



MAGENTA CORPORATION
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March 27, 1998

Dr. J. Woody Robbins
University of Alabama at Birmingham
Vector & Vaccine Facility
550 St. 11th Street
Birmingham, AL 35294

Dear Dr. Robbins:

Enclosed, please the Certificate of Analysis and Product Information Sheet for the 5 vials of MC-293 MCB (P/N: 5.40051, L/N: 2003-0025) that were sent to you on March 23, 1998. Please accept our apologies for not receiving this paperwork with the shipment. If you have any questions or require further information, please call me at (800) 756-5658, ext. 1423.

Sincerely,

A handwritten signature in black ink that reads "Angie Barthlow". The signature is fluid and cursive, with a large loop at the end.

Angie Barthlow
Project Management

PRODUCT INFORMATION SHEET

MAGENTA 293 Master Cell Bank (MC-293 MCB ATCC 40)

PASSAGE NUMBER: 40
CELLS/ML: 8.8×10^6
VIABILITY: $\geq 90\%$
VOL/AMPULE: 1.0 ml

CULTURE MEDIUM: Dulbecco's Modified Eagle Medium (DMEM), 10% heat-inactivated fetal bovine serum (FBS)

FREEZE MEDIUM: 90% FBS, 10% DMSO

SAFETY PRECAUTIONS FOR FROZEN CELL LINES

If the ampule is placed in liquid nitrogen upon receipt, special safety precautions should be followed when removing the ampule from storage. Protective gloves and clothing should be used and a face mask or safety goggles must be worn when thawing the ampule. The removal of such an ampule from liquid nitrogen can result in the explosion of the ampule creating flying fragments.

If storage of ampules is necessary, they must be stored in liquid nitrogen vapor phase instead of being submerged in liquid nitrogen.

Handle as potentially biohazardous material under at least Biosafety Level 2 containment.

HANDLING PROCEDURE FOR FROZEN CELLS

- Thaw by rapid agitation in 37°C water bath. Thawing should be completed quickly (within 40-60 seconds). As soon as the ice is melted, remove the ampule from the water bath. All of the operations from this point on should be carried out under strict aseptic conditions.

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- It is not necessary to remove the freezing additive. However, if desired, the culture medium may be changed to remove the protective freezing additive (dimethylsulfoxide) 24 hours after thawing. If it is desired that the freezing additive be removed immediately, or that a more concentrated cell suspension be obtained, centrifuge the above diluted suspension at approximately 125 x g for 10 minutes, discard the fluid and resuspend the cells in growth medium.

SUBCULTURE PROCEDURE

Remove culture medium. Rinse with PBS or serum-free media. Add fresh trypsin - EDTA solution. Place the flask at room temperature (or incubate at 37°C) until the cells detach which should only take 1 to 3 minutes. Add fresh medium, aspirate and dispense into new flasks.

Subcultivation ratio: 1:2 to 1:3 every 3-4 days.

NOTE

The cell line does not adhere to the substrate when left at room temperature for any length of time. Also, the cultures should be subcultured at 80-90% confluence since cultures maintained at 100% confluence aggregate and sloughing can occur.

DESCRIPTION

The 293 cell line is a permanent line of primary human embryonal kidney transformed by sheared human adenovirus type 5 (Ad 5) DNA. The cells are particularly sensitive to human adenovirus, are highly permissive for adenovirus DNA transfection, and contain and express the transforming genes of Ad 5. The line has been used in the isolation of transformation defective, host-range mutants of Ad 5, and is excellent for titrating human adenoviruses.

REFERENCES

J. Gen. Virol. 36: 59-72, 1977; Virology 77: 319-329, 1977; *ibid.*, 86: 10-21, 1978; American Type Culture Collection Product Sheet, CRL-1573.

**CERTIFICATE OF ANALYSIS - CELL BANK
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Cell line: MC-293 MCB ATCC p40
Part number: 5.40051
Lot number: 2003-0025

Date of cell bank freeze: 02/02/95
Fill volume (mL/vial): 1.0
Product concentration: Approximately 8.8×10^6 viable cells/vial (post thaw)
Store in liquid nitrogen

TEST	STUDY NO.	SPECIFICATION	RESULT
<i>In Vitro</i> Assay for the Presence of Viral Contaminants	B95BD27.003	None Detected	None Detected
Test for the Presence of Inapparent Viruses	B95BD27.005002	None Detected	None Detected
Transmission Electron Microscopic Evaluation of Cultured Cells	B95BD27.013	Report Result	No Identifiable Virus-Like* Particles
Detection of Human Immunodeficiency Virus (HIV) Retrovirus by Inoculation of Human Peripheral Blood Lymphocytes with the Test Article and Detection of the Presence of Virus by an Antigen Capture ELISA Technique	B95BD27.015001	None Detected	None Detected
Cell Culture Identification and Characterization	A95BD27.380	Human	Human
Growth of Mammalian Cells in Soft Agarose	B95BD27.029	Report Result	Colonies Formed
<i>In Vitro</i> Assay for the Detection of Cytomegalovirus Contamination	B95BD27.030	None Detected	None Detected
Detection of Hepatitis B Surface Antigen (HBsAg) in Cell Culture	B95BD27.040	None Detected	None Detected
<i>In Vitro</i> Assay for the Detection of EBV DNA in Cells	B95BD27.104	None Detected	None Detected
Southern Blot Hybridization Assay for the Detection of Adeno Associated Virus (AAV) DNA in the Test Article	B95BD27.104016	None Detected	None Detected
Southern Blot Hybridization Assay for the Detection of Human Parvovirus B19 DNA in the Test Article	B95BD27.104017	None Detected	None Detected
Polymerase Chain Reaction Assay for the Detection of Human T-Cell Lymphotropic Virus in Biological Samples (Types I and II)	B95BD27.105014	None Detected	None Detected
Test for the Presence of Bacterial and Fungal Contaminants: Sterility Test Using a Direct Inoculation Method	B95AH06.510	Pass	Pass
Test for the Presence of Agar-Cultivable and Non-Cultivable Mycoplasmas	B95AH06.102003	Pass	Pass

* Typographical error corrected on 05/21/96

CERTIFICATE OF ANALYSIS - CELL BANK
MAGENTA CORPORATION

Cell line: MC-293 MCB ATCC p40
Part number: 5.40051
Lot number: 2003-0025

I certify that the above information has been accurately transcribed.

By *Jean Belin*
QA Auditor

April 11, 1996
Date

Approved for Release:

[Signature]
Jeffrey M. Ostrove, Ph.D.
Senior Vice President and Chief Scientific Officer
MAGENTA Corporation

April 11, 1996
Date

Nona S. Karten
Nona S. Karten
Vice President, Regulatory Affairs/Quality Assurance
MAGENTA Corporation

April 11, 1996
Date