

TransFix®

Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent

CE

IVD

LOT : 29909

 : 2022-08-24

Start Date of Manufacture: **2020-08-24**

Start Date of Quality Control Testing: **2020-08-27**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	79.1	77.3	2.3	PASS
% CD4+	80.0	76.1	4.8	PASS
CD3+ Abs Cnt	1132	1118	1.2	PASS
CD4+ Abs Cnt	905	852	5.9	PASS
CD8+ Abs Cnt	225	206	8.4	PASS
CD45+ Abs Cnt	2937	2906	1.1	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: 08 Sept 2020