

# Ficoll-Paque PREMIUM

Ficoll-Paque™ PREMIUM, which is manufactured according to GMP (3) and ISO standards, is a density gradient medium\* used for preparation of human mononuclear cells. The medium is based on Ficoll-Paque PLUS, which has a proven track record as a sterile density medium for the isolation of high yields of mononuclear cells from bone marrow, peripheral blood, and umbilical cord blood. The medium was developed for large- or small-scale purification of mononuclear cells from human peripheral blood, using a simple and rapid centrifugation technique developed by Bøyum (1).

\* For *in vitro* use only.

## ***Ficoll-Paque PREMIUM offers the following benefits:***

- Manufactured according to GMP and ISO standards.
- Manufactured in accordance to USP <1043> recommendations for ancillary materials.
- Sterile, ready to use reagent.
- Low levels of endotoxin (< 0.12 EU/ml) secured and tested.
- Function-tested to provide consistent product performance.

Ficoll-Paque PREMIUM differs from Ficoll-Paque PLUS in that it is manufactured in a strictly controlled environment compliant with ISO and GMP (Good Manufacturing Practice), and in accordance with the recommendations of the United States Pharmacopeia (2) for the manufacture of cell therapy products. ISO and GMP compliance requires stringency in validation, documentation of manufacturing procedures, and strict adherence to US and European quality systems.



**Fig 1.** Ficoll-Paque PREMIUM is a density gradient medium used for preparation of human mononuclear cells. The medium is manufactured according to GMP and ISO standards.

## **Applications**

Ficoll-Paque PREMIUM is optimized for the isolation of mononuclear cells from human peripheral blood. However, the medium can be adapted for the isolation of human mononuclear cells from other sources, including umbilical cord blood and bone marrow. Separation of normal human peripheral blood by the recommended protocol typically yields a mononuclear cell preparation with:

- $95 \pm 5\%$  of cells present in the separated fraction are mononuclear cells.
- $> 90\%$  viability of the separated cells.
- $60 \pm 20\%$  recovery of the mononuclear cells present in the original blood sample.
- $3 \pm 2\%$  granulocytes.
- $5 \pm 2\%$  red blood cells.
- $< 0.5\%$  of the total platelets of the original blood sample.



Ficoll-Paque PREMIUM consists of a mixture of Ficoll™ PM400 and sodium diatrizoate at a density of 1.077 g/ml. The density of Ficoll-Paque PREMIUM is optimized for the isolation of mononuclear cells from human peripheral blood. Ficoll-Paque PREMIUM is sterile and stable for at least 3 yr under the recommended storage conditions.

## Specifications

Density	1.077 + 0.001 g/ml
Stability	Stable for 3 yr if stored between +4 and +30°C and protected from direct light.
Endotoxins	Contains < 0.12 EU/ml.

## References

1. Bøyum, A. *Scand. J. Clin. Lab. Invest.*, 21 Suppl. **97**, 77 (1968).
2. United States Pharmacopeia. *Recommendations for ancillary materials*, chapter <1043>.
3. EC Guide to GMP (Good Manufacturing Practice), annex 1 "Manufacture of Sterile Medicinal Products."

## Ordering information

Product	Pack size	Code No.
Ficoll-Paque PREMIUM	6 × 100 ml	17-5442-02
Ficoll-Paque PREMIUM	6 × 500 ml	17-5442-03

## Related products

Ficoll-Paque PLUS	6 × 100 ml	17-1440-02
	6 × 500 ml	17-1440-03
Ficoll™ PM400	100 g	17-0300-10
	500 g	17-0300-50
	1 kg	17-0300-01
	5 kg	17-0300-05
	40 kg	17-0300-08
RediGrad™	250 ml	17-1270-02
	1 l	17-1270-01
Percoll™	250 ml	17-0891-02
	1 l	17-0891-01
	6 × 1 l	17-0891-09
Density Marker Beads	1 kit (10 vials)	17-0459-01

[www.gehealthcare.com/cellprep](http://www.gehealthcare.com/cellprep)

GE Healthcare  
Björkgatan 30  
751 84 Uppsala  
Sweden

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GE Healthcare Bio-sciences AB, a General Electric Company

GE Healthcare Bio-Sciences AB  
Björkgatan 30, 751 84 Uppsala, Sweden

GE Healthcare  
Munzinger Strasse 9, D-79111 Freiburg, Germany

GE Healthcare  
Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK

GE Healthcare  
800 Centennial Avenue, P.O. Box 1327, Piscataway,  
NJ 08855-1327, USA

GE Healthcare  
Sanken Bldg. 3-25-1, Hyakunincho, Shinjuku-ku,  
Tokyo 169-0073, Japan

Asia Pacific Tel: +852 2811 8693 Fax: +852 2811 5251 • Australasia Tel: +61 2 9899 0999 Fax: +61 2 9899 7511 • Austria Tel: 01/57606-1619 Fax: 01/57606-1627 • Belgium Tel: 0800 73 888 Fax: 03 272 1637 • Canada Tel: 800 463 5800 Fax: 800 567 1008 • Central, East, & South East Europe Tel: +43 1 982 3826 Fax: +43 1 985 8327 • Denmark Tel: 45 16 2400 Fax: 45 16 2424 • Finland & Baltics Tel: +358 (0)9-512 39 40 Fax: +358 (0)9-512 39 439 • France Tel: 01 69 35 67 00 Fax: 01 69 41 96 77 • Germany Tel: 0761/4903-490 Fax: 0761/4903-405 • Italy Tel: 02 27322 1 Fax: 02 27302 212 • Japan Tel: +81 3 5331 9336 Fax: +81 3 5331 9370 • Latin America Tel: +55 11 3933 7300 Fax: +55 11 3933 7304 • Middle East & Africa Tel: +30 210 9600 687 Fax: +30 210 9600 693 • Netherlands Tel: 0165 580 410 Fax: 0165 580 401 • Norway Tel: 815 65 555 Fax: 815 65 666 • Portugal Tel: 21 417 7035 Fax: 21 417 3184 • Russia & other C.I.S. & N.I.S. Tel: +7 (095) 232 0250, 956 1137 Fax: +7 (095) 230 6377 • South East Asia Tel: 60 3 8024 2080 Fax: 60 3 8024 2090 • Spain Tel: 93 594 49 50 Fax: 93 594 49 55 • Sweden Tel: 018 612 1900 Fax: 018 612 1910 • Switzerland Tel: 0848 8028 12 Fax: 0848 8028 13 • UK Tel: 0800 616928 Fax: 0800 616927 • USA Tel: 800 526 3593 Fax: 877 295 8102

