












## PBS 1X - Dulbecco's Phosphate Buffered Saline Solution (PBS)

Catalog No. 9235

500 mL

For assisted reproductive procedures.

### Glossary of Symbols\*:

	Catalog Number
	Lot Number
	Sterilized using aseptic processing techniques (filtration)
	Expiration: Year - Month - Day
	Caution, consult accompanying documents
	Consult instructions for use
	Storage Temperature 15-30°C
	Manufacturer
	U.S. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

\*Symbol Reference - EN ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labeling.

## INDICATION FOR USE

PBS is intended for use in assisted reproductive procedures which include retrieval, handling and transfer of gametes and embryos.

## DEVICE DESCRIPTION

PBS 1X - Dulbecco's Phosphate Buffered Saline Solution is a synthetic, defined solution for procedures which include the retrieval, handling, and transfer of human gametes and embryos.

## COMPOSITION

### Salts and ion

Calcium Chloride  
Sodium Phosphate  
Magnesium Chloride  
Potassium Chloride  
Potassium Phosphate  
Sodium Chloride

### Other

WFI Quality Water

## QUALITY ASSURANCE

PBS is a solution which is membrane filtered and aseptically processed according to manufacturing procedures which have been validated to meet a sterility assurance level (SAL) of  $10^{-3}$ .

Each lot of PBS is tested for:

- Endotoxin by LAL methodology
- Biocompatibility by Mouse Embryo Assay
- Sterility by the current USP Sterility Test <71>

All results are reported on a lot-specific Certificate of Analysis which is available upon request.

## PROTEIN SUPPLEMENTATION

PBS does not contain protein components. In general most facilities use PBS without protein supplementation for gamete retrieval. If PBS is used for other laboratory procedures, protein supplementation may be applicable. Consult your individual laboratory protocols.

## DIRECTIONS FOR USE

The PBS Solution is ready for use as a transport medium (prewarmed at 37°C if desired), for the collection of human gametes. This solution is also used for procedures at ambient atmosphere.

For additional details on the use of these products, consult your own laboratory procedures and protocols which have been specifically developed and optimized for your individual medical program.

## STORAGE INSTRUCTIONS AND STABILITY

Store the unopened bottles at room temperature (15 -30°C).

Do not freeze or expose to temperatures greater than 39°C.

PBS is stable until the expiration date shown on the bottle label when stored as directed.

## PRECAUTIONS AND WARNINGS

Do not use any bottle of medium which shows evidence of particulate matter, cloudiness or is not clear and colorless.

To avoid problems with contamination, handle using aseptic techniques and discard any excess medium that remains in the bottle after the procedure is completed.

Note: Precipitates may occur over time when stored at low temperatures.

## REFERENCES

Dulbecco, R. and M. Vogt (1954) *Plaque formation and isolation of pure lines with poliomyelites viruses*, J. Exptl. Med. 99:167-182.3.

Dulbecco, R. and G. Freeman (1959) *Plaque production by the Polyoma virus*. Virology 8:396-397.