
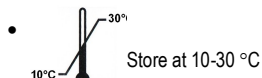


## Phosphate Buffered Saline Concentrate (20X)

Concentrated buffer solution for use in blood bank instruments


- **IVD** For in vitro diagnostic use
-  Directions Enclosed



- **Discard if turbid**

Manufacturer:

**REF** SB02 – 1

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Hailsham BN27 4EL UK

**REF** SB02 – 250

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### Intended Use:

Concentrated buffer solution for use in blood bank instruments

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Sussex Biologicals PBS concentrate is used to prepare isotonic phosphate buffered saline (PBS) solution for use as system liquid and wash buffer for Blood Grouping instruments, and other instruments which require such a solution.

### Principle of the Test:

On blood grouping instruments, PBS is used as both 'system liquid' in the pipetting system, where it is used for washing the probes and for diluting the sample in some assays, and as wash buffer.

### Reagents:

PBS concentrate is a 20X concentrate of phosphate buffered saline, which is diluted with deionized water before use.

Unopened bottles of PBS concentrate may be stored at ambient temperature (10-30°C). The complete bottle of concentrate should be used immediately when opened.

### Precautions:

For professional in-vitro diagnostic use.

Store at 10-30°C when not in use.

**Discard if turbid**

Do not use Phosphate Buffered Saline Concentrate (20X) if the liquid becomes turbid or changes color. If the product is exposed to particularly low temperatures, some crystallization may sometimes occur, this can be reversed by warming the bottle to ambient temperature and mixing before use.

Do not use beyond expiry date.

The expiry date is expressed in the format CCYY-MM-DD (year-month-day), for example 30<sup>th</sup> October 2014 would be represented as 2014-10-30.

This product is not classified according to Regulation (EC) No. 1272/2008. PBS Concentrate contains 0.2% Sodium Azide as a preservative. Good Laboratory Practice should be followed. Users should refer to Materials Safety Data Sheet.

### Specimen Collection and Preparation:

Only anti-coagulated specimens may be tested. Clotted samples must not be used because clots may block the sample probes.

Testing should be performed as soon as possible following collection to minimize the chance that falsely positive or falsely negative reactions will occur due to improper storage or contamination of the specimen. Failure to store the specimens at the correct temperature, for example, storage at higher temperature or repeated freezing and thawing may result in false positive or false negative results.

Samples that cannot be tested within 24 hours should be stored at 2-8°C. EDTA samples can be tested up to 10 days.

### Procedure:

#### Materials Provided:

Phosphate Buffered Saline Concentrate in 250mL bottles

### Additional materials required:

1. Deionized water
2. Donor or patient samples

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### Test Method

The re-fillable containers for system liquid and wash buffer should be emptied (and unused buffer discarded) and cleaned on a regular basis to avoid microbial contamination as described in the analyser operating instructions.

To prepare 5L of buffer, empty one 250mL bottle of PBS Concentrate into the container and add 4.75L of deionized water. Ensure that the buffer is mixed.

Follow the analyser operating instructions for loading the Phosphate Buffered Saline onto the instrument and for running tests.

\* It is the user's responsibility to validate the use of this product if it is used for other applications.

### Quality Control:

The performance of all assays should be evaluated at each test run with Positive and Negative Controls. These controls help to determine if technical errors or reagent failures have occurred. Continued failure of the control sera to give the expected results on repeat testing may indicate that a reagent or buffer in the system has deteriorated, or that an instrument defect prevents the test from being performed correctly.

For haemagglutination-based assays (blood grouping and Rh phenotyping etc.), a Quality Control test should be performed on each day of use to confirm that the all of the reagents are suitable for use

### Interpretation of Results:

Please refer to the directions for use for the instrument and for the reagents used in the assays concerned.

### Limitations:

Erroneous test results can occur from bacterial or chemical contamination of Phosphate Buffered Saline, or other reagents and samples, improper storage of the reagents or samples or the omission of a reagent. In addition, failures can occur if the assays in which Phosphate Buffered Saline is employed are not performed correctly.

### Specific Performance Characteristics:

The performance of this product is dependent upon adhering to the insert's recommended methodology. Additional information regarding testing performed at the time of manufacture may be furnished upon request by consulting Sussex Biologicals on +44 1323 849944



