

KCAS' flow cytometry team supports all aspects of large and small molecule bioanalysis for preclinical and clinical studies. Our experienced scientists provide custom assay development, validation, sample processing and consulting services for a wide variety of applications. We pride ourselves on being innovative problem solvers, and it's our top priority to help clients overcome any obstacles encountered while developing functional pharmacodynamic (PD) assays, live cell assays, isolation of PBMC studies, mechanism of action studies, and biomarker assays.

Our flow cytometry experts can help with your study design, implement and perform the assay, and deliver quality data. Below is a case study of a recent pharmacodynamic (PD) assay performed by KCAS.

Objective

KCAS performed a pharmacodynamic (PD) assay using flow cytometry for a preclinical non-GLP study in rats for an antibody therapeutic. Timelines were important to the client and KCAS needed to design, research, develop, and screen sample in less than four weeks.

Design

Client Need

T Cell, B Cell, NK cell absolute counts and % recovery for the monitoring of an antibody drug candidate.

KCAS Recommendation

- 1) Evaluate in parallel rat whole blood forward scatter by side scatter for lymphocyte gating. (The most cost effective method.)
- 2) Side scatter by CD45 lymphocyte gating. The addition of the CD45 marker increases cost, but offers the advantage of improved assay performance.

Results

KCAS and client selected the side scatter by CD45 lymphocyte gating in order to utilize the BD Trucount tube for absolute counts.

As a part of development, KCAS researched the utility of preserving cells for future studies to allow for batch sample analysis. (See Table 1)

Table 1: Summary of Rat Whole Blood T Cells and B Cells % and Gated of Lymphocytes (Lymph) and Absolute Count

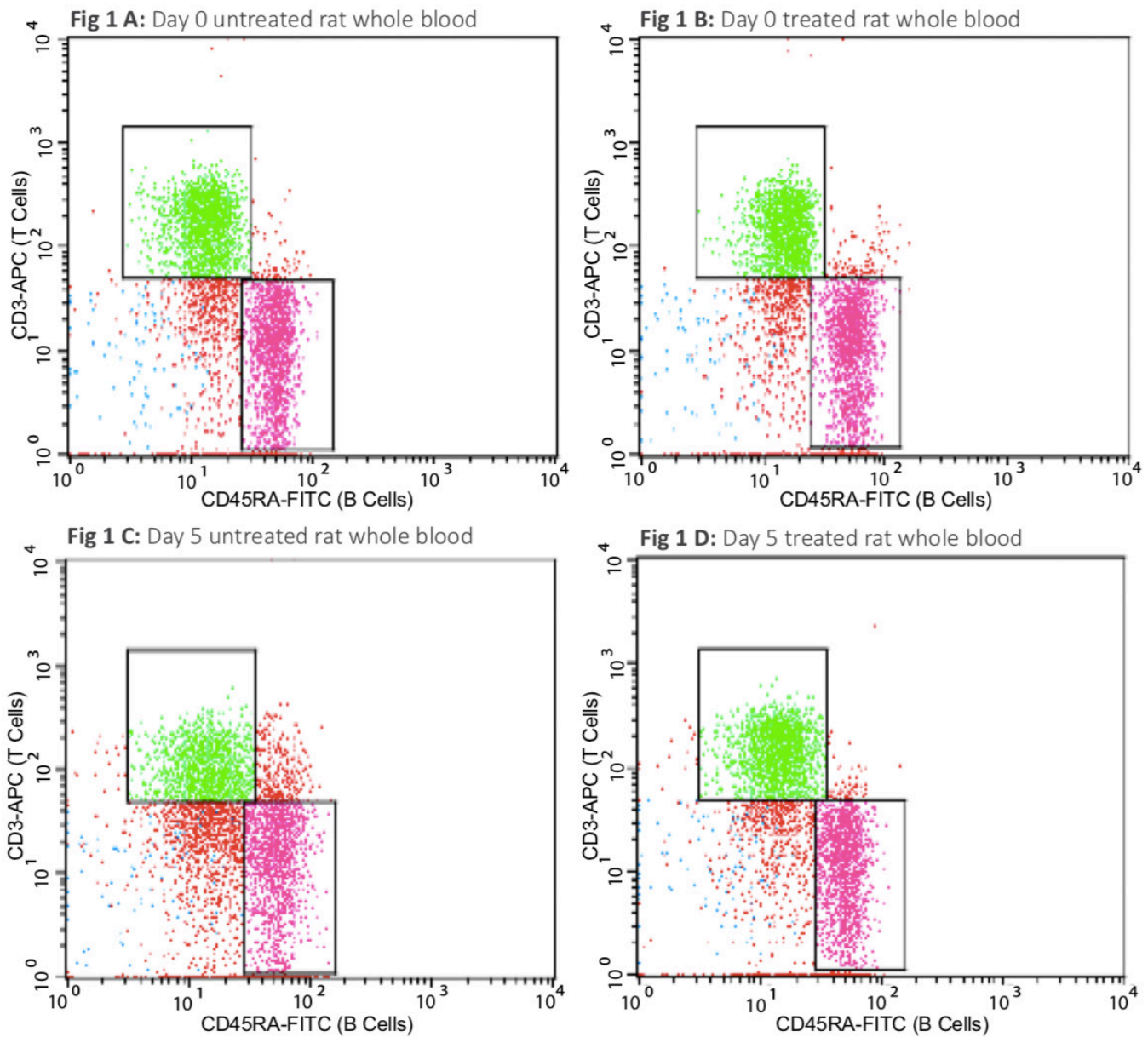
Sample ID	Dose	T Cells		B Cells	
		% Gated of Lymph	Absolute Count (Cells/uL)	% Gated of Lymph	Absolute Count (Cells/uL)
BW0004	Pres-Day 0	28.5	3554.46	25.7	3212.40
	Pres-Day 1	29.8	3422.18	22.0	2526.28
	Pres-Day 5	29.3	3333.18	24.5	2789.96
	Unpres-Day 0	32.9	3718.52	24.2	2736.42
	Unpres-Day 5	18.6	2067.15	25.5	2828.04
BW0005	Pres-Day 0	39.4	4224.52	35.1	3764.18
	Pres-Day 1	43.1	4790.88	32.3	3588.50
	Pres-Day 5	40.5	4230.46	34.0	3543.50
	Unpres-Day 0	39.8	4194.95	33.1	3483.96
	Unpres-Day 5	28.7	3008.38	30.9	3246.50

Indicates %CV > 20% compared to baseline (Unpres-Day 0)

Pres = Preserved samples

Unpres = Unpreserved samples

Figure 1 A-D: Preservation of T cell and B cells for 5 days.



Summary of Study

KCAS successfully designed, researched, developed, and screened 60 total samples for the client in less than four weeks. Additionally, KCAS demonstrated the ability to stabilize and batch samples for up to five days for future studies.