

Evaluation of the new StaRRsed Inversa 24M analyser

Mg. SCHOORL, Mi. SCHOORL and J. van PELT

Measurement of the erythrocyte sedimentation rate (ESR) is an easy and inexpensive laboratory technique to assess the acute phase response and inflammation. The ESR measures the distance in mm that the red blood cells (RBCs) have settled in the first hour of sedimentation. The ESR reflects both the concentration of certain acute-phase proteins and cellular properties of RBCs and aggregation behaviour. The ESR can be increased in various infectious diseases, infarctions, malignancies, rheumatic disorders, autoimmune diseases and mono- or polyclonal gammopathies. Higher ESR values are also found in case of anaemia.

The International Council for Standardization in Haematology has recommended the original method described by Westergren as the gold standard (1, 2). Several practical disadvantages of the original manual procedure, e.g. filling of the tubes and the risk of infection from contact with pathogen bearing blood, were met by automation of the procedure. However, the long testing time (1 hour), the necessity of using diluted blood and the inaccuracy in reading the meniscus line in the so-called 'hazy' samples are still considered as disadvantages of the Westergren-type procedure.

Recently the StaRRsed Inversa 24M is introduced. The StaRRsed Inversa 24M is an semi-automatic analyser for automatic determination of the ESR according to the Westergren method (3) using closed sample tubes filled with citrate- or EDTA-anticoagulated blood. The sample tubes must be mixed externally before loading into the sample holder one by one. Positive sample identification is achieved with a barcode-reader just before aspiration of the sample.

When the StaRRsed Inversa is operating in the EDTA mode, blood samples are diluted with sodium citrate during the aspiration process in a ratio of 4 volumes blood + 1 volume sodium citrate diluent. The diluted blood is drawn up into one of the 24 Westergren pipettes. Automatic reading of the pipettes is achieved by an optical sensor. The temperature is corrected to the standard value of 18°C and ESR may be measured at either 30 (T30) and/or 60 (T60) minutes. The T30 result is extrapolated to a *calculated* T60 result (4).

In this study performance characteristics were evaluated including correlation studies of the calculated

and measured T60 results of Inversa in comparison to the StaRRsed InteRRliner and Alifax Test-1 analysers.

Materials and Methods

The StaRRsed Inversa 24M analyser was initially checked by the manufacturer (Mechatronics Manufacturing, Hoorn, The Netherlands). Maintenance procedures were performed daily according to the manufacturers' instructions. The StaRRsed InteRRliner (Mechatronics, Hoorn, The Netherlands) and the Alifax Test-1 analyser (Beckman Coulter, Woerden, The Netherlands) are used as reference methods.

Intra-assay variation was determined in ten-fold with a patientpool and BioRad Liquichek™ Sedimentation Rate Controls (Biorad Laboratories, Veenendaal, The Netherlands). For inter-assay reproducibility, the Biorad Liquichek controls were used on ten different days. From the daily routine batch K₂EDTA blood samples (n=355) were at random selected and analyzed within 4 hours after venipuncture.

Correlation studies were performed against the StaRRsed InteRRliner and the Alifax Test-1 analyser. For clinical evaluation samples were selected with M-protein, low haemoglobin (Hb <5.0 mMol/L), icterus (bilirubin 40-350 μMol/L) and lipaemia (triglycerides 2.5-6.5 mMol/L).

Results

At an ESR level of 35 mm/hour intra- and interassay variation yielded appropriate results of CV <4%, according the specifications of the manufacturer (table 1). Linear regression results are shown in figure 1. Linear regression analysis to determine the correlation between *measured* Inversa T60 (y) and InteRRliner (x) resulted in $y = 0.91x - 0.30$ (r=0.987); between *measured* Inversa T60 (y) and Alifax (x) in $y = 0.80x - 2.09$ (r=0.897) and between *measured* Inversa T60 (y) and *calculated* Inversa at T60 (x) resulted in $y = 1.13x + 1.62$ (r=0.973).

Table 1. Intra- and inter-assay results (n=10) of Biorad Liquichek Sedimentation Rate Control 2 (lot.nr. 13942)

		30 min measured	60 min calculated	60 min measured
Intra assay	mean	17.6	35.2	35.3
	VC %	3.0	2.9	3.8
Inter assay	mean	17.6	35.2	35.3
	VC %	3.0	2.9	3.8

Laboratorium voor Klinische Chemie, Hematologie & Immunologie, Medisch Centrum Alkmaar

E-mail: m.g.schoorl@mca.nl

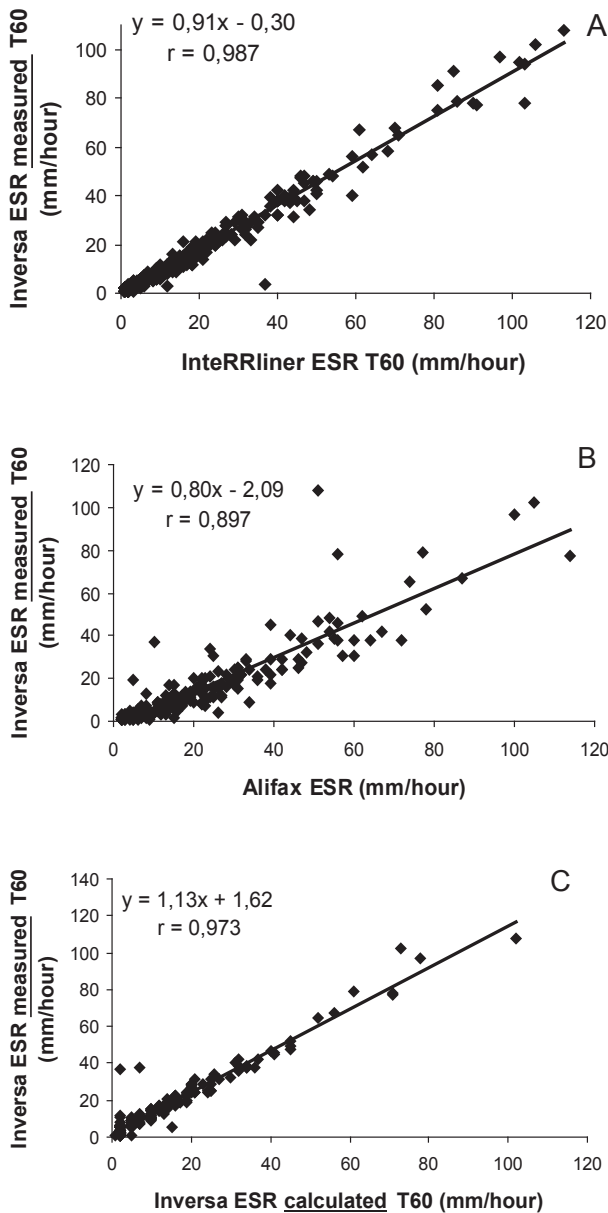


Figure 1. Linear regression results of Inversa measured at T60 (y-axis) with: A. InteRRlinier; B. Alifax; C. calculated T60 Inversa

The correlation with the Alifax is less good, which might be caused by the fact that the Alifax method for determination of the ESR is based on capillary photometry technology in which data are converted into Westergren values (5).

Possibly due to a technical problem of the Inversa three samples were established as outliers. In these cases Inversa results amounted 0 mm/hour.

Clinical samples

Calculated Inversa T60 results for samples with *low Hb* (n=28), *icterus* (n=11) or *lipaemia* (n=15) correlated well with measured Inversa T60 and InteRRlinier results ($r > 0.99$).

For samples with *M-proteins* (n=19) correlations between calculated Inversa T60 and measured Inversa and InteRRlinier resulted in $r = 0.96$ and 0.90 respectively.

Conclusion

The user friendly StaRRsed Inversa 24M analyser yields good analytical performance. The calculated T60 ESR result is a reliable method for a rapid ESR conform Westergren. Regarding to the capacity, the StaRRsed Inversa 24M is suitable for small laboratories.

References

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