Clinical Trial Concordance Data

In an independent study comparing the results of the Leica HER2 FISH System to the Abbott Molecular PathVysion® HER-2 DNA Probe Kit on 300 clinical breast cancer specimens, the Leica HER2 FISH System was found to be highly concordant to the current gold standard, FDA approved HER2 FISH test.

		Abbott Molecular PathVysion HER-2 DNA Probe Kit		
		Positive ≥2.0	Negative <2.0	Total
Leica HER2 FISH System Leica BOND III	Positive ≥2.0	102	0	102
	Negative <2.0	1	197	198
	Total	103	197	300

Overall Concordance (95% CI) = 99.67% (98.16 - 99.99%)

		Abbott Molecular PathVysion HER-2 DNA Probe Kit		
		Positive ≥2.0	Negative <2.0	Total
Leica HER2 FISH System Leica BOND Max	Positive ≥2.0	102	1	103
	Negative <2.0w	1	196	197
	Total	103	197	300

Overall Concordance (95% CI) = 99.33% (97.61 - 99.92%)

The cohort consisted of 75 3+, 150 2+ and 75 0/1+ previously characterised HER2 IHC cases

Overall concordance for Within Run, Within Instrument, Between Run, Between Laboratory, Between Observer and Lot-to-Lot precision testing was between 98.15% and 100% on both Leica BOND Systems.

This product is not for sale in the USA

Leica
MICROSYSTEMS