

TransFix[®]

Certificate of Analysis

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



 : TVT-03-1, TVT-03-2, TVT-03-50
  : 30071

 : 2026-09-30

Start Date of Manufacture: **2025-03-13**

TransFix Batch Number used in TVT manufacture: **30067**

Start Date of Quality Control Testing: **2025-04-17**

| | A | B | | |
|---------------|------------------|---------------|-------------------|-------------|
| | Control Day 0 | TVT Day 11 | % Diff (A-B)/A | Pass / Fail |
| % CD3+ | 80.4 | 77.6 | 3.5 | Pass |
| % CD4+ | 57.0 | 57.6 | 1.1 | Pass |
| CD3+ Abs Cnt | 1574 | 1604 | 1.9 | Pass |
| CD4+ Abs Cnt | 897 | 924 | 3.0 | Pass |
| CD8+ Abs Cnt | 620 | 641 | 3.4 | Pass |
| CD45+ Abs Cnt | 2002 | 2090 | 4.4 | 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

N Woodham

Date: 30 Apr 2025