

# TransFix<sup>®</sup>

## Certificate of Analysis

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



 : TVT-09-1, TVT-09-2, TVT-09-50
  : 29850

 : 2021-03-31

Start Date of Manufacture: **2019-08-13**

TransFix Batch Number used in TVT manufacture: **29843**

Start Date of Quality Control Testing: **2019-09-12**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.0	75.0	1.4	PASS
% CD4+	51.8	52.3	1.0	PASS
CD3+ Abs Cnt	1055	1061	0.6	PASS
CD4+ Abs Cnt	546	555	1.6	PASS
CD8+ Abs Cnt	347	322	7.3	PASS
CD45+ Abs Cnt	1387	1415	2.0	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: 24 Sep 2019