

## Process protocol

### TCT

**Info 1 product** V2023-03-2  
**Start of process** 2023-09-27 (09:47:05)  
**Completion of process** 2023-10-04 (11:39:21)  
**Operator** DoTe  
**Process Id** 20230927\_094705\_SN1883\_TCT  
**Process version** 2.0.22  
**Used instrument** Not Defined, S/N: 1883, 1.4.34.201

### Material used

**Medium 2** BNT2 (PN) , BNT2 (LOT) , (Use-by date)  
**Medium** BNT1 (PN) , BNT1 (LOT) , (Use-by date)  
**Process buffer** 70029 (PN) , D1019 (LOT) , 2025-04-10 (Use-by date)  
**Reagent 1** 76702 (PN) , 6230400337 (LOT) , (Use-by date)  
**Reagent 2** 76703 (PN) , 6230300686 (LOT) , (Use-by date)  
**TransAct** 76156 (PN) , 6230500163 (LOT) , 2025-04-10 (Use-by date)  
**Tubing Set** 76600 (PN) , 7230200008 (LOT) , 2026-01-03 (Use-by date)  
**Final formulation solution** Final Formulation Buffer,  
**Info supplements 2**  
**Transduction reagent** VR-0213\_R-2221

### Process information

**CO2 concentration** 5 %  
**Case selection** Full process  
**Cell product volume (mL)** 233  
**Chosen vials** 2 vial(s)  
**Concentration of WBC (x10E6/mL)** 5  
**Freq. of labeled cells (%)** 27  
**Integrity test** passed successfully  
**Priming tubing set** performed successfully  
**Seeding cnt (x10E6)** 20  
**Selection** Empty matrix  
**Set activities** Confirmed on 2023-09-27 17:31:55: Feed (port: 3, vol (+): 30) - Day 0 at 18:10 ; Activate shaker (shaker type 2) - Day 2 at 08:45 ; Deactivate shaker - Day 2 at 09:00 ; Volume reduction (port: 3, vol = 70) - Day 2 at 10:45 ; Transduction (reagent vol.: 10) - Day 2 at 11:00 ; Spin (120 min, 32 C) - Day 2 at 11:45 ; Medium bag exchange - Day 2 at 14:00 ; Culture wash (cycles: 1) - Day 3 at 11:00 ; Activate shaker (shaker type 2) - Day 4 at 11:50 ; Media exchange (port: 3, vol (-/+): 130/180) - Day 5 at 11:00 ; End of culture - Day 7 at 13:00 ;  
**Set activities** Confirmed on 2023-09-29 10:44:16: Feed (port: 3, vol (+): 30) - Day 0 at 18:10 ; Activate shaker (shaker type 2) - Day 2 at 08:45 ; Deactivate shaker - Day 2 at 09:00 ; Transduction (reagent vol.:

	10) - Day 2 at 11:00 ; Volume reduction (port: 3, vol = 70) - Day 2 at 11:45 ; Spin (120 min, 32 C) - Day 2 at 11:45 ; Medium bag exchange - Day 2 at 14:00 ; Culture wash (cycles: 1) - Day 3 at 11:00 ; Activate shaker (shaker type 2) - Day 4 at 11:50 ; Media exchange (port: 3, vol (-/+): 130/180) - Day 5 at 11:00 ; End of culture - Day 7 at 13:00 ;
<b>Set activities</b>	Confirmed on 2023-09-29 10:46:35: Feed (port: 3, vol (+): 30) - Day 0 at 18:10 ; Activate shaker (shaker type 2) - Day 2 at 08:45 ; Deactivate shaker - Day 2 at 09:00 ; Volume reduction (port: 3, vol = 70) - Day 2 at 11:45 ; Transduction (reagent vol.: 10) - Day 2 at 12:00 ; Spin (120 min, 32 C) - Day 2 at 12:45 ; Medium bag exchange - Day 2 at 15:00 ; Culture wash (cycles: 1) - Day 3 at 12:00 ; Activate shaker (shaker type 2) - Day 4 at 11:50 ; Media exchange (port: 3, vol (-/+): 130/180) - Day 5 at 11:00 ; End of culture - Day 7 at 13:00 ;
<b>Set activities</b>	Confirmed on 2023-10-04 10:29:00: Feed (port: 3, vol (+): 30) - Day 0 at 18:10 ; Activate shaker (shaker type 2) - Day 2 at 08:45 ; Deactivate shaker - Day 2 at 09:00 ; Volume reduction (port: 3, vol = 70) - Day 2 at 11:45 ; Transduction (reagent vol.: 10) - Day 2 at 12:00 ; Spin (120 min, 32 C) - Day 2 at 12:45 ; Medium bag exchange - Day 2 at 15:00 ; Culture wash (cycles: 1) - Day 3 at 12:00 ; Activate shaker (shaker type 2) - Day 4 at 11:50 ; Media exchange (port: 3, vol (-/+): 130/180) - Day 5 at 11:00 ; End of culture - Day 7 at 10:35 ;
<b>Stages</b>	1
<b>Temp. for cultivation</b>	39.0 C
<b>Total WBC (x10E9)</b>	1.165
<b>Total lab. cells (x10E9)</b>	0.314

#### Process details

Date	Time	Operator	Process
2023-09-27	09:48:31	DoTe	Choose CliniMACS Reagent Count
2023-09-27	09:48:39	DoTe	Load tubing set
2023-09-27	10:49:24	DoTe	Priming tubing set
2023-09-27	11:02:39	DoTe	Interphase camera calibration
2023-09-27	11:08:22	DoTe	Process preparation
2023-09-27	12:26:35	DoTe	Calculation of separation parameters
2023-09-27	12:26:56	DoTe	Cell product load
2023-09-27	12:32:23	DoTe	Determine sample volume and erythrocyte pellet
2023-09-27	13:06:26	DoTe	Reduction of the erythrocyte / cell pellet
2023-09-27	13:18:07	DoTe	Volume adjustment (reduce volume to 70 mL)
2023-09-27	13:35:00	DoTe	Platelet wash
2023-09-27	13:53:44	DoTe	Cell labeling
2023-09-27	14:25:26	DoTe	Removal of unbound beads
2023-09-27	14:52:00	DoTe	Cell filtration
2023-09-27	15:10:41	DoTe	Cell separation
2023-09-27	17:32:23	DoTe	Chamber cleaning
2023-09-27	17:38:33	DoTe	Setup culture
2023-09-27	17:51:51	DoTe	Stimulation
2023-09-27	17:54:26	DoTe	Setup gas mix
2023-09-27	18:03:21	DoTe	Start Cultivation
2023-09-27	18:11:01	DoTe	Feed (port: 3, vol (+): 30)
2023-09-28	09:56:07	DoTe	Take microscope picture on position 10 using brightness 100

Date	Time	Operator	Process
2023-09-28	10:00:37	DoTe	Take Sample
2023-09-29	08:46:03	DoTe	Activate shaker (shaker type 2)
2023-09-29	09:01:07	DoTe	Deactivate shaker
2023-09-29	09:11:29	DoTe	Take Sample
2023-09-29	11:46:01	DoTe	Volume reduction (port: 3, vol = 70)
2023-09-29	12:01:04	DoTe	Transduction (reagent vol.: 10)
2023-09-29	12:46:01	DoTe	Spin (120 min, 32 C)
2023-09-29	15:07:31	DoTe	Medium Bag changed
2023-09-30	12:01:02	DoTe	Culture wash (cycles: 1)
2023-10-01	11:51:04	DoTe	Activate shaker (shaker type 2)
2023-10-02	11:01:05	DoTe	Media exchange (port: 3, vol (-/+): 130/180)
2023-10-02	12:24:15	DoTe	Take microscope picture on position 10 using brightness 100
2023-10-02	12:25:00	DoTe	Take microscope picture on position 5 using brightness 100
2023-10-04	09:41:01	DoTe	Take Sample
2023-10-04	10:22:56	DoTe	Take Sample
2023-10-04	10:36:06	DoTe	Harvest
2023-10-04	11:24:49	DoTe	Removal of tubing set

**Process completed at 11:39:21**

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name

\_\_\_\_\_  
Signature