

TransFix[®]

Certificate of Analysis Circulating Tumor Cell TransFix[®]/EDTA Vacuum Blood Collection Tubes (CTC-TVT)

REF : CTC-TVT-09-2, CTC-TVT-09-50

LOT : 29860

 : 2020-10-31

 Start Date of Manufacture: **2019-09-30**

 Start Date of Quality Control Testing: **2019-10-31**

CD45-/EPCAM+ SKBR3 Cells at 10000 cells/mL			
Control Day 0	Control Day 6	CTC-TVT Day 0	CTC-TVT Day 4
Events Present	Events Present	Events Present	Events Present
PASS	-	PASS	PASS

Pass Criterion:

The pass criterion is detection of spiked CD45-/EPCAM+ SKBR3 cells at a concentration of 10000 cells/mL within the CTC-TVT on day 4.

Comments:

3 separately stained tests were performed at each of the time points.

Signature of Quality Control Manager



Date: 07 Nov 2019