



Miltenyi Biotec

Miltenyi Biotec GmbH, Friedrich-Ebert-Straße 68, D-51429 Bergisch Gladbach

To whom it may concern

Bergisch Gladbach, 2017-11-27

**Important Product Information
CD34/CD133 Enumeration Kit, human (IVD), article no. 170-070-709**

Dear Customer,

We would like to inform you that the formulas for the calculation of cell concentrations as indicated in the package insert for CD34/CD133 Enumeration Kit, human (IVO) might be misleading and could potentially lead to errors. We recommend to recalculate the results obtained when following our package insert in combination with counting beads. The adapted formulas are given in the Attachment. The package insert is currently under revision and will be provided as soon as possible. Please use the adapted formulas as defined in the attachment for your calculation of cell concentrations in combination with counting beads.

This information is not relevant if you did not use counting beads for your applications.

Please feel free to contact our Technical Support Team (macstec@miltenyibiotec.de) in case of any questions.

Yours sincerely

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Attachment: Adapted formulas

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Attachment: Adapted formulas for the calculation of cell concentrations as indicated in the package insert for CD34/CD133 Enumeration Kit, human (IVO)

Sample requirements on page 9 of the package insert

.6. The cell count of white blood cells (WBC) or positive enriched cells must not exceed 5×10^7 cells/mL.

If necessary dilute the sample with PEB buffer. Record the pre-dilution factor for the calculation of the final cell concentrations.

Formula on page 24 of the package insert

$$\text{WBCs concentration [cells/mL]} = \frac{\text{Events viable WBC (G3)} \times \text{total counting particles per tube}}{\text{Acquired counting particles (G11)}} \times 10 \times \text{pre-dilution factor}$$

Formula on page 26 of the package insert

$$\text{Viable CD34+ HPC [cells/mL]} = \frac{\text{Events CD34+ HPC (G6)} \times \text{total counting particles per tube}}{\text{Acquired counting particles (G11)}} \times 10 \times \text{pre-dilution factor}$$

Formula on page 27 of the package insert

$$\text{Viable CD34+/CD 133+ HPC [cells/mL]} = \frac{\text{Events CD133+HPC (G9)} \times \text{total counting particles per tube}}{\text{Acquired counting particles (G11)}} \times 10 \times \text{pre-dilution factor}$$

Note: The pre-dilution factor is only applicable if samples are pre-diluted for sample preparation