

**AMENDED CERTIFICATE OF ANALYSIS - CELL BANK
BIORELIANCE CORPORATION**

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 x 10⁶ 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 ^a 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
PCR Assay for Hepatitis C Virus ^b	J00YA79.105025	Pass	Pass
Test for the Presence of HIV-1/2 DNA ^c	AA31PE.105010	Pass	Pass
PCR, HHV-6 ^d	AA33KD.105020	None Detected	None Detected
PCR, HHV-7 ^e	AA33KD.105029	None Detected	None Detected

^a Typographical error corrected on 05/21/96

^b Amended 05/02/00 to include additional testing

^c Amended 08/18/00 to include additional testing

^d Amended 09/18/00 to include additional testing

^e Amended 09/18/00 to include additional testing

**AMENDED CERTIFICATE OF ANALYSIS - CELL BANK
BIORELIANCE 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 *Sherry Jackson*
QA Auditor

September 18, 2000
Date

Approved for Release:

John A. Gilly
John A. Gilly, Ph.D.
Manufacturing Division

September 18, 2000
Date

Claire Courtemanche
Claire Courtemanche
Quality Assurance

Sept 18, 2000
Date