

TransFix[®]

Certificate of Analysis

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

IVD

REF : TVT-03-2-US, TVT-03-50-US

LOT : 29711

 : 2019-11-30

Start Date of Manufacture: **2018-05-09**

TransFix Batch Number used in TVT manufacture: **29679**

Start Date of Quality Control Testing: **2018-05-31**

| | A | B | | |
|---------------|---------------|------------|----------------|-------------|
| | Control Day 0 | TVT Day 15 | % Diff (A-B)/A | Pass / Fail |
| % CD3+ | 68.0 | 66.7 | 2.0 | PASS |
| % CD4+ | 43.7 | 44.3 | 1.5 | PASS |
| CD3+ Abs Cnt | 1520 | 1560 | 2.6 | PASS |
| CD4+ Abs Cnt | 1012 | 1052 | 4.0 | PASS |
| CD8+ Abs Cnt | 479 | 413 | 13.8 | PASS |
| CD45+ Abs Cnt | 2234 | 2338 | 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 15.

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: 2018-06-15

