

Cell Therapy Systems (CTS™) Products for Clinical and/or Commercial Use

Frequently Asked Questions and Answers

CTS™ Growth Factors/Cytokines

Question: Can I use CTS™ Growth Factors/Cytokines products for in vivo clinical use?

Answer: No. CTS™ Growth Factors/Cytokines **cannot** be used for **direct** in vivo applications. CTS™ products are intended for use as ancillary reagents used in the manufacturing process which includes a wash step prior to any in vivo application.

Question: Can I use CTS™ Growth Factors/Cytokines in clinical trials?

Answer: Researchers are free to use these products in accordance with the Limited Use Label License (LULL) for early research-based clinical trials through Phase IIA. However, the proper regulatory approval is required before using CTS™ products in research-based clinical trials since they may require specific labeling and/or higher quality manufacturing standards.

Question: Can I use CTS™ Growth Factors/Cytokines for commercial use?

Answer: Researchers are free to use these products in accordance with the Limited Use Label License (LULL), but commercial use is not allowed under general purchase of these products. Commercial access to these products may be available through a formal Supply Agreement under which we **do not** anticipate that there will be any additional licensing fees for these products. In all cases, it is the researcher's responsibility to get approval from the appropriate regulatory authorities for labeling and intended use of these ancillary materials for your application beyond phase IIA trials.

CTS™ Media, Reagents and Equipment

Question: Can I use CTS™ products for in vivo clinical use?

Answer: No. CTS™ products **cannot** be used for **direct** in vivo applications. CTS™ products are intended for use as ancillary reagents used in the manufacturing process which includes a wash step prior to any in vivo application.

Question: Can I use CTS™ products in clinical trials?

Answer: Researchers are free to use these products **in accordance** with the Limited Use Label License (LULL) for early research-based clinical trials through Phase IIA. If there are LULL restrictions, an assessment of your intended use may be required. The proper regulatory approval is required before using CTS™ products in research-based clinical trials since they may require specific labeling and/or higher quality manufacturing standards.

Question: Can I use CTS™ products for commercial use?

Answer: Researchers are free to use these products **in accordance** with the Limited Use Label License (LULL), but commercial use is not allowed under general purchase of these products. If there are LULL restrictions, an assessment of your intended use may be required. Commercial access to these products may be available through a formal Supply Agreement under which we **do not** anticipate that there will be any additional licensing fees for these products. In all cases, it is the researcher's responsibility to get approval from the appropriate regulatory authorities for labeling and intended use of these ancillary materials for your application beyond phase IIA trials.