

TransFix[®]

Certificate of Analysis TransFix[®]/EDTA CSF Sample Storage Tubes

RUO

REF: TF-CSF-5-2, TF-CSF-5-10, **LOT**: 29846

TF-CSF-5-25, and TF-CSF-5-50



: 2020-07-31

Start Date of Manufacture: 2019-07-17

Start Date of Quality Control Testing: 2019-07-25

| | A | B | | |
|----------------|------------------|------------------------|-------------------|-------------|
| | Control Day 0 | TransFix/EDTA Day 4 | % Diff (A-B)/A | Pass / Fail |
| % Monocytes | 6.6 | 6.1 | 7.4 | PASS |
| % CD4+ T cells | 56.8 | 58.6 | 3.3 | PASS |
| % CD8+ T cells | 36.1 | 34.7 | 4.0 | PASS |
| % B cells | 4.4 | 4.8 | 7.4 | PASS |
| % Igκ+ B cells | 61.2 | 61.6 | 0.7 | PASS |
| % Igλ+ B cells | 38.9 | 38.4 | 1.0 | PASS |
| % NK cells | 8.8 | 8.1 | 8.3 | PASS |

Pass Criterion:

The pass criterion is a less than 15% difference between monocyte partial % (CD14+), T helper cell partial % (CD4+), cytotoxic T cell partial % (CD8+), B cell partial % (CD19+, CD20+), Ig Kappa+ B cell partial % (Igκ+), Ig Lambda+ B cell partial % (Igλ+) and NK cell partial % (CD56+) on day 0 and day 4.

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: 29 July 2019



Histograms:

Shaded histograms represent fluorescence intensity results for TransFix/EDTA stabilized human leukocytes within a CSF substitute stained with the SST screening kit (Cytgnos) after 4 days of storage at 2-8°C.

Transparent histograms represent the equivalent un-stabilized CSF preparation of leukocytes in CSF substitute (Control – Day 0) for the positive subpopulation.

Analysis was conducted using Infinicyt software (Cytgnos).

