

TransFix[®]

Certificate of Analysis

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



 : TVT-03-1, TVT-03-2, TVT-03-50
  : 30046

 : 2025-10-31

Start Date of Manufacture: **2024-04-11**

TransFix Batch Number used in TVT manufacture: **30034**

Start Date of Quality Control Testing: **2024-05-13**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	78.1	77.9	0.2	Pass
% CD4+	47.1	45.0	4.6	Pass
CD3+ Abs Cnt	1459	1374	5.8	Pass
CD4+ Abs Cnt	688	618	10.1	Pass
CD8+ Abs Cnt	649	603	7.1	Pass
CD45+ Abs Cnt	1901	1811	4.7	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: 2024-05-24