

# TransFix<sup>®</sup>

## Certificate of Analysis

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

**CE** **IVD** **REF** : TVT-09-1, TVT-09-2, TVT-09-50 **LOT** : 29991

 : 2024-03-31

Start Date of Manufacture: **2022-09-08**

TransFix Batch Number used in TVT manufacture: **29985**

Start Date of Quality Control Testing: **2022-10-13**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.1	74.7	1.8	PASS
% CD4+	79.5	80.2	0.9	PASS
CD3+ Abs Cnt	1099	1116	1.5	PASS
CD4+ Abs Cnt	873	894	2.5	PASS
CD8+ Abs Cnt	217	209	3.6	PASS
CD45+ Abs Cnt	1490	1576	5.8	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: 27 Oct 2022