

TransFix®

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



LOT : 29510

 : 2018-03

Start Date of Manufacture: **2016-09-20**

TransFix Batch Number used in TVT manufacture: **29475**

Start Date of Quality Control Testing: **2016-11-11**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	82.5	75.9	8.0	PASS
% CD4+	32.8	32.0	2.2	PASS
CD3+ Abs Cnt	1378	1322	4.1	PASS
CD4+ Abs Cnt	452	423	6.3	PASS
CD8+ Abs Cnt	780	748	4.2	PASS
CD45+ Abs Cnt	1670	1740	4.2	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: 2016-12-09

