

Data Sheet

EX-CYTE®

Growth enhancement media supplement

Improves cell culture productivity, streamlines processing

When working in cell culture, enhanced productivity and product yield as well as streamlined processing are important goals. EX-CYTE® supplement can help achieve these goals and reduce the use of costly fetal bovine serum (FBS) of inconsistent quality. An ideal enhancer for reduced-serum cell culture, it supplies critical growth factors and eliminates the need for full-serum supplementation. When used in conjunction with Merck Millipore's other critical media supplements, EX-CYTE® supplement can significantly improve the cell culture manufacturing process.

EX-CYTE® supplement is a water-soluble concentrate of cholesterol, lipoproteins, and fatty acids that provides a balanced profile of metabolic factors proven to enhance cell growth and protein production in a variety of mammalian cells including hybridoma, myeloma, CHO, and HEK293 cells.

EX-CYTE® supplement is manufactured in an ISO 9001:2008 quality system in large batch sizes and tested for consistency, microbial content, clearance of bovine viruses (9 CFR 113), mycoplasma, and endotoxins. Heat-pasteurized, organic-solvent and detergent-free, EX-CYTE® supplement is made from US-sourced serum while EX-CYTE® NZ supplement is made from New Zealand-sourced serum.



Features and Benefits:

- Excellent source of essential nutrients to prolong cell culture viability and promote productivity
- Increases antibody and protein production in cholesterol and lipid-dependent cell lines
- Undetectable IgG simplifies downstream purification
- Complete 9 CFR 113 virus testing and patented prion clearance manufacturing process (U.S. Patent No. 6,743,899)
- ISO 9001:2008 quality system for consistent, high-quality products
- EDQM Certificate of Suitability for product traceability
- Large lot sizes enable product uniformity and minimize testing and qualification
- Reduce or eliminate FBS usage

Accepted. Effective. Approved.

For more than a decade, EX-CYTE® supplement has been proven to enhance cell proliferation and productivity (Figure 1) as well as reduce downstream processing time and cost. As a result, approved therapeutic products now on the market including monoclonal antibodies and recombinant proteins are being produced using the advantages offered by EX-CYTE® supplement. Because of the consistency of its manufacturing process, and the gains in productivity and downstream processing, EX-CYTE® supplement has been chosen by very successful biopharmaceutical manufacturers to enhance their cell culture performance.

All materials used in production of EX-CYTE® supplement are fully traceable and together with the final product are certified free of a broad range of viruses and mycoplasma. In addition, a patented prion reduction step in the manufacturing process has been validated to enable reliable product quality.

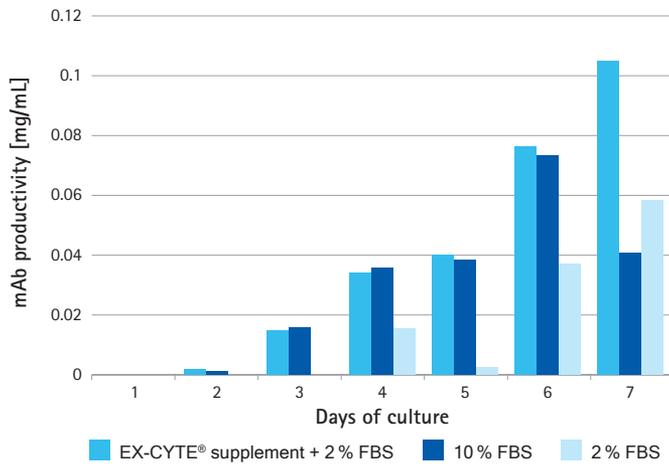


Figure 1. Antibody productivity comparison

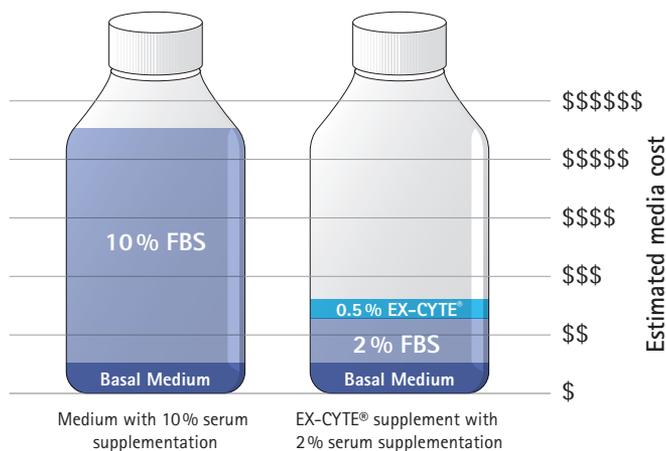


Figure 2. Media cost comparison

Reduce downstream costs

Purifying antibodies or other proteins from cell culture is easier and less costly when produced in a defined or reduced-serum media formulation. EX-CYTE® supplement is ideal for these applications as it supplies the required growth factors and eliminates the need for full-serum supplementation (Figure 2). Unlike costly FBS, which can vary widely due to seasonal effects and herd characteristics, EX-CYTE® supplement is manufactured in an ISO 9001:2008 quality system to ensure consistent performance. EX-CYTE® supplement is one of many critical media supplements offered by Merck Millipore to enhance your cell culture application including cell culture grade Probumin® BSA and CellPrime® r Insulin. Used together, these products represent a cost-effective way to optimize production of your protein.

Applications

- For use in mammalian cell culture in low-serum or serum-free conditions, to enhance cell growth and production of antibodies or recombinant proteins
- Proven to effectively enhance productivity in a variety of mammalian cell types
- The use of Probumin® Media Grade (Cat. No. 81-068) or Probumin® NZ Bovine Serum Albumin (Cat. No. 82-150) in conjunction with EX-CYTE® supplement or EX-CYTE® NZ supplement, respectively, is recommended

EX-CYTE® NZ supplement: New Zealand-sourced

EX-CYTE® supplement is available sourced from either US or New Zealand raw material. New Zealand is one of the few countries with a negligible BSE risk classification by the OIE (World Organization for Animal Health) – the lowest risk category indicating that the chance of bovine prion disease being present is very low. Careful herd management, strict regulations and geographical isolation has created in New Zealand a highly controlled source of bovine serum that has a low risk of bovine spongiform encephalopathy (BSE). EX-CYTE® NZ supplement is manufactured using the same patented and proprietary manufacturing processes as original EX-CYTE® supplement, but is made from bovine serum collected exclusively in New Zealand. The result is a superior product with the same growth promotion characteristics as EX-CYTE® supplement, but with an enhanced safety profile for prions.

Specifications

Assay	Specification
Cholesterol By Enzymatic Assay	9.0 – 11.0 g/L
Protein By Biuret Assay	13.0 – 18.0 g/L
pH	7.0 – 8.4
Endotoxin By Limulus Amebocyte Lysate Assay	0 – 6.0 EU/mg
IgG By Radial Immunodiffusion Assay	None detected
Microbial content By USP 61	< 20 cfu/mL
Mycoplasma	None detected
Viral Agents Tested in accordance with 9 CFR 113	None detected
Vesicular Stomatitis Virus	None detected
Recommended storage	2 – 8 °C in original container

Ordering information

Product description	Catalog No.
EX-CYTE® 10 mL	81-129-N
EX-CYTE® 50 mL	81-129-1
EX-CYTE® 1 L	81-129-2
EX-CYTE® NZ 10 mL	81-150-N
EX-CYTE® NZ 50 mL	81-150-1
EX-CYTE® NZ 1 L	81-150-2

Product traceability

Merck Millipore provides traceability of our raw materials and necessary documentation with our final products. Bovine serum used to manufacture EX-CYTE® supplement is collected only from US animals and bovine serum used to manufacture EX-CYTE® NZ supplement is collected only from New Zealand animals. Each animal is individually inspected and abattoirs are licensed by the appropriate national authorities.

Certificates of Analysis and Certificates of Suitability issued by the European Directorate for the Quality of Medicines (EDQM) are also available to provide proof of quality and traceability.

We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

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