Micro-Dispette FH-1531M

For qualitative estimation of the Erythrocyte Sedimentation Rate (ESR or Sed-Rate), using only 240µl of blood sample.
For In Vitro Diagnostic Use Only

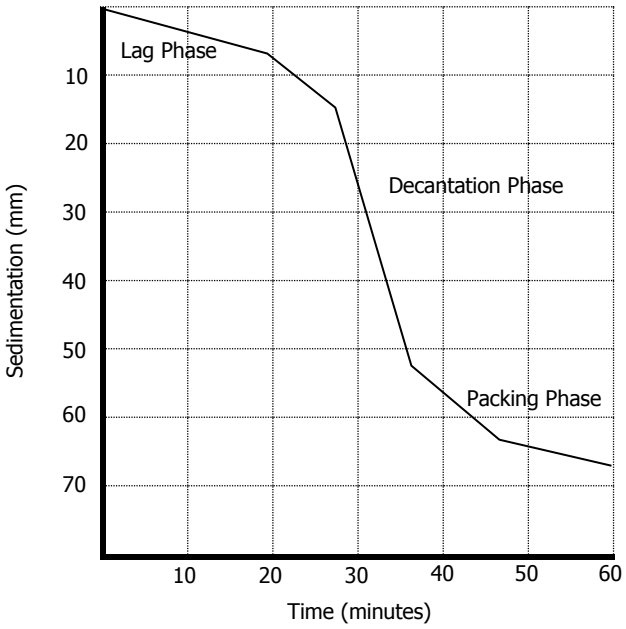
Contents: (sufficient for 100 ESR determinations)
100 Micro-Dispettes* plus 100 white filling reservoirs.
***Note:** The word Dispette or Dispettes used throughout this document is the Trade Name for the Disposable ESR Pipette manufactured by Guest Scientific AG.

Storage Conditions:
The reservoirs and Micro-Dispettes may be stored at room temperature, which may be cold, cool or warm: However the test itself must be performed at temperatures between 18 – 25^{0}C (64 – 77^{0}F) see note c) on page 3.

Background: The erythrocyte sedimentation rate (ESR) is one of the most widely requested laboratory tests throughout the world and micro methods, can be of particular help where it is not possible to obtain a full 1ml of blood sample such as is required for the Dispette 2 system.[1]
While infection may be the most common cause of elevated ESR results, many other conditions such as malignant tumors and renal disease have been associated with raised values; hence its role has become established in the Clinician's mind as a screening test for the presence of clinical illness.[2, 3, 4.]
Elevated ESR results correlate well to the severity of acute inflammatory disease and the test has been cited as a useful indicator of stroke severity and predictor of early relapse or survival in Hodgkin Disease.[5, 6, 7]
In 1926 Alf Westergren, published 'The Technique of the Red Cell Sedimentation Reaction', [8] based on the work of Robin Fahreus in 1918. His technique included the use of a combined diluent and anticoagulant (tri-sodium citrate) for the blood sample and specified the length (200mm) and bore diameter (2.5mm) of the measuring tube. His technique became the basis of the test we know today as the Westergren method and the pipet dimensions and dilution factor were adopted as the reference method for erythrocyte sedimentation rate by the International Committee for Standardization in Hematology (ICSH) in 1973.[9]
Since 1926 various workers have proposed variations to the Westergren method, (e.g. Wintrobe in 1935 and the 'zeta' sedimentation rate in 1972), however in 1993 the ICSH stated that a slightly modified Westergren method should be used for the reference method to which all other techniques, if not conforming, should be standardised.[10] The most recent review by the ICSH published in April 2011 and the latest CLSI Approved Standard both confirm that the reference or standardized method for measurement of the ESR should be based on the Westergren method using diluted blood.[11,12] Thus the technique using the Micro-Dispette should be checked against a Westergren standard method such as the Dispette2 as a Quality Control measure.

Physical basis of blood sedimentation: To this day the phenomenon of erythrocyte sedimentation is still only partly understood, however three definite phases of the process have been identified: During the first, or Lag Phase, the red cells form a characteristic rouleaux pattern and sedimentation is generally slow. The rate accelerates in the second period, the Decantation Phase and slows again in the final Packing Phase as the red cell aggregates pile up towards the lower part of the tube.

Fig1. The Phases of Blood Sedimentation.



Note: Sedimentation is not linear and the time taken over each of the Lag, Decantation and Packing phases will differ between patients, hence the observer must never try to 'estimate' the final result before the full 60 minute time period for the test has elapsed. The size of rouleaux aggregates formed in the Lag Phase is the critical factor affecting the final result. Rouleaux appears to be mainly influenced by plasma proteins including fibrinogen, IgM and alpha$_2$-macroglobulin. Opinions vary as to the accelerating and retarding properties of glycoprotein and albumin. IgG appears to increase the sedimentation rate only at high concentrations.

Items required but not provided in the Micro-Sed box:

1. Transfer pipettes.
2. Sodium citrate (see below) or Normal saline .
3. An ESR stand to hold the Micro-Dispette and reservoir assemblies in a vertical position, controlled by means of a levelling bubble & adjusting screws (code: GS-1705).
4. A laboratory or similar timer capable of alarming after exactly one hour (60 minutes) elapsed time.

Sample requirement:

Whole blood should be obtained by clean venipuncture over a maximum period of 30 seconds without excessive stasis.
A traditional syringe or a vacuum extraction system may be used. The blood sample may be taken into an EDTA tube or a pre-citrated sample tube (using 3.3% - 0.109 mol/L, tri-sodium citrate; $C_6H_5O_7Na_3$ -2 H_2O; CAS number 6132-04-3) to give a dilution ratio of 1 part citrate to 4 parts blood sample (minimum 60µl+240µl)
The blood sample and anticoagulant mixture must be immediately mixed gently, but thoroughly at least 8 times by complete inversion of the sample tube.
The ESR (Sed-Rate) must be performed within 4 hours if left at room temperature, but may be kept for up to 12 hours in a refrigerator (temperature range 2 – 8^{0}C). However the blood specimen must return to room temperature before testing starts.
If a sample is left for any amount of time before testing, either at room or refrigerator temperature, it must be well mixed by at least 8 gentle inversions of the tube before transfer to the reservoir.