



Miltenyi Biotec



# CliniMACS Prodigy® Adherent Cell Culture System

## GMP-compliant human pluripotent stem cell expansion process

### Application

The CliniMACS Prodigy® Adherent Cell Culture System allows GMP-compliant and scalable human pluripotent stem cell (PSC) cultivation.

This application sheet gives an overview of the entire process and quality control assays, and provides information about the required materials. In addition, it elucidates the setup of the tubing set CliniMACS Prodigy TS 730 and the performance data.

### Specifications

<b>Process capacity:</b>	scalable (up to $5 \times 10^7$ PSCs in the CliniMACS Prodigy chamber; up to $2 \times 10^8$ PSCs in one Corning® CellSTACK® 1 Chamber; up to $1 \times 10^9$ PSCs in one Corning CellSTACK 5 Chamber)
<b>Starting cell number:</b>	$1 \times 10^6$ cells
<b>Final cell number:</b>	approx. $5 \times 10^8$ cells
<b>Total process time:</b>	10 days
<b>Total hands-on time:</b>	approx. 5 h

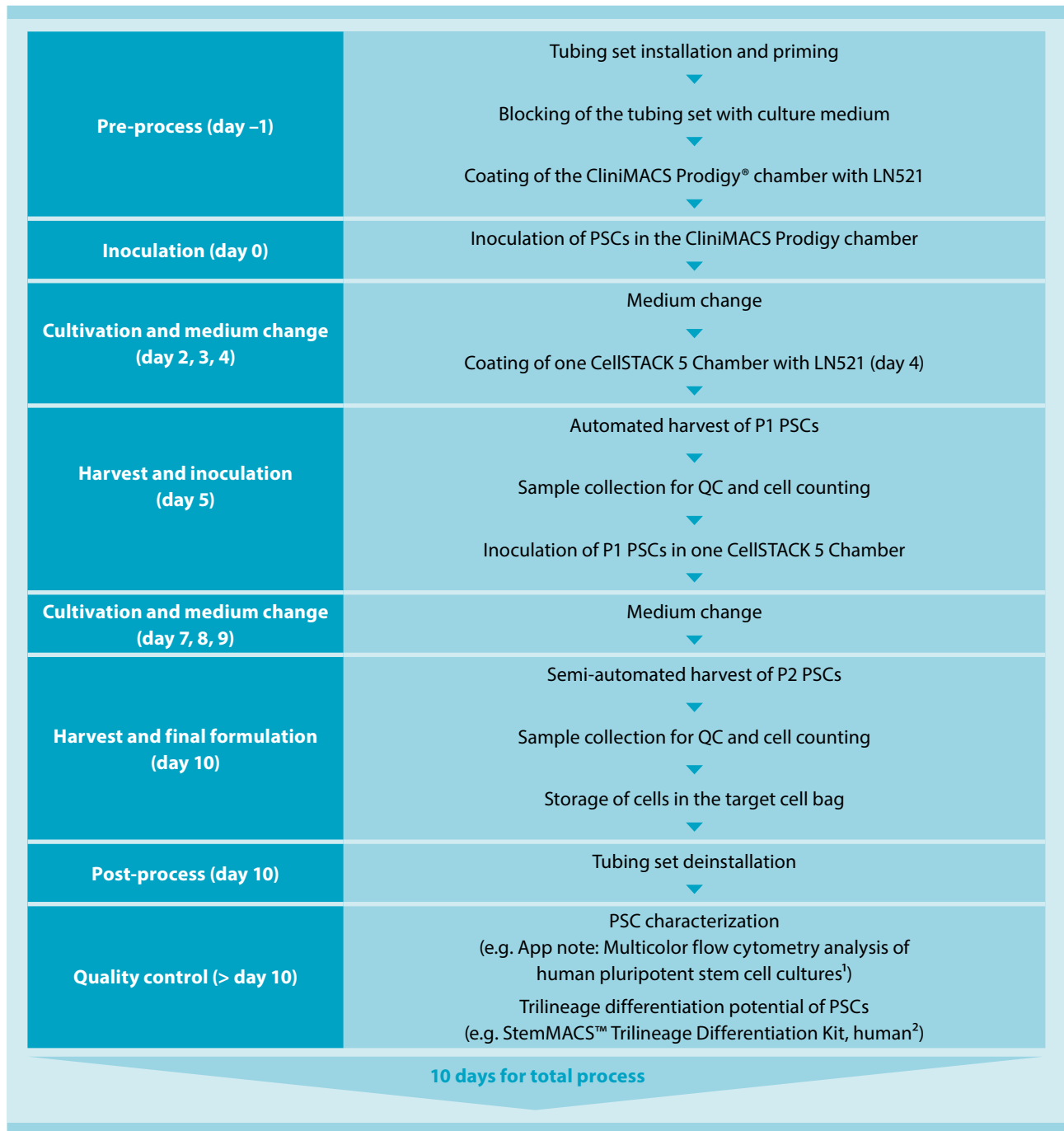
### Products

Consumables	Amount required
CliniMACS Prodigy® Instrument	1 piece
CliniMACS Prodigy TS 730	1 set
iPS-Brew GMP Medium	3 L
CliniMACS® PBS/EDTA Buffer (2x3 L)	3 L
MACS GMP Recombinant Human TGF-β1 (25 µg)	1 vial
1 m Tube Extension	2 pieces

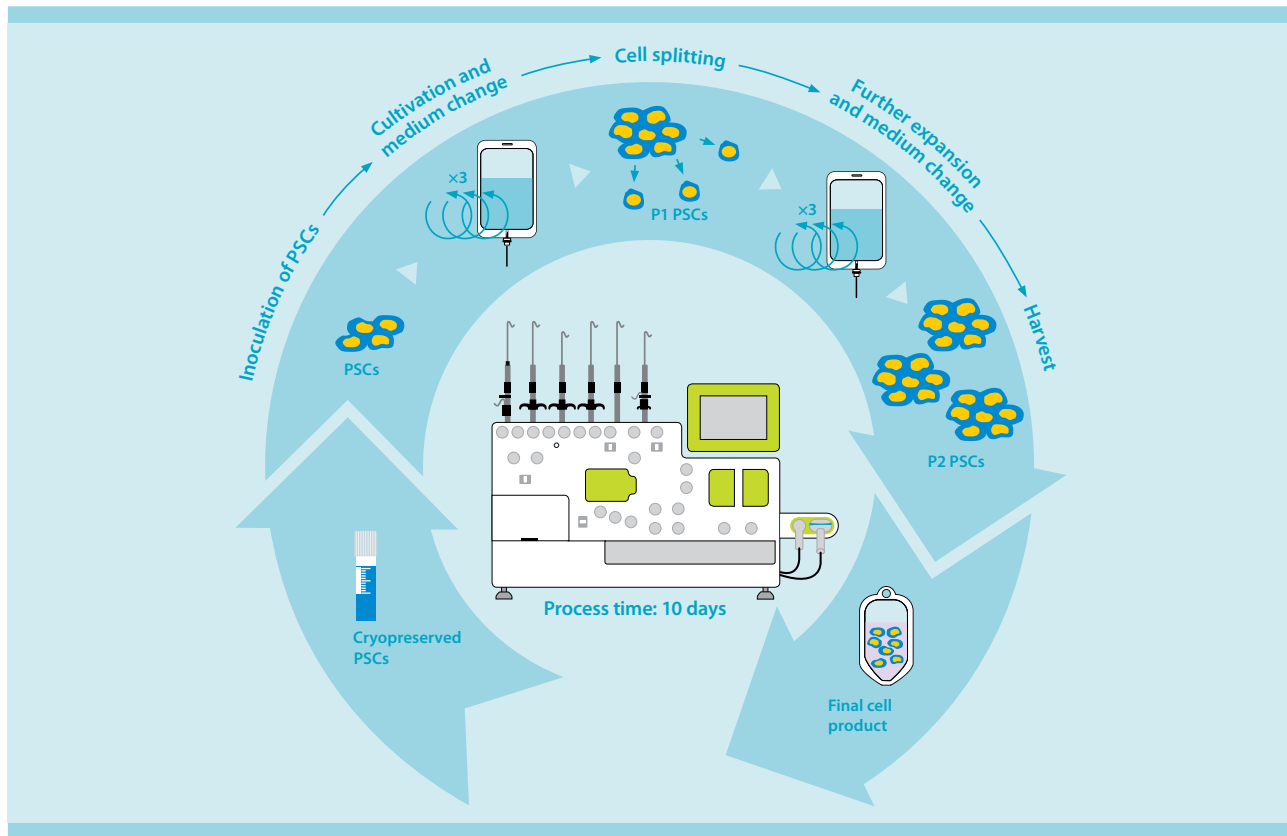
Additional materials	Amount required
Corning® CellSTACK® accessories, fill cap, 3.2 mm I.D. tubing, female Luer Lock with male luer plug	1 piece
Corning CellSTACK 5 Chamber	1 piece
Corning 1000 mL Easy Grip Polystyrene Storage Bottles with Dip Tube, with 0.2 µm MLL/FLL Filter*	2 pieces
Flexboy® Bag 50 mL, Inlet: Luer Lock male + cap, Outlet: Luer Lock female + cap, Sartorius	3 pieces
Flexboy Bag 500 mL, Inlet: Luer Lock male + cap, Outlet: Luer Lock female + cap, Sartorius	2 pieces
CTS™ TrypLE™ Select Enzyme, 100 mL, Thermo Fisher	300 mL
Defined Trypsin Inhibitor, 100 mL, Thermo Fisher	100 mL
Biolaminin 521 LN (LN521), 500 µg, BioLamina	4 vials

\*Used as alternative vessels for iPS-Brew GMP Medium

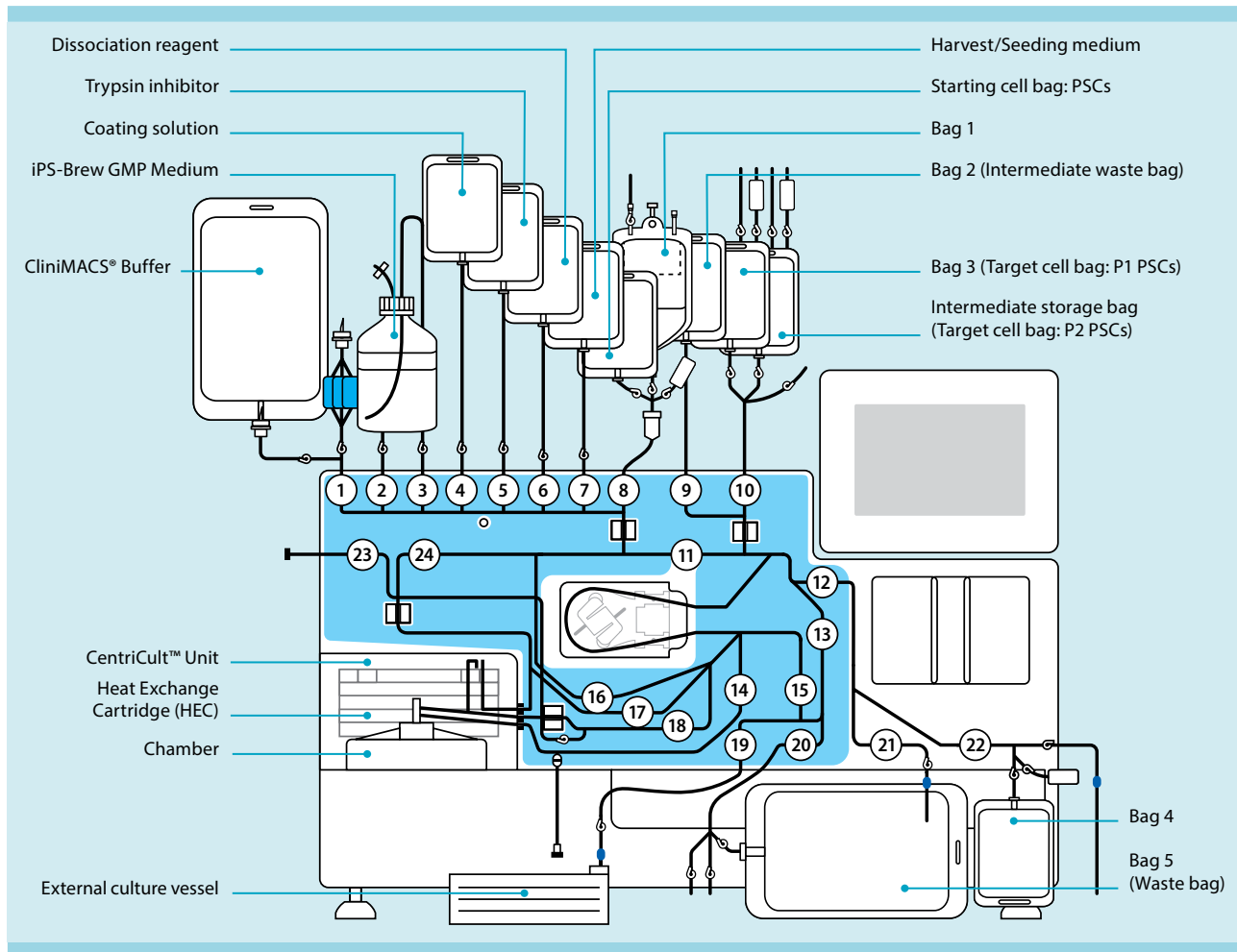
## Process overview for PSC expansion



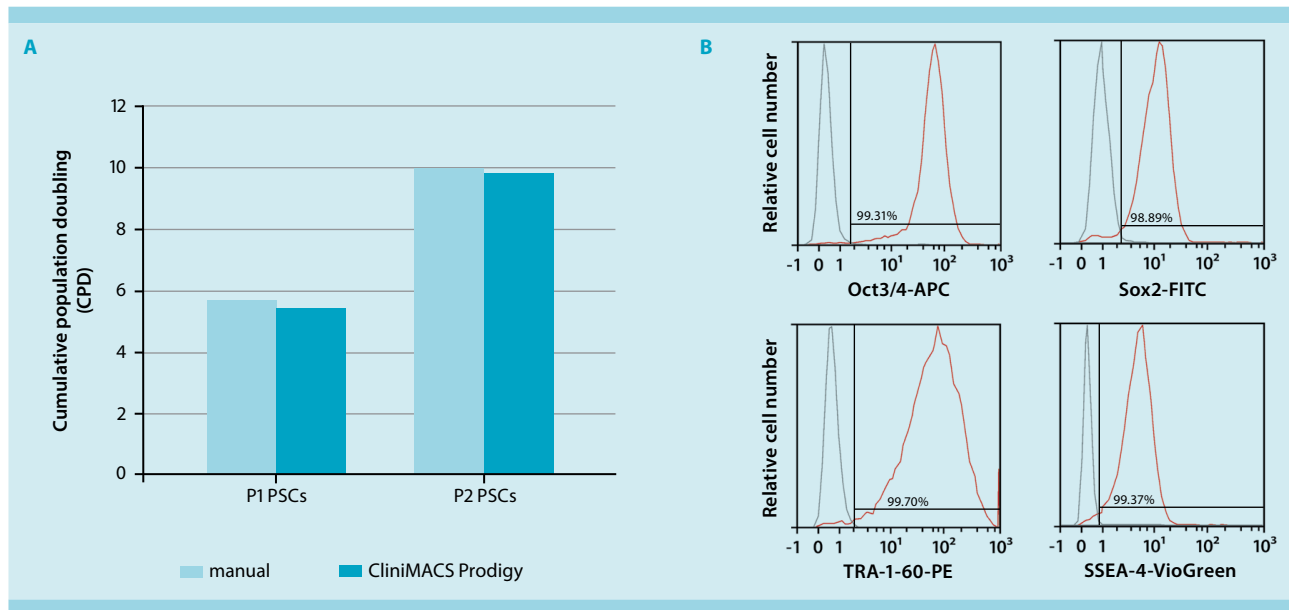
# Principle of the PSC expansion process using the CliniMACS Prodigy®



## CliniMACS Prodigy TS 730 setup for PSC expansion



## Performance data



$1 \times 10^6$  cryopreserved human PSCs were initially seeded and cultured in the CliniMACS Prodigy® chamber until day 5 and further expanded in one Corning® CellSTACK® 5 Chamber from day 5 to day 10 in iPS-Brew GMP Medium using the CliniMACS Prodigy Adherent Cell Culture System. As a control, cells were cultured with manual laboratory standard using 6-well plates and T75 flasks. (A) After 10 days of expansion, a clinically relevant number of P2 PSCs (approx.  $5 \times 10^8$  cells) was harvested using the CliniMACS Prodigy Adherent Cell Culture System. The cumulative population doubling rate was comparable to the one obtained with manual laboratory standard. (B) Flow cytometry analysis confirmed the quality of PSCs processed with the CliniMACS Prodigy Adherent Cell Culture System. Harvested PSCs showed high expression levels of the key pluripotency markers Oct3/4, Sox2, TRA-1-60, and SSEA-4.

## References

1. Miltenyi Biotec (2016) Multicolor flow cytometry analysis of human pluripotent stem cell cultures. [www.miltenyibiotec.com/flow-analysis-PSC](http://www.miltenyibiotec.com/flow-analysis-PSC)
2. Miltenyi Biotec (2017) StemMACS™ Trilineage Differentiation Kit – Protocol for flow analysis. [www.miltenyibiotec.com/Tri-Dif-Kit](http://www.miltenyibiotec.com/Tri-Dif-Kit)



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