CONCENTRATED ISO-OSMOTIC PHOSPHATE BUFFERED SALINE
FOR SEROLOGICAL APPLICATIONS

SUMMARY
The pH of reaction medium is an important factor in antigen antibody interaction. It has been observed that irrigation/infusion saline solution of low pH, isotonic saline autoclaved and stored in plastic containers could severely compromise the sensitivity and specificity of antiglobulin test when used as wash solutions/resuspension medium in immunohaematological procedures. Hence careful consideration should be given to the source, pH and storage container of isotonic saline solutions intended for use in immunohaematological procedures. Usage of buffered isotonic phosphate saline such as OSMOSOL maintains the pH at 7.0-7.2 thereby improving the sensitivity and specificity of tests employed in immunohaematological procedures.

REAGENT
OSMOSOL is a concentrated 20X buffered isotonic phosphate saline useful for preparing iso-osmotic saline preparation especially for immunohaematological use. Inclusion of sodium azide in the final formulation prevents contamination during use.

REAGENT STORAGE AND STABILITY
Store the reagent at room temperature. Once opened, store at 2-8°C. The shelf life of the concentrated OSMOSOL reagent is as per the expiry date mentioned on the reagent vial label. Upon dilution, the isotonic buffered saline solution so obtained is stable for at least a month provided it is not contaminated during use.

PRINCIPLE
OSMOSOL with osmolarity similar to blood serum or plasma, incorporating phosphate buffer maintains red blood cell membrane integrity and optimum pH of the reaction medium for antigen antibody reaction during immunohaematological tests thereby improving the sensitivity and specificity of the test.

NOTE
1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagent contains 0.2% sodium azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. Extreme turbidity may indicate contamination. Such reagent must be discarded.

ADDITIONAL MATERIAL REQUIRED
Distilled water for blood bank use, pH paper capable for reading pH at 6.5-7.5 or pH meter, sterile and scrupulously clean glassware for preparing the isotonic buffered saline solution.

METHOD OF PREPARATION
1. Invert the contents of OSMOSOL vial into a scrupulously clean, sterile glass jar/bottle. Make the volume to 500 ml with distilled water. Gently mix the contents. Alternatively if lesser quantity of isotonic buffered saline is required then dilute 1 part of concentrated OSMOSOL with 19 parts of distilled water. The glasswares used for preparing the isotonic buffered saline should be sterile and scrupulously clean.
2. Check the pH of isotonic buffered saline. The pH of the isotonic buffered saline should be in the range 6.9-7.2.
3. The isotonic buffered saline so obtained is ready to use for washing and preparing red blood cell suspension, dilution medium for antibodies in serological applications.

REMARKS
1. Erroneous test results can occur from microbial or chemical contamination of buffered saline. The final reagent so obtained should be a clear solution.
2. Isotonic buffered saline obtained from OSMOSOL should not cause haemolysis of red blood cells, gel formation with serum under test. Any observable change in serum or cellular elements, the reagent must be discarded.
3. Occasionally it is recommended that the pH of the isotonic buffered saline obtained from OSMOSOL should be checked before using for serological applications. The pH should be in the range 6.9-7.2. Any change in pH value out of the specified range, the reagent should be discarded.

4. The isotonic buffered saline obtained from OSMOSOL should be strictly stored in scrupulously clean, sterile beakers/glasswares and not in plastic containers.

5. The 20X concentrated OSMOSOL vial may show fine particulate appearance if stored at 2-8°C. This can be overcome by gently warming the concentrated solution to 25°C, before dilution.

WARRANTY
This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty for use and sale for any other purpose.

BIBLIOGRAPHY
3. A serious source of error in antiglobulin testing, M. Bruce, A.H. Watt, W. Hare, A. Blue, R. Mitchell, Transfusion, 26, 177-181,1986.
4. Data on file: Tulip Diagnostics (P) Ltd.