

August 7, 2018

## **XCell statement of cell products**

The cell products we provide are from induced pluripotent stem cells (iPSC) which are different from embryonic stem cells (ESC) and governed under different rules.

Our products are made from iPSC lines under approved guidelines and appropriate donor consent, which is required for all commercial cell provision. <u>The cell source was cord blood that was collected</u> <u>from an FDA approved and inspected cord blood bank based in Cleveland Ohio</u>. The donor acquisition agency was an approved collection agency and the collection was approved for commercial indications. The confirmation was provided to the NIH which made them available to commercial entities such as XCell Science Inc.

The Certificate of Analysis of the lines is available and provided with each sample. The actual donor consent forms and IRB approval are maintained by the tissue collection agency. Under US HIPAA rules the donor consent forms and IRB approval are not shared routinely but only under a formal request by an approved agency.

We always provide an assurance letter for any company that requires assurance that these were collected under appropriate guidelines and that we have obtained the parent line from the US government agency under the same assurance. These assurances are sufficient for import and export to all countries that we supply cells to, including cells we produce for clinical use.

Mickiy Domer Operations Manager

Above information is provided and confirmed by Mahendra Rao XCell Science Inc. Consultant



## XCL-1 Neuron and Neuron is derived from XCL-1

## Standard test

TEST (Method)	SPECIFICATIONS		
	Min.	Max.	Results
Fill Volume	***	***	1 mL
VIRUS TESTING	1	1	1
HIV test	***	***	Not detected
HBV test	***	***	Not detected
HCV test	***	***	Not detected
MICROBIAL TESTING		1	
Sterility test	***	***	Negative
Mycoplasma	***	***	Negative
CELL PERFORMANCE TESTING		I	I
Alkaline Phosphatase	***	***	Positive
Immunofluorescence Oct3/4, SSEA-4	***	***	Positive
Flow Cytometry SSEA-4, Tra1-60, Tra1-81	Pass ≥ 70%	***	Pass
EB formation Positive for all 3 germ layers	***	***	Positive
"Zero-footprint" Confirmation	***	***	Confirmed
Plating Efficiency	Pass ≥ 20 colonies	***	Pass
Identity Testing (STR Analysis)	***	***	Confirmed

Mickiy Domer

Operations Manager

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