Dispette 2 saline

FH-1600
FH-1675

For qualitative estimation of the Erythrocyte Sedimentation Rate (ESR or Sed-Rate)
For In Vitro Diagnostic Use Only

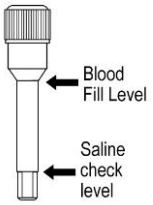
Contents: (sufficient for 100 ESR determinations)

100 plugged Dispette 2 pipets (Westergren dimensions) plus 100 filling reservoirs containing 0.25ml Normal saline diluent. This solution is not defined as a hazardous material under the OSHA Hazard Communication standard (29 CFR 1910.1200).

Storage Conditions:

Reservoirs should be stored in a cool, dry place at 50 to 75°F (10 to 24^{0}C). Never freeze the Dispette 2 reservoir.
Evaporation of saline in the reservoir can affect the ESR result. To know if your product has evaporated beyond acceptable levels please observe when the saline in the reservoir FAILS the following checklist:
Check the saline in the reservoir BEFORE EVERY USE to ensure:

- ☑ All saline is at the BOTTOM of the reservoir
- ☑ Check saline solution is CLEAR.
- ☑ Check saline volume is NOT MORE THAN 1 mm below the saline check level (see illustration)



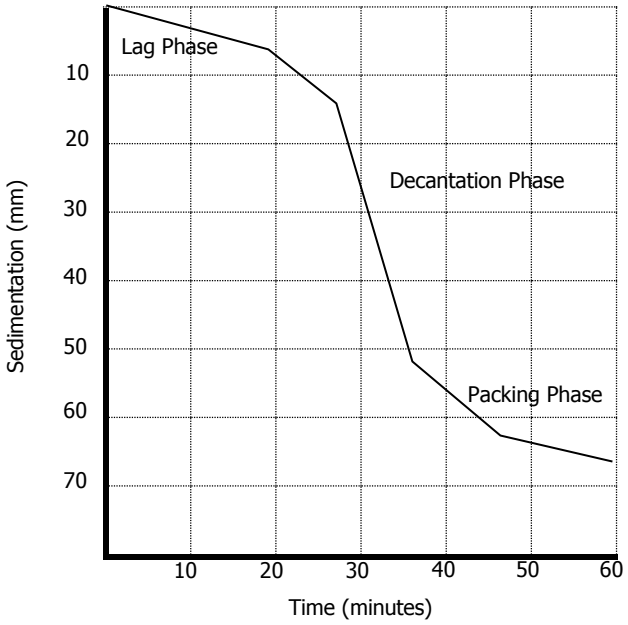
If the saline is MORE THAN 1 mm BELOW the saline check level, or if it is cloudy, the reservoir MUST be discarded.

Background: The erythrocyte sedimentation rate (also known as the ESR or Sed-Rate) is one of the most widely requested laboratory tests and manual methods, such as the Dispette 2, are particularly popular in the outpatient's setting in the USA.[1]
While infection may be the most common cause of elevated results, many other conditions such as malignant tumours and renal disease have been associated with raised values; hence its role in the Clinician's mind as a screening test for the presence of clinical illness has become established.[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 and survival in Hodgkin Disease.[5, 6, 7]
The work of Robin Fahreus in 1918 defined almost all the important characteristics of the test as it is performed today.
In 1926 Alf Westergren, published 'The Technique of the Red Cell Sedimentation Reaction', [8] which 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 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]
Over time several workers have proposed variations to the Westergren method, those of some note being the Wintrobe technique (1935) and Bull & Brailsford's 'zeta' sedimentation rate (1972), however in 1993 the ICSH stated that the Westergren method and dimensions 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 confirms that the reference method for measurement of the ESR should be based on the Westergren method using diluted blood.[11] In similar manner the most recent CLSI Approved Standard (5th Ed.), for ESR recognises the Westergren method as the standardized or selected procedure.[12]

The Dispette 2 system conforms to the dimensions and dilution factor of the Westergren method, but being a closed system, and disposable, offers operators a greater margin of protection from infection by blood borne viruses.

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



Please note that the sedimentation 'rate' is not linear and remember the time taken over the Lag, Decantation and Packing phases will differ between patients, hence the observer must never try to 'estimate' or 'guess' 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. The rouleaux appears to be mainly influenced by certain 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 Dispette2 box:

1. Transfer pipets.
2. A Guest ESR stand to hold the Dispette2 pipet and reservoir assemblies in a vertical position, controlled by means of a leveling bubble and adjusting screws. (code: GS or FH 1705)
3. 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 venepuncture over a maximum period of 30 seconds without excessive stasis.
A traditional syringe or a vacuum extraction system may be used.
The sample should be taken into an EDTA anticoagulant tube and immediately well mixed by 8 gentle inversions of the container. The most recent ICSH review[12] states that citrated blood samples must be tested within 2 hours if left at room temperature, or 4 hours if stored at 4^{0}C. Note: In the USA current CLSI guidance [13] states that the blood sample may be stored for up to 24 hours in a refrigerator. **Blood specimens stored in a refrigerator must return to room temperature naturally before testing starts.**

If the 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.