

TransFix[®]

Certificate of Analysis

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



 : TVT-03-1, TVT-03-2, TVT-03-50
  : 30065

 : 2026-06-30

Start Date of Manufacture: **2024-12-03**

TransFix Batch Number used in TVT manufacture: **30060**

Start Date of Quality Control Testing: **2025-01-09**

	A	B		
	Control Day 0	TVT Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	80.9	81.3	0.6	PASS
% CD4+	60.2	60.1	0.3	PASS
CD3+ Abs Cnt	2823	2840	0.6	PASS
CD4+ Abs Cnt	1700	1706	0.4	PASS
CD8+ Abs Cnt	1139	1082	5.0	PASS
CD45+ Abs Cnt	3559	3580	0.6	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: 22 Jan 2025