





TransFix[®]

Certificate of Analysis

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



 : TVT-09-1, TVT-09-2, TVT-09-50
  : 29800

 : 2020-09-30

Start Date of Manufacture: **2019-02-25**

TransFix Batch Number used in TVT manufacture: **29783**

Start Date of Quality Control Testing: **2019-04-17**

	A	B		
	Control Day 0	TVT Day 15	% Diff (A-B)/A	Pass / Fail
% CD3+	74.3	72.7	2.2	PASS
% CD4+	53.0	52.3	1.3	PASS
CD3+ Abs Cnt	1678	1676	0.1	PASS
CD4+ Abs Cnt	1188	1185	0.2	PASS
CD8+ Abs Cnt	471	438	6.9	PASS
CD45+ Abs Cnt	2263	2307	1.9	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: 2019-05-20