



**Miltenyi Biotec**

# CliniMACS® Specification Sheet

The following table will assist you in identifying the relevant components needed for each application. Please refer to the product description on our webpage for information regarding regulatory status and availability. This is relevant for all countries where the instrument is CE-marked.

Antigen/ Reagent	Application	Application capacity	No. of vials	Tubing set (TS)	No. of TS required for application	Software (Separation program)
CD1c (BDCA-1)- Biotin REF 277-01	Part 1 depletion	5×10 <sup>9</sup> CD19 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells (WBC)	1 CD19 Reagent, 1 CD1c (BDCA-1)- Biotin	TS LS (REF 162-01)	1	DEPLETION 2.1
	Part 2 enrichment	0.2×10 <sup>9</sup> CD1c (BDCA-1) <sup>+</sup> cells from 40×10 <sup>9</sup> total cells (WBC)	1 Anti-Biotin Reagent	TS (REF 161-01)	1	ENRICHMENT 3.2
CD3 REF 273-01	depletion	15×10 <sup>9</sup> CD3 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1	TS LS (REF 162-01)	1	DEPLETION 2.1
CD3 REF 273-01	depletion (large scale)	20×10 <sup>9</sup> CD3 <sup>+</sup> cells from 80×10 <sup>9</sup> total cells	2	TS LS (REF 162-01)	1	DEPLETION 2.1
CD3 REF 273-01	depletion	15×10 <sup>9</sup> CD3 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1	DTS (REF 261-01)	1	DEPLETION 3.1
CD3 REF 273-01	depletion (large scale)	30×10 <sup>9</sup> CD3 <sup>+</sup> cells from 80×10 <sup>9</sup> total cells	2	DTS (REF 261-01)	1	DEPLETION 3.1
CD3/CD19 Combination	depletion	15×10 <sup>9</sup> CD3 <sup>+</sup> and 5×10 <sup>9</sup> CD19 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1 each	TS LS (REF 162-01)	1	DEPLETION 2.1
CD3/CD19 Combination	depletion	15×10 <sup>9</sup> CD3 <sup>+</sup> and 5×10 <sup>9</sup> CD19 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1 each	DTS (REF 261-01)	1	DEPLETION 3.1
CD3/CD19 Combination	depletion (large scale)	30×10 <sup>9</sup> CD3 <sup>+</sup> and 10×10 <sup>9</sup> CD19 <sup>+</sup> cells from 80×10 <sup>9</sup> total cells	2 each	DTS (REF 261-01)	1	DEPLETION 3.1
CD4 REF 276-01	enrichment	5×10 <sup>9</sup> CD4 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1	TS (REF 161-01)	1	ENRICHMENT 1.1
CD4 REF 276-01	depletion	12×10 <sup>9</sup> CD4 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1	TS LS (REF 162-01)	1	DEPLETION 2.1
CD4 REF 276-01	depletion (large scale)	20×10 <sup>9</sup> CD4 <sup>+</sup> cells from 80×10 <sup>9</sup> total cells	2	TS LS (REF 162-01)	1	DEPLETION 2.1
CD8 REF 275-01	enrichment	4×10 <sup>9</sup> CD8 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1	TS (REF 161-01)	1	ENRICHMENT 1.1
CD8 REF 275-01	depletion	4×10 <sup>9</sup> CD8 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1	TS LS (REF 162-01)	1	DEPLETION 2.1
CD8 REF 275-01	depletion (large scale)	8×10 <sup>9</sup> CD8 <sup>+</sup> cells from 80×10 <sup>9</sup> total cells	2	TS LS (REF 162-01)	1	DEPLETION 2.1
CD4/CD8 Combination	depletion	12×10 <sup>9</sup> CD4 <sup>+</sup> and 4×10 <sup>9</sup> CD8 <sup>+</sup> from 40×10 <sup>9</sup> total cells	1 each	TS LS (REF 162-01)	1	DEPLETION 2.1

Antigen/ Reagent	Application	Application capacity	No. of vials	Tubing set (TS)	No. of TS required for application	Software (Separation program)
CD14 REF 272-01	enrichment	4×10 <sup>9</sup> CD14 <sup>+</sup> cells from 20×10 <sup>9</sup> total cells	1	TS (REF 161-01)	1	ENRICHMENT 1.1
CD19 REF 179-01	depletion	5×10 <sup>9</sup> CD19 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1	TS LS (REF 162-01)	1	DEPLETION 2.1
CD19 REF 179-01	depletion (large scale)	10×10 <sup>9</sup> CD19 <sup>+</sup> cells from 80×10 <sup>9</sup> total cells	2	TS LS (REF 162-01)	1	DEPLETION 2.1
CD25 REF 274-01	enrichment CD25 <sup>+</sup> cells	0.6×10 <sup>9</sup> CD25 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells (WBC)	1	TS (REF 161-01)	1	ENRICHMENT 3.2
CD25 REF 274-01	enrichment CD25 highly expressing cells	0.6×10 <sup>9</sup> highly expressing CD25 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells (WBC)	1	TS (REF 161-01)	1	ENRICHMENT 3.2
CD25 REF 274-01	depletion CD25 <sup>+</sup> cells	6×10 <sup>9</sup> CD25 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells (WBC)	1	TS LS (REF 162-01)	1	DEPLETION 2.1
CD25 REF 274-01	depletion CD25 <sup>+</sup> cells (large scale)	12×10 <sup>9</sup> CD25 <sup>+</sup> cells from 80×10 <sup>9</sup> total cells (WBC)	2	TS LS (REF 162-01)	1	DEPLETION 2.1
CD34 REF 171-01	enrichment	0.6×10 <sup>9</sup> CD34 <sup>+</sup> cells from 60×10 <sup>9</sup> total cells	1	TS (REF 161-01)	1	CD34 SELECTION 1
CD34 REF 171-01	enrichment (large scale)	1.2×10 <sup>9</sup> CD34 <sup>+</sup> cells from 120×10 <sup>9</sup> total cells	2	TS LS (REF 162-01)	1	CD34 SELECTION 2
CD45RA REF 701-46	depletion	20×10 <sup>9</sup> CD45RA <sup>+</sup> cells from 50×10 <sup>9</sup> total cells	1	DTS (REF 261-01)	1	DEPLETION 3.1
CD56 REF 271-01	enrichment	5×10 <sup>9</sup> CD56 <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1	TS (REF 161-01)	1	ENRICHMENT 1.1
CD133 REF 172-01	enrichment	0.6×10 <sup>9</sup> CD133 <sup>+</sup> cells from 60×10 <sup>9</sup> total cells	1	TS (REF 161-01)	1	CD133 SELECTION 1
CD133 REF 172-01	enrichment (large scale)	1.2×10 <sup>9</sup> CD133 <sup>+</sup> cells from 120×10 <sup>9</sup> total cells	2	TS LS (REF 162-01)	1	CD133 SELECTION 2
CD133 REF 172-01	enrichment (bone marrow)	50 mL aspirate and max. 120×10 <sup>9</sup> total cells	1 or 2	TS LS (REF 162-01)	1	CD133 SELECTION 2
CD304 (BDCA-4) REF 278-01	enrichment	0.2×10 <sup>9</sup> CD304 (BDCA-4) <sup>+</sup> cells from 40×10 <sup>9</sup> total cells	1	TS (REF 161-01)	1	ENRICHMENT 3.2
TCRa/β-Biotin REF 701-48	depletion	24×10 <sup>9</sup> TCRa/β <sup>+</sup> cells from 60×10 <sup>9</sup> total cells	1 TCRa/β- Biotin 2 Anti-Biotin Reagent	DTS (REF 261-01)	1	DEPLETION 3.1
CCS REF 279-01	enrichment	IFN-secreting cells from 1×10 <sup>9</sup> total cells	1 kit	TS (REF 161-01)	1	ENRICHMENT 3.2
Anti-Biotin REF 173-01	enrichment	max. 40×10 <sup>9</sup> total cells	1	TS (REF 161-01)	1	ENRICHMENT 1.1
Anti-Biotin REF 173-01	depletion	max. 40×10 <sup>9</sup> total cells	1	TS LS (REF 162-01)	1	DEPLETION 2.1
Anti-Biotin REF 173-01	depletion (large scale)	max. 80×10 <sup>9</sup> total cells	2	TS LS (REF 162-01)	1	DEPLETION 2.1



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Unless otherwise specifically indicated, Miltenyi Biotec products and services are for research use only and not for therapeutic or diagnostic use. The CliniMACS® System components, including Reagents, Tubing Sets, Instruments, and PBS/EDTA Buffer, are designed, manufactured and tested under a quality system certified to ISO 13485.

In the EU, the CliniMACS System components are available as CE-marked medical devices for their respective intended use, unless otherwise stated. The CliniMACS Reagents and Biotin Conjugates are intended for *in vitro* use only and are not designated for therapeutic use or direct infusion into patients. The CliniMACS Reagents in combination with the CliniMACS System are intended to separate human cells. Miltenyi Biotec as the manufacturer of the CliniMACS System does not give any recommendations regarding the use of separated cells for therapeutic purposes and does not make any claims regarding a clinical benefit. For the manufacturing and use of target cells in humans the national legislation and regulations – e.g. for the EU the Directive 2004/23/EC ("human tissues and cells"), or the Directive 2002/98/EC ("human blood and blood components") – must be followed. Thus, any clinical application of the target cells is exclusively within the responsibility of the user of a CliniMACS System.

In the US, the CliniMACS CD34 Reagent System, including the CliniMACS Plus Instrument, CliniMACS CD34 Reagent, CliniMACS Tubing Sets TS and LS, and the CliniMACS PBS/EDTA Buffer, is FDA approved as a Humanitarian Use Device (HUD), authorized by U.S. Federal law for use in the treatment of patients with acute myeloid leukemia (AML) in first complete remission. The effectiveness of the device for this indication has not been demonstrated. Other products of the CliniMACS Product Line are available for use only under an approved Investigational New Drug (IND) application, Investigational Device Exemption (IDE), or FDA approval. CliniMACS GMP MicroBeads are for research use and *ex vivo* cell processing only. CliniMACS MicroBeads are for research use only and not for human therapeutic or diagnostic use.

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