

Evaluation of the Ves-matic 20 - An automated system for the determination of the Erythrocyte Sedimentation Rate.

The Ves-matic 20 is an automated analyzer for the determination of the erythrocyte sedimentation rate. It has been evaluated in the department of hematology at the Princess Iman Research and Laboratory Sciences Center to establish whether it can replace the manual method currently in use, which employs disposable tubes (Sediplast LP/ Italiana), based on the Westergren method.

Introduction

Attempts to assign diagnostic significance to the ESR date from the early studies of Fahraeus⁽¹⁾ who explored the possibilities of using the ESR as a test for pregnancy in 1921; in the same year Westergren recognized a relationship between the degree of sedimentation and the clinical activity of tuberculosis⁽²⁾.

In 1924 Westergren published a paper⁽³⁾ where the technique for the red cell sedimentation reaction was described and since that time the techniques for determining the ESR have changed little over the years, with the choice of the Westergren method by the International Council for Standardization in Haematology⁽⁴⁾, followed by guidelines allowing for the use of alternative ESR techniques, provided that the Westergren method is adopted

as the reference⁽⁵⁾.

Before 1985 we, in the Department of Hematology at King Hussein Medical Center, used the original Westergren method employing the 300 mm long glass tubes. After 1985, we started to use disposable plastic tubes (Sediplast) manufactured by LP Italiana SpA which are based on the original Westergren tubes.

The increased awareness of biohazard risks for the laboratory staff and the need for modern automated methods which can provide less contact with blood, automated mixing of the samples, and reading of the results, led us to evaluate different automated instruments in an attempt to replace the manual method currently used.

We had the opportunity to evaluate the Diesse Ves-matic 20, which was

AUTOTON
Ahmed K. Fares BSc. DCBA.
P.O.B 340875
Princess Iman Research &
Laboratory Sciences Center
King Hussein Medical Center
(KHMC)
Amman 11134 Jordan

PRODUCT EVALUATION

supplied by the representative agent in Jordan and the objective of this study was to evaluate the performance of the Ves-matic 20, in order to establish whether it can replace the manual routine method.

Materials and methods

Instrumentation

The Ves-matic 20 is a bench top analyzer designed to measure the erythrocyte sedimentation rate in 20 blood samples at the same time and to provide results of sedimentation within 20 minutes.

It uses specially designed evacuated plastic tubes (Vacu-tec), containing sodium citrate as anticoagulant, to draw 1 ml of blood. The tubes are the key component of the system, as they double as collection tubes and testing cuvettes.

The tubes fit in a special holder plate to keep them at an angle of 18 degrees to the vertical, the sample holder plate is turned 90 degrees on its axis, and rotates by means of the shaft to ensure a homogeneous mixing of blood and anticoagulant for about 5 minutes. After the mixing phase, the sample holder plate returns to its original position and an infrared diode sensor checks the original level of blood in the tubes and, after 20 minutes of static sedimentation, records the new height of the red cells column. The results are given after mathematical correction for the decrease in the blood column height, and are referred to the standard temperature of 18 °C (optional selection) as described by Manley⁽⁶⁾. The results are printed on 58 mm thermal paper by means of a built-in printer or transferred to a personal computer⁽⁷⁾.

Precision studies

The precision of the system was de-

termined on 10 replicate ESR measurements on eight patients known to have low, intermediate, and high ESR results.

Correlation studies

Correlation studies were performed comparing the ESR results on 249 venous blood specimens tested by both the Ves-matic 20 and the manual routine methods.

Agreement studies

Agreement studies were done to assess differences between the two methods as described by Bland and Altman⁽⁸⁾, plotting the ESR results of each single blood specimen obtained by the routine method taken as the reference against the difference between the reference and the Ves-matic results.

The limits of agreement were calculated by estimation of mean differences (-d) and the standard deviations of differences (SD). The limits of agreements will be $-d \pm 2SD$.

Time stability

It is well known⁽⁵⁾ that blood samples for ESR must be tested within three hours from collection if they are kept at room temperature. Should the analysis be delayed, samples must be stored at 4°C, not exceeding 24 hours from the collection time.

To study the effect of storage in Vacu-tec tubes on the stability of blood, 218 samples were collected and their ESR was determined. These samples were divided in two groups: the first group (93 samples) was stored at room temperature, while the second group (125 samples) was stored in the refrigerator. After 24 hours, the ESR was determined again on the samples of both groups; samples of the second group were allowed to reach room tem-

perature before performing the test. The results were compared with the previous determination.

Reference ranges

Normal values were established on 267 apparently health persons, 155 males and 112 females by both routine and Ves-matic 20 methods. They ranged in age from 24 to 37 years and had no known active disease. As ESR rithms, then means, standard deviations, and the upper limits were calculated. Antilogarithms of those values were then used.

Results

Table 1 shows the results of precision studies performed on 10 consecutive measurements in eight different blood samples. Coefficients of variation demonstrated good results concerning precision.

High correlation between the Ves-matic 20 and the routine method was obtained with a coefficient of correlation (r) of 0.99 (Fig. 1).

Agreements between the results obtained by the manual method and the Ves-matic 20 method are shown in figure 2. The results obtained with the routine method were plotted against the difference between routine method and Ves-matic. There was a very slight tendency to false high results (bias = 0.88 mm/hour), although the difference was practically of negligible magnitude.

The effects of storage of blood in Vacu-tec tubes on the ESR results are shown in table 2. After a period of 24 hours a drop in all the results was observed with a minimal difference when the tubes were stored under refrigerated conditions (4°C), and allowed to return to room temperature before reanalysis.

Table 1. Coefficient of variation (CV) for 10 replicate ESR measurements on each of eight patients using the Ves-matic 20 instrument.

	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Sample 7	Sample 8
Average	1	13.8	11.6	57.8	135.2	85.8	34	76
SD	0	1.03	0.69	4.13	6.40	2.78	1.70	1.88
CV%	0	7.48	6.02	7.14	4.73	3.24	5.00	2.48

PRODUCT EVALUATION

Table 2. Variation in the ESR determination 24 hours from the determination

Method	Results of ESR, mm/h		Difference in ESR, mm/h		Statistical Significance
	Mean (baseline)	Mean (24 hour)	Mean (0 h - 24 h)	Range	
Measurement after storage at 4 °C, allowing to return to room temperature	22.8	21.4	1.4	-7 to 14	P<0.001
Measurement after storage at room temperature	21.6	17.4	4.2	-13 to 36	P<0.001

Table 3 demonstrates the reference ranges by the two methods. No differences between the two methods were found, except in females in whom the upper limit values by the Ves-matic 20 was higher than by the routine manual method.

Discussion

It was recommended by the manufac-

turer to compare the results of Ves-matic 20 with the International Committee for Standardization in Haematology (ICSH) procedure. As we wish to replace the manual method currently in use by a safe, automated method, the authors compared the results obtained by the Ves-matic 20 with the manual method which employs disposable ESR tubes (Sediplast LP Italiana). This latter method was

evaluated previously in this laboratory with the (ICSH) method 15 years ago and found to correlate with the standard Westergren method (not published).

The Ves-matic 20 provided precise results over a range of ESR values, as previously obtained by others⁽⁹⁾.

Vacu-tec tubes showed high correlation with the routine manual method, and the differences between the two methods were minimal and of

Ves-matic system: The evolution still goes on

Ves-matic 30

*ESR determination in only 10 minutes using 1 mL of blood
in complete automation*



**SAFE
STANDARDIZED
RELIABLE
FAST
INTERNAL BAR-CODE READER**

DIESSE Diagnostica Senese S.p.A.
Via del Pozzo, 5 - Loc. S. Martino
53035 Monteriggioni SIENA (Italy)
Tel. +39/0577/319560-1 Fax: +39/0577/318763
e-mail: salesoffice@diesse.it

**DIESSE
DIESSE**

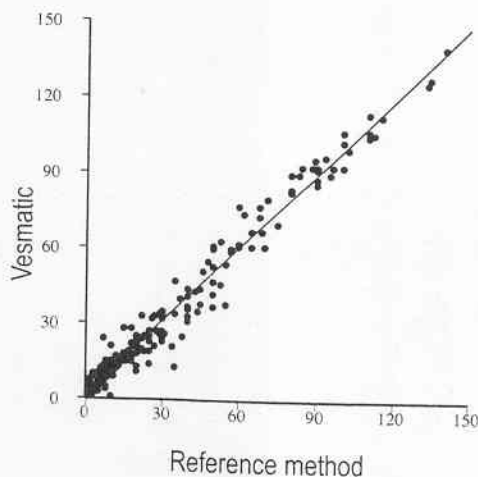
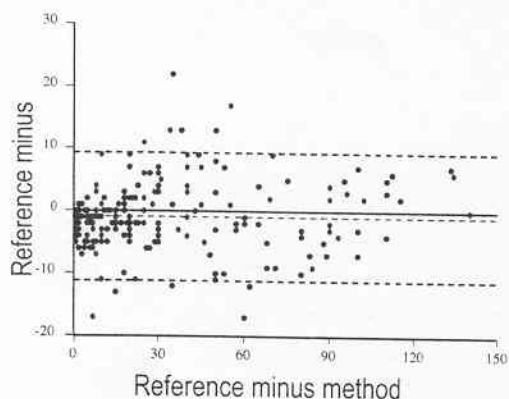
DIESSE Scientific office
PO Box 369 Riyadh 11372
Kingdom of Saudi Arabia
Tel. +966 1473 0833 - Fax +966 1405 6177
e-mail: i_salem@hotmail.com

PRODUCT EVALUATION

Figure Legends

Figure 1 – Linear regression analysis of the comparison between Reference method and Ves-Matic. The coefficients of the equation $y = a + bx$ are $a = 1.54$ and $b = 0.98$. The correlation coefficient is $r = 0.987$

Figure 2 – Bland and Altman analysis of the comparison between Reference method and Ves-Matic. The bias is -0.9 , the limits of agreement are from -11.2 to 9.4 .



no clinical significance. Those results closely met the results obtained by others^(10,11), who evaluated the same analyzer.

Minimal differences on repeat testing were obtained when the blood samples were stored at 4°C for 24 hours and allowed to return to room temperature before analyzing the specimens, whereas the maximal differences were obtained in the measurements after 24-hour storage at room temperature. This was probably due to a marked erythrocyte swelling, which caused decreases in the ESR value, as proposed by Bull and Braislford⁽¹²⁾. Blood samples collected in Vacu-tec tubes can therefore be stored at 4°C and tested for ESR within 24 hours without any appreciable difference in the expected result.

The results of storage at 4 °C were better than others obtained⁽⁹⁾, but also of no particular importance from the clinical viewpoint.

The normal ESR values obtained with the Ves-matic 20 for males compare well with

those published in the literature⁽¹⁰⁾, while they differ for females; this may be due to the range of ages used in the above cited paper, that was different from that used in the present work.

Conclusion

In the clinical practice, different ESR ranges have been established for screening, predicting and monitoring

the activity of many diseases^(13,14,15,16,17). The Ves-matic 20 showed precise and accurate results on all of the ESR ranges, thus ensuring a high degree of reliability.

We recommend the Ves-matic 20 to replace the manual method. This method can improve the quality control, reduce the biohazard risks, and improve the speed of results, thus making ESR tests simpler in laboratory work.

Table 3. Reference ranges of ESR (mm/h) by manual and Ves-matic 20 methods.

Manual method	Mean	SD	Conf.Interv	Limit	No
Total	5	3	4.6 to 5.4	Up to 11	267
Female	7	3	6.2 to 7.7	Up to 13	112
Male	5	3	4.5 to 5.5	Up to 11	155
Ves-matic 20					
Total	7	3	6.6 to 7.4	Up to 11	267
Female	10	3	9.3 to 10.7	Up to 16	112
Male	7	3	6.5 to 7.5	Up to 11	155

PRODUCT EVALUATION

REFERENCES

- 1) Fahraeus R. The suspension stability of the blood. *Acta Med Scand* 1921; 55: 70-92.
 - 2) Westergren A. Studies on the suspension stability of the blood in pulmonary tuberculosis. *Acta Med Scand* 1920-21; 54: 247-282.
 - 3) Westergren A. Die Senkungsreaction. *Ergebn d inn Med u Kinderheilk* 1924; 26:577
 - 4) International Committee for Standardization in Haematology. Recommendation for measurement of erythrocyte sedimentation rate of human blood *Am J Clin Pathol* 1977; 68:505-509.
 - 5) International Committee for Standardization in Haematology (Expert Panel on Blood Rheology). Guidelines on selection of laboratory tests for monitoring the acute phase response. *J Clin Pathol* 1988; 41:1203-1212.
 - 6) Manley RW. *J Clin Pathol* 1957; 10: 384
 - 7) Instructions Manual. Ves-matic 20 & Ves-matic 20 plus. (2000). Diesse Diagnostica Senese S.p.A (Italy).
 - 8) Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *The Lancet* 1986; 1: 307-310.
 - 9) Caswell M, Stuart J. Assessment of Diesse Ves-matic 20 automated system for measuring erythrocyte sedimentation rate. *J Clin Pathol* 1991; 44: 946-949
 - 10) Bucher WC, Gall EP, Wooworth R. Zeta sedimentation ratio in rheumatic diseases - comparison of Zeta sedimentation ratio-with the Wintrobe and the Westergren Sedimentation. *Am J Clin Pathol* 1975 ; 64: 613-617
 - 11) Fernandez de Castro M, *et al*. Evaluation of a fully automated system for determining the erythrocyte sedimentation rate. *Sangre* 1989; 34(1).
 - 12) Thomas N, Karpic A. An evaluation of the Diesse Diagnostica Ves-matic 20, an automated system for the determination of the Erythrocyte Sedimentation Rate. *NZJ Med Lab Science* 1993; 47(2): 59-61.
 - 13) Fincher R-ME, Page MI. Clinical significance of extreme elevation of the erythrocyte sedimentation rate. *Arch Intern Med* 1986; 146:1581-1583.
 - 14) Thomas Ng. Erythrocyte sedimentation rate, plasma viscosity and C-reactive protein in clinical practice. *British Journal of Hospital Medicine* 1997; 58(10): 521-523.
 - 15) Rouf J, Stucki G. Validity aspects of erythrocyte sedimentation rate and C-reactive protein in Ankylosing Spondylitis. *J Rheumatol* 1999 ; 26:966-970.
 - 16) Haber HL, *et al*. The erythrocyte sedimentation rate in congestive heart failure. *N Engl J Med*; 1991; 324:353-358.
- Ahmed YF, *et al*. Erythrocyte sedimentation rate during steady state, painful crisis and infection in

E V E N T S

Preparations for MEDICA/ ComPaMED 2001 now in top gear

Very good registration figures - exhibitors from around the globe will be hoisting the colours in Düsseldorf Preparations for the global No. 1 medical fair - MEDICA -, 33rd World Forum for Doctors' Surgeries and Hospitals (21st - 24th November 2001), are in full swing! Bookings are looking very good. Net space rented to date totals 113,000 m² (last year: 108,000 m²). Messe Düsseldorf GmbH as organiser is forecasting that the trade show will draw around 3,500 exhibi-

tors and over 120,000 visitors.

While registrations by German exhibitors are on a par with last year's high level for the same booking period, international demand for space has soared. Horst Giesen, Messe Düsseldorf's MEDICA Project Director, traces the reason why: „Last year we welcomed many new exhibitors, who started with small stands, did well, and are now all set to hoist the colours in Düsseldorf. And many newly merged companies will be high-

lighting their new scale and strengths.“ MEDICA will cover the entire spectrum of out-patient and in-patient care.

MEDICA/ComPaMED 2001
Press Office
Messe Düsseldorf GmbH
Martin-Ulf Koch

Kerstin Schmidt (Assistant)
Tel.: +49(0)211/4560-444/-549
Fax: +49(0)211/4560-8548
E-mail: KochM@messe-duesseldorf.de