

TransFix®

Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29820

 : 2021-05-04

Start Date of Manufacture: **2019-05-04**

Start Date of Quality Control Testing: **2019-05-30**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	70.1	69.6	0.7	PASS
% CD4+	61.6	60.9	1.0	PASS
CD3+ Abs Cnt	1148	1230	7.1	PASS
CD4+ Abs Cnt	707	750	6.0	PASS
CD8+ Abs Cnt	319	365	14.2	PASS
CD45+ Abs Cnt	1638	1767	7.9	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: 17 Sep 2019

