

TransFix[®]

Certificate of Analysis

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



 : TVT-03-1, TVT-03-2, TVT-03-50
  : 29980

 : 2023-11-30

Start Date of Manufacture: **2022-06-13**

TransFix Batch Number used in TVT manufacture: **29946**

Start Date of Quality Control Testing: **2022-07-14**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	74.1	73.1	1.2	PASS
% CD4+	58.9	60.2	2.1	PASS
CD3+ Abs Cnt	1302	1277	1.9	PASS
CD4+ Abs Cnt	768	769	0.2	PASS
CD8+ Abs Cnt	496	476	4.0	PASS
CD45+ Abs Cnt	1800	1778	1.2	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 July 2022