

TransFix®

Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29797

⏳ : 2021-02-05

Start Date of Manufacture: 2019-02-05

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	77.7	2.0	PASS
% CD4+	59.0	58.8	0.3	PASS
CD3+ Abs Cnt	1297	1295	0.2	PASS
CD4+ Abs Cnt	766	762	0.5	PASS
CD8+ Abs Cnt	406	412	1.5	PASS
CD45+ Abs Cnt	1703	1666	2.1	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: 27 Feb 2019

