Immunoglobulin panel for anti-D antibodies test BRP batch 1 consists of two freeze-dried preparations of immunoglobulin in ampoules with haemagglutination reciprocal titres of anti-D of

**Immunoglobulin (anti-D antibodies test) BRP batch 1: 8**

**Immunoglobulin (anti-D antibodies test negative control) BRP batch 1: <2**

It is intended to be used for the test for anti-D antibodies in human immunoglobulin for intravenous administration (2.6.26).

**STORAGE**

Keep ampoules unopened at -20°C ± 5°C.

**USE**

- Tap the ampoule gently to collect the material at the bottom end. Ensure that the disposable ampoule safety breaker is pushed down on the stem of the ampoule and against the shoulder of the ampoule body. Hold the body of the ampoule in one hand and the disposable ampoule breaker covering the ampoule stem between the thumb and first finger of the other hand. Apply an ending force to open the ampoule.
- Care should be taken to avoid cuts and projectile glass fragments that might enter one’s eyes. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure.
- Reconstitute the contents of each ampoule to be tested on the day of the test with 1 mL of purified water. Allow several minutes, with occasional vortexing, for reconstitution. Transfer the reconstituted contents to a capped tube. Store at +5°C ± 3°C if necessary. The product may be reconstituted in 1 mL of a solution at 0,2g/L sodium azide in purified water or frozen in small aliquots provided that stability under the conditions used is validated by the user.

**CAUTION**

**Immunoglobulin panel for anti-D antibodies test BRP batch 1 is not appropriate for administration to humans. This preparation must be handled according to the appropriate QA system for biological testing laboratories. Please refer to the corresponding safety data sheet, which can be downloaded from the internet web site of the EDQM (http://www.edqm.eu) or delivered upon request.**

---

1 This haemagglutination reciprocal titre of anti-D is the consensus value that was determined in the establishment study run in the frame of project BSP074
LITTERATURE


Pharmeuropa Bio is an open-access publication that is freely available on the EDQM website (www.edqm.eu).

SIGNATURE

This document is electronically signed by:

Dr Pierre Leveau
Head of the Quality, Safety and Environment Division