

TransFix[®]

Certificate of Analysis TransFix[®]/EDTA CSF Sample Storage Tubes

RUO
LOT : 29590

 : 2018-06-30

 Start Date of Manufacture: **2017-06-29**

 Start Date of Quality Control Testing: **2017-06-30**

	A	B		
	TransFix/EDTA Day 0	TransFix/EDTA Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	71.3	71.8	0.7	PASS
% CD4+	63.4	62.1	2.1	PASS
CD3+ Abs Cnt	1828	1625	11.1	PASS
CD4+ Abs Cnt	1158	1008	12.9	PASS
CD8+ Abs Cnt	429	391	8.8	PASS
CD45+ Abs Cnt	2562	2264	11.6	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: 2017-07-12

