

# TransFix<sup>®</sup>

## Certificate of Analysis

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

**RUO** **REF** : TVT-09-1-RUO, TVT-09-2-RUO, TVT-09-50-RUO **LOT** : 30056

 : 2026-01-31

Start Date of Manufacture: **2024-07-09**

TransFix Batch Number used in TVT manufacture: **30047**

Start Date of Quality Control Testing: **2024-08-01**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	81.5	80.2	1.7	PASS
% CD4+	73.8	71.5	3.2	PASS
CD3+ Abs Cnt	1058	958	9.5	PASS
CD4+ Abs Cnt	781	684	12.4	PASS
CD8+ Abs Cnt	255	218	14.6	PASS
CD45+ Abs Cnt	1329	1241	6.7	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: 15 Aug 2024