

# TransFix<sup>®</sup>

## Certificate of Analysis

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



 : TVT-09-1, TVT-09-2, TVT-09-50
  : 29694

 : 2019-11-30

Start Date of Manufacture: **2018-04-16**

TransFix Batch Number used in TVT manufacture: **29679**

Start Date of Quality Control Testing: **2018-05-17**

	A	B		
	Control Day 0	TVT Day 12	% Diff (A-B)/A	Pass / Fail
% CD3+	74.3	74.1	0.3	PASS
% CD4+	65.3	64.7	1.0	PASS
CD3+ Abs Cnt	1459	1391	4.7	PASS
CD4+ Abs Cnt	954	900	5.7	PASS
CD8+ Abs Cnt	382	374	2.2	PASS
CD45+ Abs Cnt	1963	1878	4.4	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 12.

#### 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: 2018-05-31

