

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

RUO

LOT : 29946

 : 2023-11-30

Start Date of Manufacture: **2021-11-22**

Start Date of Quality Control Testing: **2021-12-09**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.6	75.4	1.5	PASS
% CD4+	78.2	78.8	0.7	PASS
CD3+ Abs Cnt	1206	1119	7.2	PASS
CD4+ Abs Cnt	942	882	6.4	PASS
CD8+ Abs Cnt	250	219	12.3	PASS
CD45+ Abs Cnt	1622	1524	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



Date: 2022-04-08