

TransFix[®]

Certificate of Analysis

TransFix[®]/EDTA Vacuum Blood Collection Tubes (TVT)

**REF**

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

LOT

: 30005



: 2024-07-31

Start Date of Manufacture: **2023-01-05**TransFix Batch Number used in TVT manufacture: **29985**Start Date of Quality Control Testing: **2023-02-09**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	75.9	74.3	2.1	PASS
% CD4+	43.0	43.9	2.1	PASS
CD3+ Abs Cnt	1076	964	10.4	PASS
CD4+ Abs Cnt	462	423	8.6	PASS
CD8+ Abs Cnt	425	370	12.9	PASS
CD45+ Abs Cnt	1460	1319	9.6	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: 28 Feb 2023