

TransFix[®]

Certificate of Analysis

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

RUO **REF** : TVT-03-1-RUO, TVT-03-2-RUO, TVT-03-50-RUO **LOT** : 30030

 : 2025-03-31

Start Date of Manufacture: **2023-09-06**

TransFix Batch Number used in TVT manufacture: **30021**

Start Date of Quality Control Testing: **2023-10-02**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	76.4	68.7	10.0	PASS
% CD4+	78.0	76.5	2.0	PASS
CD3+ Abs Cnt	1477	1311	11.3	PASS
CD4+ Abs Cnt	1154	1003	13.1	PASS
CD8+ Abs Cnt	271	244	10.0	PASS
CD45+ Abs Cnt	1987	1910	3.9	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: 17 Oct 2023