

Biosafety Documentation:

iCell® Hepatocytes 2.0

Donor ID	01434	Cell Line ID	01434.1028
Donor Sex	Female	Phenotype	Apparently Healthy Normal
Starting Material	Fibroblast	Catalog #	C1026
Age at Collection	< 18 years		
Race	Caucasian		
Ethnicity	Unknown		

Cell Source and Biosafety Level Classification

iCell® products are human cells differentiated from a master bank of stably induced pluripotent stem (iPS) cells. FUJIFILM Cellular Dynamics, Inc. (FCDI), classifies these cells as Biosafety Level 1 (BSL1) based on the United States Centers for Disease Control and Prevention publication: *Biosafety in Microbiological and Biomedical Laboratories*. Handle the cells according to the biosafety guidelines applicable in your region.

Reprogramming

The iPS cell line was generated from human fibroblasts through ectopic expression of reprogramming factors by retroviral transduction. The retroviral particles used in this process were obtained from cell culture supernatant of HEK 293T cells transfected with plasmids containing the reprogramming factor genes as well as the coding regions of the gag, pol, and env retroviral genes.

Polymerase chain reaction analysis did not detect retroviral components in the starting fibroblast material or the iPS cell line, confirming that the iPS cell line cannot spontaneously produce infectious virus.

Engineering

The iPS cell clones were engineered using nuclease-mediated methodologies to exhibit neomycin resistance under the control of a hepatic-specific promoter. Puromycin resistance was also included in the targeting vector to allow selection of the iPS cell clones.

None of the engineering vectors used contain oncogenes.

Infectious Disease Testing

The cell line was tested and non-reactive for HBV, HCV, HIV-1, and HIV-2.