PLT-I | × 10 ⁹ /L | 1,287 – 62 | 0.9946 |
| PLT-I | × 10 ⁹ /L | 101 – 13 | 0.9822 |
| PLT-O | × 10 ⁹ /L | 1,870 – 89 | 0.9975 |
| PLT-O | × 10 ⁹ /L | 87 – 13 | 0.9591 |
| WBC | × 10 ⁹ /L | 244.1 – 12.1 | 0.9948 |
| WBC | × 10 ⁹ /L | 7.76 – 0.82 | 0.9960 |
| RET | × 10 ⁹ /L | 170.7 – 20.4 | 0.9485 |

Table 4 Comparison of flagging of the XE-2100 and the XT-2000i analysers

| AL/ALB*1 | XE | | Blasts | XE | | IG*2 | XE | |
|----------|-----|----|--------|-----|----|------|-----|----|
| | — | + | | — | + | | — | + |
| XT — | 207 | 4 | XT — | 208 | 6 | XT — | 151 | 3 |
| XT + | 9 | 1 | XT + | 8 | 8 | XT + | 3 | 43 |
| LS*3 | XE | | NRBC*4 | XE | | PC*5 | XE | |
| | — | + | | — | + | | — | + |
| XT — | 205 | 1 | XT — | 195 | 5 | XT — | 196 | 9 |
| XT + | 5 | 11 | XT + | 17 | 13 | XT + | 7 | 18 |

*1 AL/ALB = Atypical lymphocytes? or Abnormal lymphocytes?/Blasts?

Q-flags for XE-2100 and XT-2000i = 160

*2 IG = Immature Granulocytes? Q-flags for XE-2100 and XT-2000i = 160

*3 LS = Left Shift? Q-flags for XE-2100 and XT-2000i = 160

*4 NRBC = Nucleated red blood cells. A positive result for the XT-2000i is a flagging message; for the XE-2100 an NRBC count of more than 0.5% is considered as positive.

*5 PC = Platelet Clumps?

Table 5 Specificity and sensitivity of the XT-2000i analyser flagging

| Flag | Specificity (%) | Sensitivity (%) | Efficiency (%) |
|-------------------------------|-----------------|-----------------|----------------|
| Abnormal lymphocytes/ blasts? | 71.0 | 92.0 | 89.9 |
| Atypical lymphocytes? | | | |
| Blasts? | 96.6 | 100.0 | 96.0 |
| Immature Granulocytes? | 79.7 | 100.0 | 81.3 |
| Left Shift? | 95.6 | 70.4 | 92.6 |
| NRBC? | 92.5 | 81.3 | 91.7 |
| Red Cell suspect flags * | 98.1 | 53.3* | 95.2 |
| Platelet Clumps? | 90.3 | 66.7 | 95.2 |

*Microscopic red cell criteria not recognised by the instrument included: spherocytes, elliptocytes, schistocytes, target cells, basophilic stippling.

DISCUSSION

In this study we evaluated the Sysmex XT-2000i. With almost 500 measured samples representative for a routine haematology laboratory, linearity, reproducibility, and carryover were evaluated (in both open and capillary modes). All features can be described as satisfactory to excellent.

Furthermore various parameters measured by the XT-2000i were compared with the measurements performed with the Sysmex XE-2100. Statistical analysis revealed that the correlation was very good, but that for the RET count and the optical platelet (PLT-O) count differences were observed. Both parameters are obtained from the same instrument channel and it is interesting to note that the differences increase in a linear manner with increasing concentration. This suggests that these differences may be due to a calibration anomaly. With regard to the flagging performance it was found in general that both analysers performed identically.

Flagging capabilities of the XT-2000i are similar to those of the XE-2100.

The Sysmex XT-2000i would be a very useful analyser in variously sized laboratories.

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