Instructions for Use:

Note: *Always wear appropriate personal protective clothing as indicated by Good Laboratory Practice before commencing this procedure. If blood is spilled follow your laboratory policy or national guidance, for safe disposal.*

1. Select a translucent blue filling reservoir from the box and perform the following check:

- ☑ 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 diagram 1)

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

Having established the correct volume of saline, keep reservoir upright and carefully remove cap.

2. Using a transfer pipet add **1ml *well mixed* EDTA anticoagulated whole blood** to the reservoir. Total volume of saline + blood should come up to the blood fill level (see diagram 2).

3. Ensure that the blood/saline mixture reaches, but does not go beyond the Blood fill level (see diagram 3) before replacing the cap securely.

4. Gently mix the reservoir, either mechanically or manually by inversion. A minimum of 8 inversions are recommended.

5. Before proceeding ensure that all the blood/saline mixture returns to the bottom section of the reservoir (diagram 5).

6. While firmly holding the filling reservoir with one hand and the Dispette2 pipet with the other hand positioned at the 180mm mark, penetrate the cap membrane and stop.

7. Gently continue inserting the Dispette2 pipet to the bottom of the reservoir causing the blood/saline mixture to rise up the inner bore of the pipet until it reaches to or beyond the blue grommet at the zero level (diagram 8a). The Dispette2 pipet must be fully inserted to the bottom of the reservoir – any excess of blood will be accommodated by the plugged overflow chamber.

8. Place the full Dispette2 assembly (pipet and reservoir) in a correctly levelled ESR stand ensuring that the pipet is at 90 degrees, plus or minus one degree, to the horizontal (diagram 8b). Immediately start the timer.

9. At the end of the timed hour, the result is read by aligning the eye to the level where the red cell column has dropped – leaving clear plasma above (see illustration d). Record the number of mm the red cells have dropped from the mm scale printed on the Dispette2 pipet.

10. Record the result as ESR = *x* mm
(note: in some countries the term Sed-Rate = *x* mm would be acceptable, also see footnote on page 3)

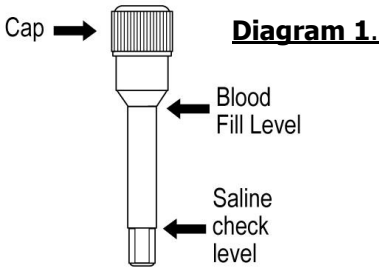


Diagram 1.

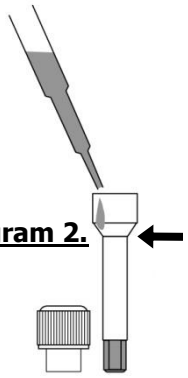


Diagram 2.

Blood fill level

Maximum total volume of saline + blood = 1.25ml

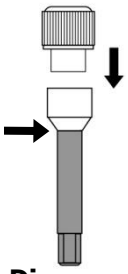
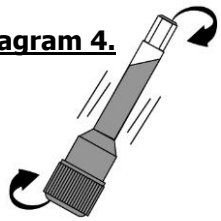


Diagram 3.

Diagram 4.



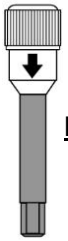
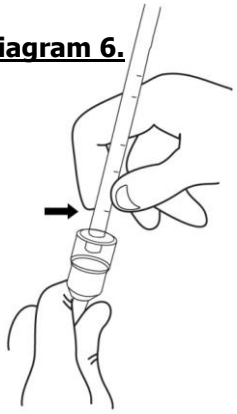


Diagram 5.

Diagram 6.



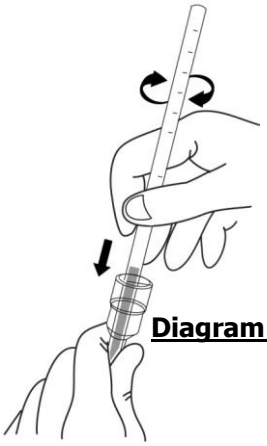


Diagram 7.

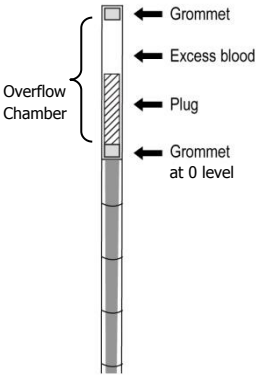


Diagram 8a.

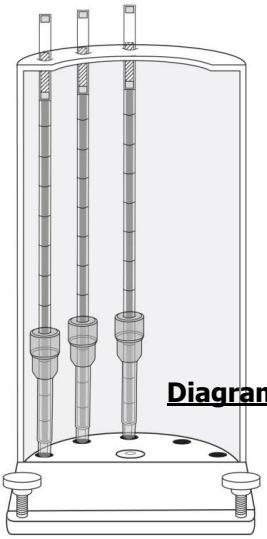


Diagram 8b

PRECAUTIONS:

a) Thorough mixing of the blood sample both before adding to the reservoir and immediately before inserting the Dispette2 pipet into the reservoir is essential. However it must be done gently, shaking the sample will result in haemolysis which may obscure the end point.

b) Shaking the sample also creates bubbles which will seriously affect the result. If bubbles are present in the pipet repeat the test with a fresh ESR test preparation that has been more carefully mixed.

c) The ESR must be performed at room temperature (defined by the ICSH as 18 to 25^0C or 64 to 77^0F). Do not place the stand near a window, in direct sunlight or where it may be subjected to drafts.

d) The ESR is affected by vibration; ensure the stand is placed well away from machinery and that the bench is not subjected to knocks. Remember that vibration mat only occur intermittently and/or may be as a result of machinery (e.g. a centrifuge) sited in another part of the building.

e) Do not pick up the stand to read the result as this will affect other tests in progress. Bring the eye to the level of the red cells to read accurately from the scale (see illustration d).

f) If the result falls between 130 and 155mm, the exact end point may be obscured by the filling reservoir cap. In this case report the result as >130 mm. If a numerical value is requested estimations can be made (but are not recommended), by reading from the scale of an unused Dispette2 pipet held next to the test Dispette2 assembly.
Note: Before reporting an estimated result be sure to verify that this complies with your laboratory's best practice and standards. Record and report that the result has been estimated.

g) Occasionally the level of the red cells is not clear-cut and a 'Christmas Tree' effect may be observed. In such cases the level where the red cells become fully concentrated should be recorded (see illustration f).

h) In cases of serious infection or leukaemia a heavy layer of white cells may be present on top of the column of red cells. This should be ignored and the reading taken from the level of the red cells only.

i) It must be remembered that the red cells will continue to settle after one hour has elapsed. Therefore it is most important to read the test at exactly one hour after setting up the test in the stand (e.g. the test reading will generally be higher at 1hour 15 minutes than at 1 hour).

j) It must not be assumed that the reading at 60 minutes will be twice that at 30 minutes because the rate of fall is not linear (see Physical basis of blood sedimentation on page 1)

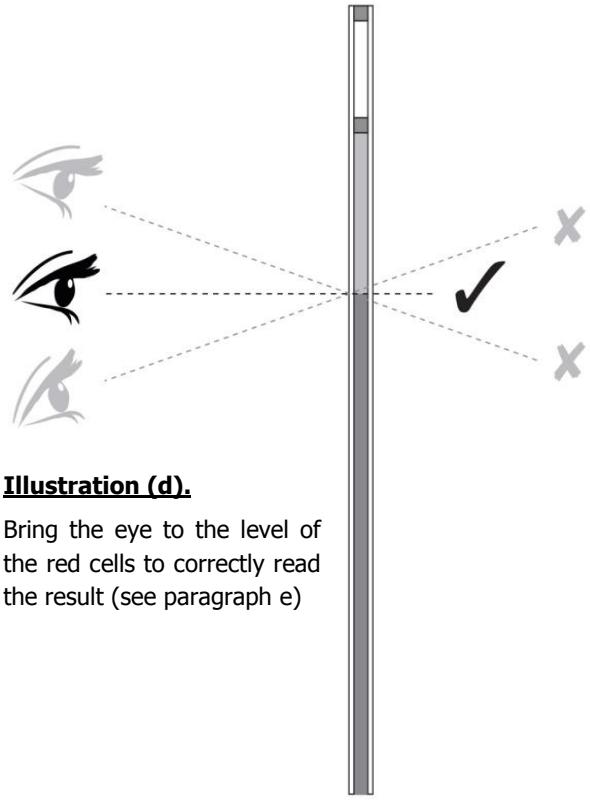


Illustration (d).

Bring the eye to the level of the red cells to correctly read the result (see paragraph e)

Please note: Illustrations are not to scale

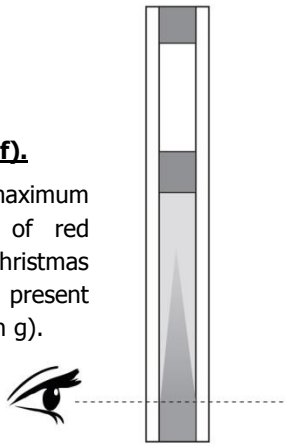


Illustration (f).

Reading the maximum concentration of red cells where 'Christmas Tree' effect is present (see paragraph g).

Footnote relating to paragraph 10 of Instructions for Use:

It is common, though incorrect, practice to record ESR results as *x* mm/hour or *x* mm per hour. Both the ICSH and CLSI point out that despite the title Erythrocyte Sedimentation *Rate*, it is not in fact a rate but a measurement at one hour. Hence both organisations currently recommend that results should be reported as: ESR = *x* mm.