

# TransFix®

## Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent



**LOT** : 29475

 : 2018-06-08

Start Date of Manufacture: **2016-06-08**

Start Date of Quality Control Testing: **2016-07-08**

|               | A             | B               |                |             |
|---------------|---------------|-----------------|----------------|-------------|
|               | Control Day 0 | TransFix Day 11 | % Diff (A-B)/A | Pass / Fail |
| % CD3+        | 77.3          | 76.7            | 0.9            | PASS        |
| % CD4+        | 42.2          | 40.9            | 3.1            | PASS        |
| CD3+ Abs Cnt  | 1954          | 1813            | 7.2            | PASS        |
| CD4+ Abs Cnt  | 1511          | 1390            | 8.1            | PASS        |
| CD8+ Abs Cnt  | 638           | 568             | 11.0           | PASS        |
| CD45+ Abs Cnt | 733           | 692             | 5.6            | PASS        |

### Pass Criterion:

The pass criterion is a less than 15% difference between the 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: 2016-07-21

