



Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent

CE

Description: TransFix Bulk

Reference: TFB-01-1, TFB-01-10, TFB-01-50 and TFB-20-1

Start Date of Manufacture: 2024-08-08

Start Date of Quality Control Testing: 2024-09-05

	Α	В		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	78.7	79.1	0.5	Pass
% CD4+	64.7	64.5	0.3	Pass
CD3+ Abs Cnt	1438	1407	2.1	Pass
CD4+ Abs Cnt	930	908	2.4	Pass
CD8+ Abs Cnt	498	478	3.9	Pass
CD45+ Abs Cnt	1862	1810	2.8	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: 18 Sep 2024