



Training statement

Janssen V&P trial: VAC18195RSV1001 Sr

Assay: Isolation, cryopreservation and thawing of PMBCs

SOP reference: PBMC and plasma processing from whole blood specimens for JVP clinical trials Version 5.0; PBMC thawing SPL training v1.0

- ☐ Small whole blood volumes (≤ 5 mL)
☒ Large whole blood volumes (≥ 10 mL)

Worksheet reference: Sample data sheet for Janssen PBMC processing / SOP Thawing form Thaw Count v4.0

Date training performed: 16MAY2022

☒ Full training

☐ Re-training

The trainee has obtained the required relevant experience through training by an experienced operator. During training the trainee performed at least 3 isolations from 3 donors. The below described isolation criteria were met. See appendix 1 for quality data.

The trainee has maintained a qualified status by performing at least one isolation including cryopreservation within six months after the previous training. The below described criteria after isolation (viability and yield) were met. See appendix 1 for quality data.

Criteria after isolation

- | | | |
|--------------------|--------------------------------------|---------------------|
| • Viability: | $\geq 95\%$ | |
| • Yield | | |
| • Adults: | $0.8 \times 10^6 - 3.2 \times 10^6$ | PBMC/mL whole blood |
| • 2 - 5 year's: | $1.0 \times 10^6 - 6.0 \times 10^6$ | PBMC/mL whole blood |
| • 6 months - 2y's: | $2.0 \times 10^6 - 9.0 \times 10^6$ | PBMC/mL whole blood |
| • <6 months: | $3.0 \times 10^6 - 10.0 \times 10^6$ | PBMC/mL whole blood |

Criteria after thawing

- Viability: $\geq 80\%$
- Recovery: 80-120%

Trainee: Branco Porcile (BP)

Trainer/supervisor: Jose Arrais

Date: 07/08/22

Date: 07/11/2022

Signature:

Signature:

E-signature Janssen V&P SME:

Appendix 1. Quality data.

Operator	Date	Donor ID	Isolation and Freezing down					Thawing aliquot 1			Thawing aliquot 2			Thawing aliquot 3		
			Whole Blood volume (mL)	Viability (%)	Total viable cells (x10e6)	Cell Yield in x10e6 cells/mL of whole blood	Viable cells per vial frozen (x10e6)	Viability (%)	Total viable cells (x10e6)	Recovery (%)	Viability (%)	Total viable cells (x10e6)	Recovery (%)	Viability (%)	Total viable cells (x10e6)	Recovery (%)
BP	04-Apr-22	N/AP	26.4	100.0	107.30	4.0	35.8									
BP	05-Apr-22	N/AP	25.0	100.0	31.9	1.3	10.6									
BP	06-Apr-22	N/AP	24.4	100.0	13.7	0.6	13.7									
BP	26-Apr-22	N/AP	22.8	100.0	23.0	1.0	11.5	80.8	7.0	60.9	83.1	7.8	67.8			
BP	26-Apr-22	N/AP	24.4	100.0	21.9	0.9	21.9	98.5	10.3	47.0						
BP	30-Apr-22	N/AP	23.5	100.0	23.1	1.0	23.1	99.1	9.9	42.9						
BP	30-Apr-22	N/AP	24.5	99.4	24.3	1.0	12.2	93.3	10.9	89.3	93.3	12.0	98.4			
BP	01-May-22	N/AP	25.1	99	31.6	1.3	10.5	96.5	8.8	83.8	97	9.6	91.4	97	15	142.9
BP	02-May-22	N/AP	25.1	99.2	23.6	0.9	11.8	97	10.6	89.8	96.5	11.2	94.9			