

TransFix[®]

Certificate of Analysis TransFix[®] Cellular Antigen Stabilisation Reagent

CE**IVD****LOT** : 30021 : 2025-04-30Start Date of Manufacture: **2023-04-24**Start Date of Quality Control Testing: **2023-05-25**

	A	B		
	Control Day 0	TransFix Day 11	% Diff (A-B)/A	Pass / Fail
% CD3+	77.5	76.4	1.3	Pass
% CD4+	58.5	56.5	3.5	Pass
CD3+ Abs Cnt	2141	1970	8.0	Pass
CD4+ Abs Cnt	1253	1113	11.1	Pass
CD8+ Abs Cnt	855	762	10.9	Pass
CD45+ Abs Cnt	2812	2686	4.5	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: 14 Jun 2023