

# TransFix<sup>®</sup>

## Certificate of Analysis TransFix<sup>®</sup>/EDTA Vacuum Blood Collection Tubes (TVT)

CE

IVD

LOT : 29543

 : 2018-08

Start Date of Manufacture: **2017-02-07**

TransFix Batch Number used in TVT manufacture: **29507**

Start Date of Quality Control Testing: **2017-02-24**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.3	75.5	1.0	PASS
% CD4+	63.5	67.4	6.2	PASS
CD3+ Abs Cnt	1276	1272	0.7	PASS
CD4+ Abs Cnt	809	858	0.3	PASS
CD8+ Abs Cnt	303	312	6.0	PASS
CD45+ Abs Cnt	1673	1685	3.2	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:

5 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: 2017-03-07

