Specimen Quality for Multicenter Clinical Trials:

Comparing Novel Blood Preservation Methods to Cryopreserved PBMC

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Study goal:

To identify an alternative blood preservation method to reduce blood volume and logistical challenges associated with standard PBMC isolation

Study Design

Blood Source	Blood Collection Tube
3 Healthy Donors	Sodium Heparin

Hold Time	Aliquot Storage Temperature
30 hrs for PBMC to model transit time 3 hrs for Test Matrices to model processing at clinical sites	LN^2 for PBMCs -80° C for CT and ST -80° C overnight then LN^2 for CS10

Sample Analysis

- Samples were evaluated after 1-week of storage by a 26-color spectral flow cytometric method for T cell subsets.
- The variance (%CV) was calculated between the results generated with each Test Matrix and the results from the PBMC sample processed at 30 hours post-collection.
- The resolution of each subset was scored as comparable, improved, or lower.

Multi-Center Clinical Trial Challenge: Specimen Integrity for Flow Cytometric Analysis

Main Challenge: Specimen Integrity for Flow Cytometry Analysis

- Many clinical sites lack the expertise and/or infrastructure required for PBMC isolation, cryopreservation and shipment
- Variation in transit times can affect cellular phenotype, signaling states and protein expression

Feasibility Study: Evaluation of 3 whole blood preservation products as alternatives to PBMC isolation

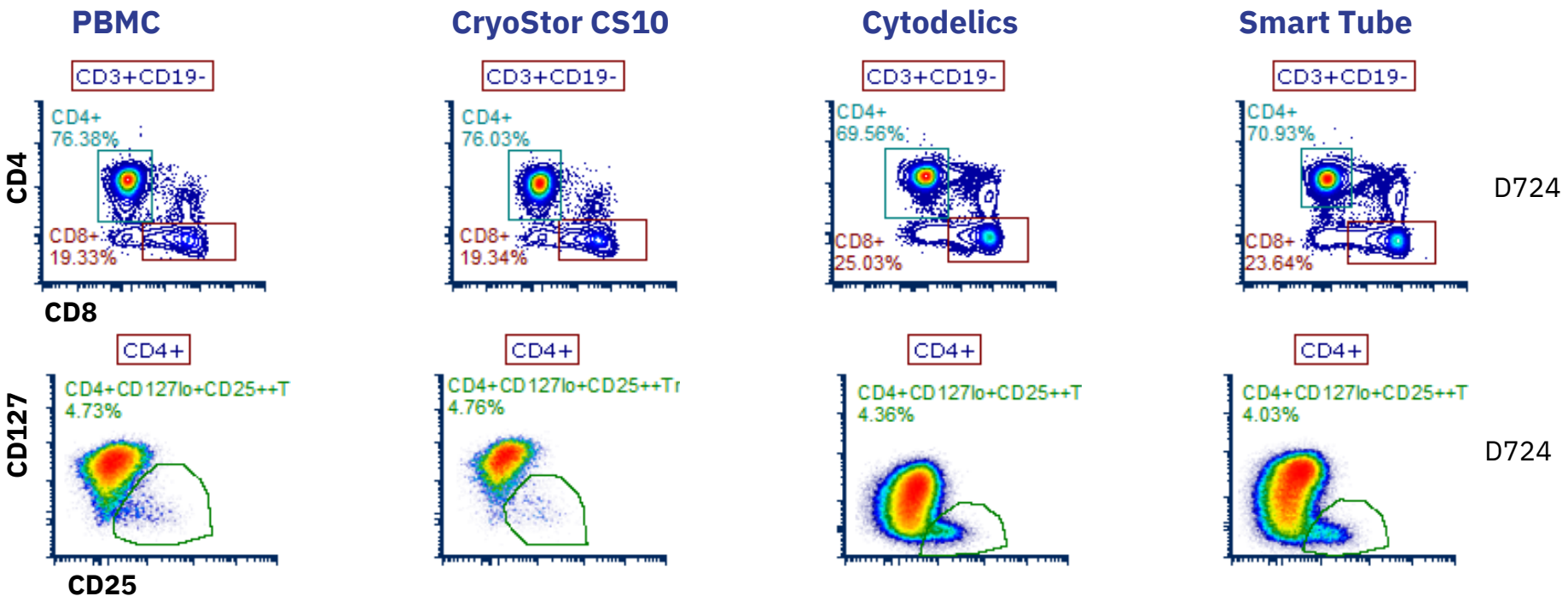
Control Matrix: PBMC Isolation	Test Matrix 1: Whole Blood Cryopreservation with CryoStor (CS10)	Test Matrix 2: Whole blood fixation with Cytodelics Stabilizer (CT)	Test Matrix 3: Whole blood fixation with Smart Tube Proteomic Stabilizer (ST)

Blood samples are like undeveloped film — if exposed to the wrong conditions, the image is lost forever

Results

CD4⁺, CD8⁺, and Treg cell populations were sufficiently resolved in each test matrix, although there was donor variability in percent of population

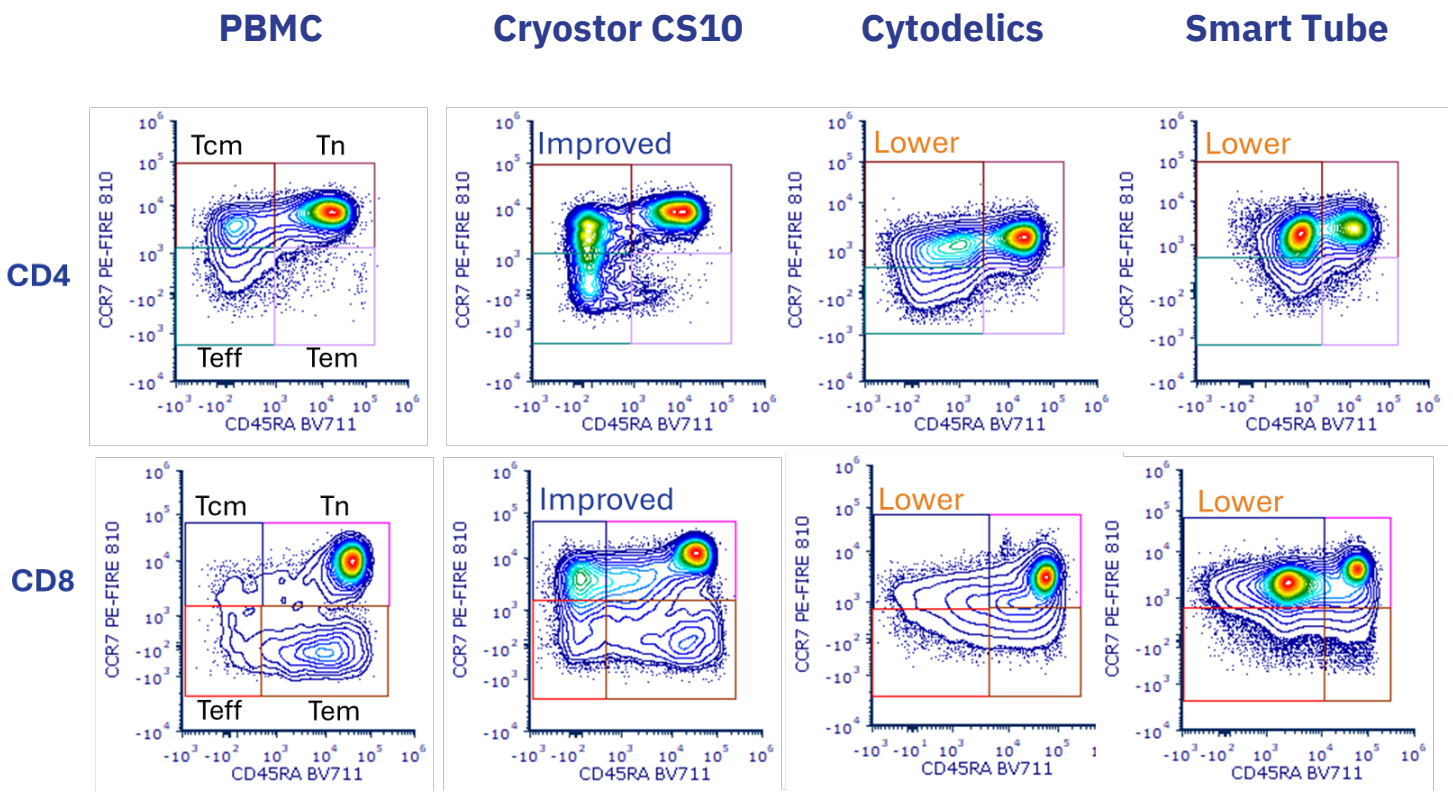
Cytodelics and SmartTube stabilizers yielded lower resolution for these subsets, suggesting that their fixation-based chemistry may alter epitope accessibility or signaling states



Population	Donor	PBMC	CryoStor CS10			Cytodelics			Smart Tube		
		% Pop	% Pop	% CV	Staining Pattern	% Pop	% CV	Staining Pattern	% Pop	% CV	Staining Pattern
CD4⁺ T cells	724	**76.38**	76.03	0.32	Comparable Resolution	69.56	6.61	Comparable Resolution	70.93	5.23	Comparable Resolution
	514	**47.37**	63.02	20.05		44.84	3.88		61.94	18.85	
	780	**65.14**	46.49	23.63		62.94	2.43		46.22	24.03	
CD8⁺ T cells	724	**19.34**	19.34	0.00	Comparable Resolution	25.03	18.14	Comparable Resolution	23.64	14.15	Comparable Resolution
	514	**47.43**	32.47	26.48		50.66	4.66		31.63	28.26	
	780	**30.13**	48.42	32.93		32.37	5.07		49.30	34.13	
Treg	724	**6.19**	6.26	0.80	Comparable Resolution	6.26	0.80	Comparable Resolution	5.68	6.08	Comparable Resolution
	514	**11.25**	7.04	32.55		14.18	16.29		4.17	64.93	
	780	**5.02**	13.36	64.17		5.62	7.97		13.16	63.32	

Results

For CD4⁺ and CD8⁺ naïve and memory T cells, CS10 had improved or comparable resolution to PBMC isolation, but the resolutions of CT and ST were lower



All methods compared to PBMC cryopreservation processed at 30 hrs

Study Outcomes

Pilot Study Results of Test Matrices

- Based on this pilot study, whole blood preservation using Cyrostor CS10 is the preferred matrix when traditional PBMC cryopreservation is not possible due to blood volume restrictions or logistical challenges.
- Cell population comparisons should be confined to samples preserved in the same matrix.
- Donor variability highlights the importance of including multiple donors in feasibility studies.
- Cytodelics and Smart Tube matrices contain fixatives; therefore, antibody re-titration may improve resolution.

SafeGUARD

SAFety and Efficacy of Human Antithymocyte ImmunoGlobUlin
SAB-142 ARresting Progression of Type 1 Diabetes

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Conclusion

These findings align with published evidence that cryoprotectant formulations maintain cellular integrity and viability better than fixation-based stabilizers for flow cytometry applications

As clinical trials increasingly incorporate high-dimensional immune profiling, practical solutions can help democratize access to high-quality data without the constraints of centralized processing.

Phase 2 Clinical Trial SAFEGUARD has Launched

U.S., Australia, and New Zealand are approved with sites being initiated and submissions under review with EMA and MHRA.

SAB-142 data in depth at ISPAD

Nov 5th, 6th, and 7th, 2025

Profiling the Binding Specificities of SAB-142, a Fully Human Anti-Thymocyte Globulin, against T cell Surface Proteins

Immunomodulation Without Sustained Lymphodepletion: SAB-142, a Fully Human Anti-Thymocyte Globulin

Mechanism of Action of a fully Human Anti-Thymocyte Globulin, SAB-142, for the Treatment of Type 1 Diabetes

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Novel Pharmacokinetic (PK) Assay for Measuring SAB-142, a Fully Human Anti-Thymocyte Globulin

Safety Profile of SAB-142: A Fully Human Anti-Thymocyte Globulin