

TransFix®

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



LOT : 29503

 : 2018-03

 Start Date of Manufacture: **2016-08-23**

 TransFix Batch Number used in TVT manufacture: **29474**

 Start Date of Quality Control Testing: **2016-09-16**

	A	B		
	TVT Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	77.7	71.3	8.3	PASS
% CD4+	53.8	51.6	4.2	PASS
CD3+ Abs Cnt	1248.7	1337.2	7.1	PASS
CD4+ Abs Cnt	970.3	953.2	1.8	PASS
CD8+ Abs Cnt	522	491.6	5.8	PASS
CD45+ Abs Cnt	297	284.8	4.1	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: 2016-10-07

