

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29783

 : 2021-01-07

Start Date of Manufacture: **2019-01-07**

Start Date of Quality Control Testing: **2019-02-14**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.2	77.9	2.2	PASS
% CD4+	59.0	58.9	0.2	PASS
CD3+ Abs Cnt	1297	1244	4.1	PASS
CD4+ Abs Cnt	766	733	4.3	PASS
CD8+ Abs Cnt	406	395	2.7	PASS
CD45+ Abs Cnt	1703	1599	6.1	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

Nhaeng

Date: 27 Feb 2019

