

TransFix®

Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent



LOT : 30007



: 2025-01-31

Start Date of Manufacture: **2023-01-09**

Start Date of Quality Control Testing: **2023-01-19**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.0	76.6	0.7	PASS
% CD4+	58.9	58.8	0.3	PASS
CD3+ Abs Cnt	1480	1441	2.6	PASS
CD4+ Abs Cnt	871	846	2.9	PASS
CD8+ Abs Cnt	569	562	1.3	PASS
CD45+ Abs Cnt	1987	1905	4.1	PASS

Pass Criterion:

The pass criterion is a less than 15% difference between the lymphocyte absolute count (CD45+ Abs Cnt), T cell absolute count and % (CD3+), T helper cell absolute count and % (CD4+) and cytotoxic T cell absolute count (CD8+) on day 0 and day 11.

Comments:

3 separately stained tests were performed at each of the time points. These results were averaged and all parameters passed the acceptance criterion.

Signature of Quality Control Manager



Date: 13 Feb 2023