

TransFix®

Certificate of Analysis TransFix®/EDTA Vacuum Blood Collection Tubes (TVT)

CE

IVD

LOT : 29549

 : 2018-09

Start Date of Manufacture: **2017-03-02**

TransFix Batch Number used in TVT manufacture: **29508**

Start Date of Quality Control Testing: **2017-03-22**

	A	B		
	Control Day 0	TVT Day 15	% Diff (A-B)/A	Pass / Fail
% CD3+	64.7	63.5	1.8	PASS
% CD4+	35.7	33.0	7.5	PASS
CD3+ Abs Cnt	1413	1380	2.3	PASS
CD4+ Abs Cnt	782	706	9.6	PASS
CD8+ Abs Cnt	533	457	14.3	PASS
CD45+ Abs Cnt	2176	2180	0.2	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: 2017-05-10

