

# TransFix<sup>®</sup>

## Certificate of Analysis

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

**IVD**
**REF** : TVT-03-2-US, TVT-03-50-US

**LOT** : 29811

 : 2020-09-30

 Start Date of Manufacture: **2019-03-11**

 TransFix Batch Number used in TVT manufacture: **29783**

 Start Date of Quality Control Testing: **2019-04-04**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	71.7	65.3	8.8	PASS
% CD4+	52.3	46.3	11.5	PASS
CD3+ Abs Cnt	1666	1704	2.2	PASS
CD4+ Abs Cnt	1246	1244	0.2	PASS
CD8+ Abs Cnt	414	396	4.3	PASS
CD45+ Abs Cnt	2326	2619	12.6	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: *03 May 2019*


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