	SISTEMAS Y SERVICIOS ONCOLÓGICOS DE LATINOAMÉRICA	Code	CBC-AC-CER-04
CBCells BIO TECHNOLOGY	**QUALITY CONTROL CERTIFICATE** WHARTON'S JELLY MESENCHYMAL STEM CELL	Batch	PLMSC300824
		Data	30/AGO/2024
		Exp.	02/SEP/2024

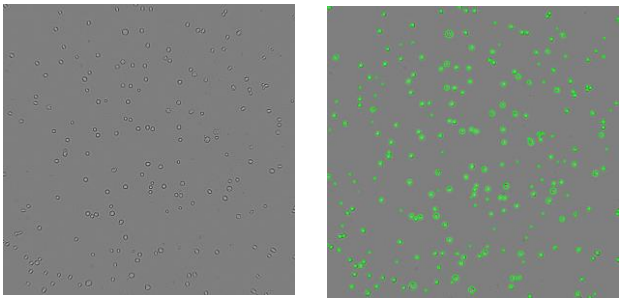
MORPHOLOGY, COUNT AND CELL VIABILITY

Processed sample
Primary culture of placenta mesenchymal stem cells

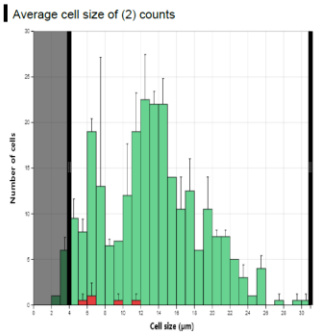
Cultivation conditions
Culture monitored for 3 days until reaching 90% confluence, in an environment of 37°C at 5% CO2

Harvest date 03/12/2024
Fresh non-cryopreserved dose

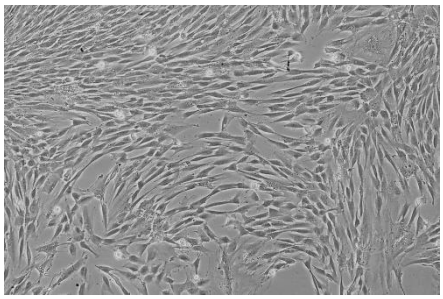
The characterization was carried out according to the parameters set by the International Society for Cellular Therapy (ISCT).



Micrograph of mesenchymal cells in the cell counter



Cell population size



Micrograph of placenta mesenchymal cells 10X

	Average of 2 counts
Gating	4 µm - 31 µm
Live cells	2.64e+6 ± 7.68e+3 cells/mL
Dead cells	2.71e+4 ± 3.84e+4 cells/mL
Total cells	2.67e+6 ± 3.07e+4 cells/mL
Viability	99.0 ± 1.43 %
Live size	13.4 ± 0.6 µm
Dead size	7.7 µm

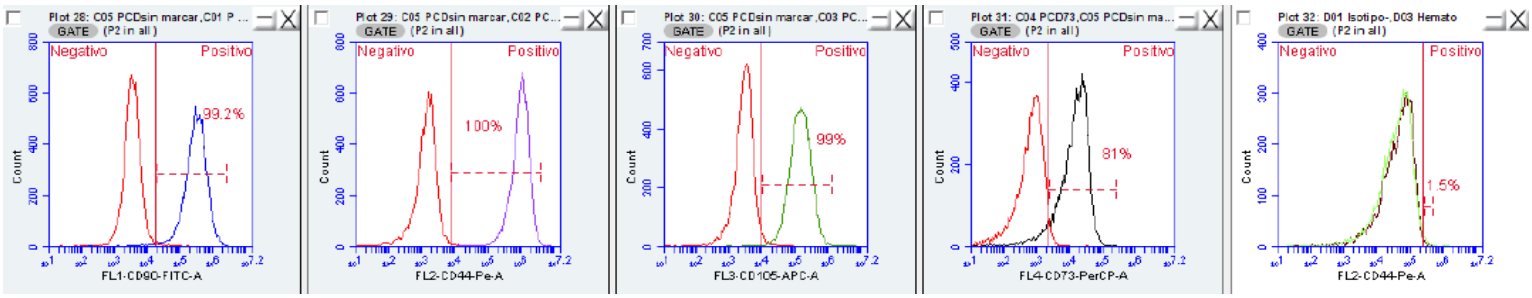
Summary of the automated cell count report

Descriptive: adherent phenotype cells corresponding to the mesenchymal phenotype are collected using an enzymatic detachment technique, which are washed with a buffered solution and the isolated cells are counted using the CytoSmart automated cell counter system, Corning™ using the trypan blue technique. to discriminate between live and dead cells.

CELL PHONETYPE BY FLOW CYTOMETRY

Descriptive: The identification of the individual markers CD73, CD90, CD105 and CD 44 was carried out, as well as in a cocktail, the hematopoietic markers CD34, CD45, CD11b, CD14, CD79, HLA class II, the selection of the analysis population, regarding the size (FSC) and granularity (SSC) graph. For each analysis, 10,000 events were run.

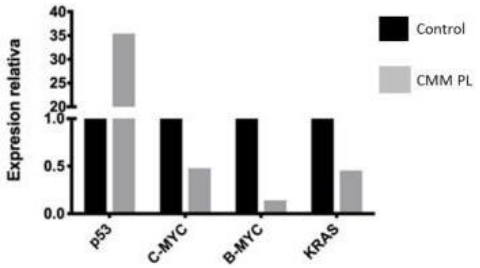
Antigen	% percentage	Result
CD105+	99%	POSITIVE
CD73+	81%	POSITIVE
CD44+	100%	POSITIVE
CD90+	99.2%	POSITIVE
CD34, CD45, CD11b, CD14, CD19 y HLA Class II	1.5%	NEGATIVO



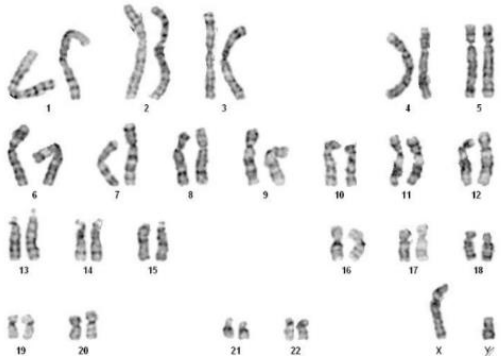
Flow cytometry histograms

ONCOGENICITY ANALYSIS

Muestra	P53	C-MYC	B-MYC	KRAS
CMM PL	35.4090859	0.47752133	0.14132138	0.45450272
Control	0^{2}	$>17.9^{3}$	$>10^{4}$	$>4^{5}$



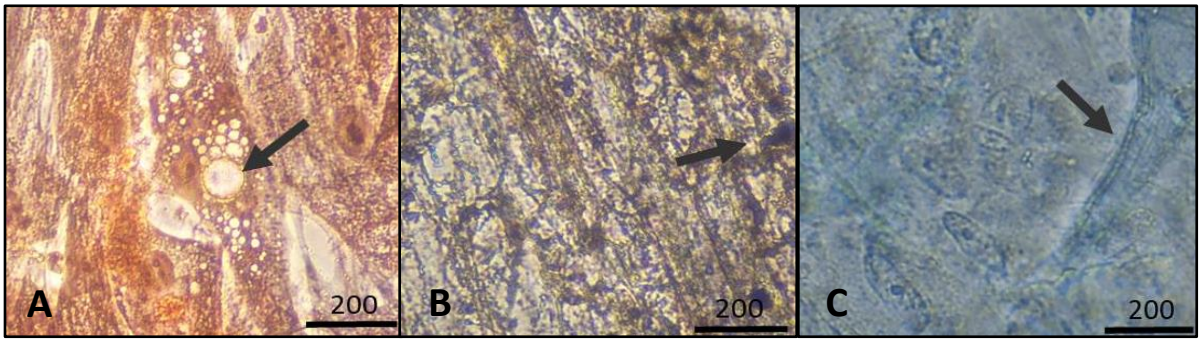
Relative expression of proto-oncogenes (C-MYC, B-MYC and KRAS) and antioncogenes (P53)



Micrograph of cell karyotype

TRANSDIFFERENTIATION ANALYSIS

The differentiation capacity is processed by inducing differentiation towards adipocytes, chondrocytes and osteocytes using the media formulated for differentiation for each cell line for 30 days. On day 21, stains were used to determine the phenotype of each cell line. Oily red staining demonstrates fatty vacuoles characteristic of adipocytes, alcian blue shows collagen fibers and representative chondrocytes, and Von kossa staining exposes calcium deposits in osteoblasts.



A) Differentiation of placental mesenchymal cells to the adipogenic lineage. B) Differentiation to the osteogenic lineage C) differentiation to the chondrogenic lineage

MICROBIOLOGICAL ANALYSIS

Determinación	Resultado	Unidades	Metodología
Bacterias mesofílicas aerobias	<1	UFC/mL	NOM 092 SSA1 1994
Bacterias mesofílicas anaerobias	<1	UFC/mL	NOM 092 SSA1 1994
Bacterias esporuladas	<1	UFC/mL	Método interno
Hongos	<1	UFC/mL	NOM 111 SSA1 1994
Levaduras	<1	UFC/mL	NOM 111 SSA1 1994

Results: the cell count showed 99% viability of the batch, adherent fibroblastic cells with morphology corresponding to human mesenchymal cells, normal proliferative capacity, without evident morphological or genetic alterations, positive for CD44, CD90, CD73 and CD105, analyzed by cytometry. flow. The differentiation capacity was determined by inducing differentiation towards adipocytes, chondrocytes and osteocytes, evidencing transdifferentiation capacity, with negative results in the microbiological analyzes carried out.

VIRAL PANEL

Descriptive: The donor was analyzed for viruses, bacteria and parasites related to transfusions, the result was Non-Reactive, which is interpreted as negative for their presence.

Determinación	Técnica	Resultado
Anti-Cytomegalovirus IgG Antibodies	Chemiluminescence	No Reactive
Anti-Cytomegalovirus IgM Antibodies	Chemiluminescence	No Reactive
Anti-HIV Antibodies 1/2	Immunochromatography	No Reactive
Anti-Hepatitis C Virus Antibodies	Chemiluminescence	No Reactive
Anti-Treponemal Antibodies (FTA-ABS) Treponema Pallidum (VDRL)	RPR Carbon	No Reactive
ANTIBODIES Anti-Trypanosoma cruzi IgG (Chagas)	Chemiluminescence	No Reactive

CBCells Bio Technology
Anillo Periférico Norte Manuel Gómez Morin 6071, Miramar,
45070 Zapopan, Jal. Tel: 52 (33) 23010460

Biol. Eréndira Alvarado Cordero
Quality control department
CBCells ID: 09297760