



Certificate of Analysis TransFix® Cellular Antigen Stabilisation Reagent

CE

Start Date of Manufacture: 2024-04-18

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

	А	В		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	78.5	81.0	3.2	PASS
% CD4+	56.6	58.6	3.5	PASS
CD3+ Abs Cnt	1546	1628	5.3	PASS
CD4+ Abs Cnt	875	955	9.1	PASS
CD8+ Abs Cnt	609	642	5.5	PASS
CD45+ Abs Cnt	2005	2044	1.9	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: 20 May 2024