



# EX-CYTE<sup>®</sup> Growth Enhancement Media Supplement

## Enhance Cell Culture Productivity

### MEDIA SUPPLEMENTS

#### Increase Protein Yield with EX-CYTE<sup>®</sup>

Cell culture manufacturing process engineers continuously strive to improve product yields, streamline processes and drive down costs. These goals can be achieved by reducing or eliminating dependence on costly and inconsistent fetal bovine serum.

EX-CYTE<sup>®</sup>, an aqueous lipoprotein concentrate containing a consistent profile of metabolic factors, is an ideal media supplement for serum-free or serum-reduced cell culture. When used in conjunction with Serologicals' other critical media supplements, EX-CYTE<sup>®</sup> can significantly improve the cell culture manufacturing process (see Figure 1).

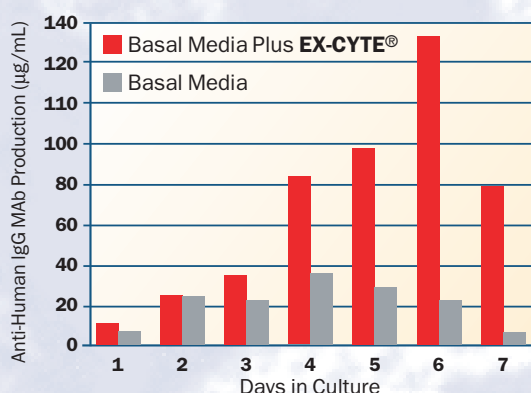


Figure 1. Cell growth and antibody production of a hybridoma cell line supplemented with EX-CYTE<sup>®</sup> were measured for 7 days. Cells were adapted for growth in media supplemented with EX-CYTE<sup>®</sup> at 30 µg cholesterol/ml. Other media supplements were HSA (10 mg/ml), human APO-transferrin (2.5 µg/ml), insulin (5 µg/ml) and 10<sup>-7</sup> M sodium selenite.

At Serologicals' dedicated production suite, EX-CYTE<sup>®</sup> is manufactured under cGMP in large batch sizes to reduce customer testing and qualification. Each production lot is tested for consistency, microbial content, bovine viruses (9 CFR 113), mycoplasma and endotoxins.



#### Advantages

- Demonstrated 6-fold increase in protein yield
- Fully traceable US source material
- Used with mammalian and insect cells
- Validated process yields significant prion reduction
- Quality assured throughout the entire proprietary cGMP manufacturing process
- ISO 9002 certified since 1994, Certificate of Suitability issued by EDQM
- Dedicated single-product production suite
- Second independent production facility coming soon



## EX-CYTE® Production Process Ensures Reduced Levels of Adventitious Agents and Lot-to-lot Consistency

EX-CYTE® is a water soluble concentrate of lipids and fatty acids. Studies have demonstrated the patented EX-CYTE® production process does not result in biased selection, but in a balanced profile of naturally occurring lipids. The raw materials used in production are fully traceable to US source and these together with the final product are certified free of a broad range of viruses and mycoplasma. In addition, a step in the process has been validated (patent applied for) to significantly reduce prion levels.

Proteins of *in vitro* cell culture are less costly when produced in, and purified from a defined serum-free media. EX-CYTE® is an ideal additive for serum-free cell culture since it supplies the required growth factors and eliminates the need for full-serum supplementation. EX-CYTE® is one of many critical media supplements offered by Serologicals® including Albumin, Transferrin, Fetuin, Aprotinin and Insulin. Used together, this collection represents a cost-effective way to optimize production of your protein.

Over the last ten years, EX-CYTE® has been proven to enhance *in vitro* cell proliferation and productivity as well as reduce downstream processing time and cost. As a consequence, many of the biotechnology therapeutic products in production and development, including monoclonal antibodies and recombinant proteins, are being produced using the advantages offered by EX-CYTE®. Because of the consistency of its manufacturing process, the traceability of the raw materials and the improvements gained in productivity and downstream processing, EX-CYTE® is being used in the production of several drugs on the market today.

## EX-CYTE® Quality Features

- Fully traceable US source material
- ISO 9002 certified quality systems
- Certificate of Suitability issued by EDQM
- Validated 3.7-log prion reduction during manufacture
- Complete 9 CFR 113 virus testing
- Derived from bovine serum collected in a segregated environment
- Viral clearance studies in progress
- cGMP-compliant manufacturing process

## Product Specifications

### EX-CYTE® Growth Enhancement Media Supplement

Assay	Specification	Typical Value
Catalog No. 81-129      Volume 1 liter		
Cholesterol	9.0 – 11.0 g/L	10.1 g/L
<i>By Enzymatic Assay</i>		
Protein	13.0 – 18.0 g/L	14.5 g/L
<i>By Biuret</i>		
pH	7.0 – 8.4	8.3
IgG	None detected	None detected
<i>By Radialimmunodiffusion</i>		
Endotoxin	0 – 6.0 EU/mg	2.1 EU/mg
<i>By Limulus Amebocyte Lysate</i>		
Microbial Content	No growth	No growth
<i>By USP</i>		
Mycoplasma	None detected	None detected
Viral Agents	None detected	None detected
<i>Tested in accordance with 9 CFR 113</i>		
Lipid Composition of EX-CYTE® includes Cholesterol, Linoleic Acid, Arachidonic Acid, Oleic Acid, Lecithin, Lysolecithin, Sphingomyelin and Phosphatidylethanolamine.		

## ORDERING INFORMATION

For further information or to place an order, please contact us at:

### Serologicals Corporation

5655 Spalding Drive  
Norcross, GA 30092

### North America

**Phone** 800.227.9412  
**Fax** 815.937.8285  
**Email** tech.cellculture@serologicals.com

**World Wide Web** [www.serologicals.com](http://www.serologicals.com)

**Customer Service** [customerservices@serologicals.com](mailto:customerservices@serologicals.com)

### Europe

**Phone** 44.1865.784.646  
**Fax** 44.1865.784.648  
**Email** tech.europe@serologicals.com

### All Others

**Phone** 815.937.8270  
**Fax** 815.937.8285

