

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29985

 : 2024-07-31

Start Date of Manufacture: **2022-07-12**

Start Date of Quality Control Testing: **2022-07-21**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	79.5	79.2	0.5	PASS
% CD4+	56.7	56.8	0.2	PASS
CD3+ Abs Cnt	872	956	9.7	PASS
CD4+ Abs Cnt	494	544	10.0	PASS
CD8+ Abs Cnt	281	304	8.3	PASS
CD45+ Abs Cnt	1128	1224	8.5	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: 01 Sep 2022