Product Description

1. Celpresol™
bioCSL Celpresol™ is a specially formulated isotonic solution designed for suspending and preserving human red blood cells for use in \textit{in vitro} blood grouping and antibody detection tests. It is an isotonic phosphate buffered solution which contains glucose, sodium citrate and amino acids. Neomycin Sulphate and Chloramphenicol are included as antibacterial agents and Thiomersal is added as a preservative. bioCSL Celpresol™ is issued ready for use in 500mL bottles. bioCSL Celpresol™ is not designed to be used as a preservative solution for red blood cells to be used for blood transfusion.

<table>
<thead>
<tr>
<th>Catalogue No.</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>06332301</td>
<td>1 x 500mL</td>
</tr>
</tbody>
</table>

2. Celpresol™ LISS
bioCSL Celpresol™ LISS is a specially formulated low-ionic strength solution designed for suspending and preserving 0.8% human red blood cells for use in \textit{in vitro} blood grouping and antibody detection tests in Column Agglutination Test (CAT) systems. It is a low-ionic phosphate buffered solution which contains glucose, sucrose, glycine, and amino acids. Sulphamethoxazole and Trimethoprim are included as antibacterial agents. Celpresol™ LISS is issued ready for use in 50mL bottles. bioCSL Celpresol™ LISS is not designed to be used as a preservative solution for red blood cells to be used for blood transfusion.

<table>
<thead>
<tr>
<th>Catalogue No.</th>
<th>Pack Size</th>
</tr>
</thead>
<tbody>
<tr>
<td>26331701</td>
<td>1 x 50mL</td>
</tr>
</tbody>
</table>

 Suitable Testing Platforms

- Column Agglutination Technology (CAT)
- Tube (Celpresol™ only)
- Tile (Celpresol™ only)
- Microplate (Celpresol™ only)

Recommended Applications

- Storage of patient red cells to accommodate repeat testing of blood groups and phenotypes.
- Storage of patient sample red cells for investigative testing.
- Storage of patient red cells for the purposes of investigating suspected transfusion reactions. bioCSL Celpresol™ and bioCSL Celpresol™ LISS may be used to store and maintain post-transfusion patient blood sample red cells for up to ten weeks from the date of blood collection.
- Storage of donor red cells for repeat testing of blood groups.
- Storage of donor red cells for the purposes of investigating suspected transfusion reactions. bioCSL Celpresol™ and bioCSL Celpresol™ LISS may be used to store and maintain crossmatching donor tube segment cells for up to 10 weeks from the date of donor unit collection.
- Storage of special or rare red cells.
- Dilution of bioCSL’s Reagent Red Blood Cell (RRBC) products to a lower cell concentration.
- Long term storage of laboratory panel red cells.
- Resuscitation and subsequent storage of frozen red cells (Celpresol™ only).
- Resuscitation of old or aged samples (Celpresol™ only).

This document includes:

- Product specifications
- Recommended applications
- Product performance
Benefits of bioCSL Celpresol™ and Celpresol™ LISS

- **Reliable** – When bioCSL Celpresol™ solutions are used in conjunction with bioCSL’s 0.8% and 3% RRBCs, ensures consistency in reagent, patient and donor red cell suspensions.
- **Dual Application** – Validated suspension and preservation solutions.
- **Superior Performance** – Contain buffers and a carbohydrate substrate to accommodate continued red cell metabolism, amino acids to maintain red cell membrane and antigen integrity and antibacterial agents to prevent or restrict bacterial growth and subsequent red cell damage or destruction.
- **Durable** – Cells stored in bioCSL Celpresol™ or Celpresol™ LISS may last for up to ten weeks.
- **Stable** – Confirmed expiry of 12 (Celpresol™ LISS) and 24 months (Celpresol™) from the date of manufacture.
- **Convenient** – Liquid solutions that are ready to use.
- **Cost-Effective** – Affordable red cell storage solutions.

Background

Immunohaematology testing laboratories are required to perform diagnostic tests using stored human red cells. These cells may be RRBCs, patient or donor red cells. Under normal circumstances human red cells in saline or buffered saline will shrink, crenate, lyse or suffer antigen degradation over time. In order for red cells to remain in a good condition for serological testing for extended periods, a special storage medium is required to maintain cell viability, antigen condition and presentation.

### Product Characteristic and Performance Criteria

<table>
<thead>
<tr>
<th>Description</th>
<th>Celpresol™</th>
<th>Celpresol™ LISS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>pH</strong></td>
<td>7.05 - 7.25</td>
<td>6.80 - 7.00</td>
</tr>
</tbody>
</table>

**Dilution of bioCSL's Reagent Red Blood Cells**

bioCSL Celpresol™ and Celpresol™ LISS are used as the diluents in bioCSL’s 0.8% and 3% RRBC products and have been shown to preserve red cell suspensions satisfactorily for a period of at least ten weeks. They may be used to formulate RRBCs for antibody screening and identification, and bioCSL Celpresol™ is also suitable for preparing reverse grouping cells. Provided the dilutions are performed aseptically, the diluted red cell suspensions may be used until the expiry date of the original RRBC product.

**Red Cell Storage**

bioCSL Celpresol™ and bioCSL Celpresol™ LISS allow storage of donor and patient red blood cells for prolonged periods. They will ensure that cells and their antigens are stabilised to allow testing to occur over prolonged periods of time. Celpresol™ also enables suspensions of rare cells to be kept for several weeks at 2° to 8° celsius.

**Red Cell Resuscitation**

Old, aged or incorrectly stored samples may be resuscitated using Celpresol™ to allow emergency testing or investigation. Correct results in immunohaematology testing is reliant on good quality, well identified and correctly stored samples. These sample types may include the following:

- Aged donor packs.
- Testing that may be required for delayed transfusion reactions.
- Old “special cells” which have rare antigens or have a desired antigen mix for complex antibody identification.
- Frozen cells.

"Old, aged or incorrectly stored samples may be resuscitated using Celpresol™..."
Precautions

- Very rarely, human serum may contain antibodies active against the antibiotics or the nucleosides present in the red cell suspending fluids. Suspension of the patient’s red cells in Celpresol™ or Celpresol™ LISS in such a case would result in the autocontrol of any test also being positive, so preventing a false conclusion that the serum contains alloantibodies to a high-incidence antigen.

- Serum samples which react against red cells suspended in Celpresol™ or Celpresol™ LISS, but not in red cells suspended in physiological saline, should be retested against the same red cells which have been washed three times and resuspended in physiological saline.

- As Celpresol™ and Celpresol™ LISS are produced from non-human sources, there is no risk of HBsAg or HIV infection. However good laboratory practice requires safe handling procedures.

- For in vitro diagnostic use only.

- Despite the inclusion of antibiotics and preservatives, bacterial growth may still occur if aseptic techniques are not employed. Any product showing turbidity should be discarded.

- Exposure of Celpresol™ solutions to direct light may cause deterioration of the antibiotics, resulting in a yellow colouration of the product. Product should not be stored in direct sunlight.

- Celpresol™ solutions are not designed to be used as a preservative solution for red blood cells to be used for blood transfusion.

Incorrect reactions may occur due to:

1. Failure to comply with the recommended procedures.
2. Variations in time and temperature of incubation, centrifuge speeds and reaction reading methods.
3. Contamination of test samples, reagents or supplementary materials.
4. Use of aged or expired samples or reagents.

Summary

In order to maintain the viability of red cells suspended in an isotonic or low ionic strength solution, it is necessary to include glucose, purines and nucleosides. For short-term preservation, various solutions have been formulated, including those of Alsever, Rous & Turner, Burgess and Vos and Low and Messeter.

Celpresol™ is an improved version of these types of reagents and can be used to preserve and resuscitate cells for up to ten weeks. Celpresol™ LISS is a low ionic strength solution designed to support human red cells at a 0.8% concentration for use in CAT systems. Such solutions will assist in prolonging the life of red cell suspensions and preserve their antigens for up to ten weeks, when stored at 2° to 8°C. For longer-term storage, red cells should be stored frozen in glycerol or liquid nitrogen.

Red cell suspensions may be prepared in bioCSL Celpresol™ and bioCSL Celpresol™ LISS from clotted or anticoagulated samples. It is preferable to wash the cells once or twice in bioCSL Celpresol™ or bioCSL Celpresol™ LISS before resuspending them to the required concentration. Red cells other than those from clotted or anticoagulated samples should be gently washed with a sufficient volume of bioCSL Celpresol™ or bioCSL Celpresol™ LISS to ensure the complete replacement of the suspending diluent. The washing procedure may be carried out at 1000rcf for 1 minute (ie. high speed in a serological centrifuge).

Storage and Handling

- Store at 2° to 8°C (Do Not Freeze)
- Protect from light
- Refrigerate at 2° to 8°C when not in use
- Take appropriate precautions to maintain sterility
- Do not use if:
  - Turbid or if there is undue yellow colouration
  - Expiration date has passed.

Specimen Collection and Preparation

Blood samples should be withdrawn by aseptic technique. Red cell suspensions in bioCSL Celpresol™ and bioCSL Celpresol™ LISS will retain adequate antigen reactivity for up to 10 weeks from the date of blood collection providing sterility is maintained. Appropriate controls should be used when testing red cells stored for prolonged periods. Longer-term storage may result in some reduction of the reaction strength of some antigen types.
References


October 2013

No expressed, implied or contingent liability is assumed for product use or patent infringements. Products detailed are for purposes described within the product leaflet only. All information contained is copyright bioCSL Limited.