

# Certificate

## CD34+ CELL ENUMERATION SYSTEM SUITABILITY

USP Catalog No.:	1084292
USP Lot No.:	F045V0

### Additional Information:

USP CD34+ Cell Enumeration System Suitability Reference Standard is made from mobilized peripheral blood collected by apheresis of a G-CSF mobilized donor. The reference standard contains human leukocytes, erythrocytes and CD34+ cells that have been fixed and lyophilized.

Store USP CD34+ Cell Enumeration System Suitability Reference Standard in a freezer. Allow the vial to warm up to room temperature. Reconstitute the entire contents of the vial with 500  $\mu$ L of water, use immediately as a system suitability standard as described in <127> Flow Cytometric Enumeration of CD34+ Cells. After reconstitution in 500  $\mu$ L of water, the concentration range is 16-34 CD34+ cells/ $\mu$ L.

**LABEL TEXT**

<p>For use with specified USP compendial tests. Not for use as a drug. See SDS prior to use at <a href="http://www.usp.org/sds">www.usp.org/sds</a>.</p>  <p>Lot: F045V0</p>	<p><b>USP REFERENCE STANDARD</b></p> <p><b>CD34+ CELL ENUMERATION SYSTEM SUITABILITY</b></p> <p><b>1.24 x 10<sup>4</sup> CD34+ Cells</b></p> <p> <b>Danger!</b> Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging fertility or the unborn child.</p> <p>Store in a freezer. See USP Certificate for reconstitution instructions and additional information.</p> <p>USP, 12601 Twinbrook Pkwy, Rockville, MD, +1-301-881-0666 Cat. No. 1084292      Material mfd. in United Kingdom</p>	<p>Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing dust. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention.</p>
	<p><i>Jeri L. Joth</i> <u>Quality Assurance</u></p>	

**Calculation Value**

If a value is not provided on the label or accompanying documentation and the Reference Standard has a quantitative USP compendial application, a value of 100.0% is used. The purity value is not applicable for qualitative uses. Please refer to the specific Reference Standard label for further information.

**Expiration**

Current lots are identified in the current USP Catalog. In some cases, the previous lot may still be considered valid for use. If so, it is identified in the column marked "Previous Lot/Valid Use Date."

It is the responsibility of each user to determine that this lot is current or valid when used. For the most up-to-date information, please refer to the USP Store at [www.usp.org](http://www.usp.org).

**Instructions for Use**

Follow the instructions on the label of the USP Reference Standard and in the appropriate USP documentary standard(s).

**Non-Monograph Use**

The suitability of this Reference Standard for use in non-compendial applications is solely the responsibility of the user.

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