

TransFix®

Certificate of Analysis

TransFix®/EDTA Vacuum Blood Collection Tubes (TVT)

CE IVD

REF : TVT-03-1, TVT-03-2, TVT-03-50

LOT : 29762

 : 2020-05-31

Start Date of Manufacture: **2018-10-26**

TransFix Batch Number used in TVT manufacture: **29722**

Start Date of Quality Control Testing: **2018-11-15**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	71.2	71.0	0.2	PASS
% CD4+	64.2	64.8	1.0	PASS
CD3+ Abs Cnt	1467	1502	2.4	PASS
CD4+ Abs Cnt	941	973	3.4	PASS
CD8+ Abs Cnt	440	436	1.1	PASS
CD45+ Abs Cnt	2061	2114	2.6	PASS

Pass Criterion:

The pass criterion is a less than 15% difference between the blood 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: 2018-11-27

