

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

RUO

LOT : 29985

 : 2024-07-31

Start Date of Manufacture: **2022-07-12**

Start Date of Quality Control Testing: **2022-07-21**

| | A | B | | |
|---------------|------------------|--------------------|-------------------|-------------|
| | Control Day 0 | TransFix Day 11 | % Diff (A-B)/A | Pass / Fail |
| % CD3+ | 79.5 | 79.2 | 0.5 | PASS |
| % CD4+ | 56.7 | 56.8 | 0.2 | PASS |
| CD3+ Abs Cnt | 872 | 956 | 9.7 | PASS |
| CD4+ Abs Cnt | 494 | 544 | 10.0 | PASS |
| CD8+ Abs Cnt | 281 | 304 | 8.3 | PASS |
| CD45+ Abs Cnt | 1128 | 1224 | 8.5 | 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: 30 Sep 2022