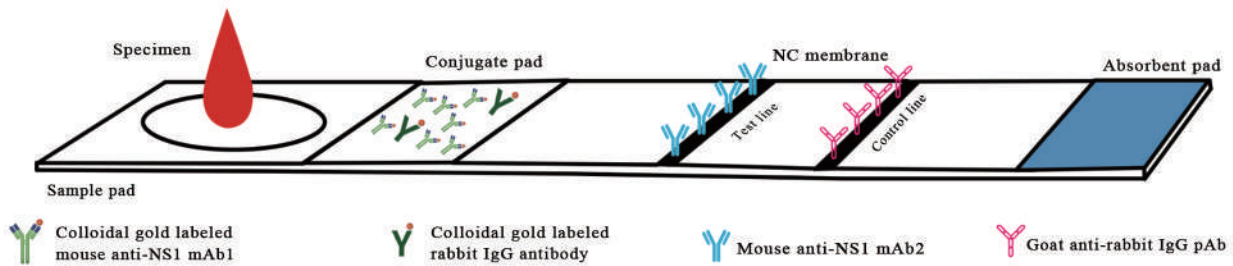


Dengue NS1 Antigen Rapid Test Strip (WB/S/P)

The Dengue NS1 Antigen Rapid Test Strip is a lateral flow chromatographic immunoassay for the qualitative detection of antigens to Dengue viruses in human Whole Blood/Serum/Plasma. It provides an aid in the diagnosis of infection with Dengue viruses.



Principle



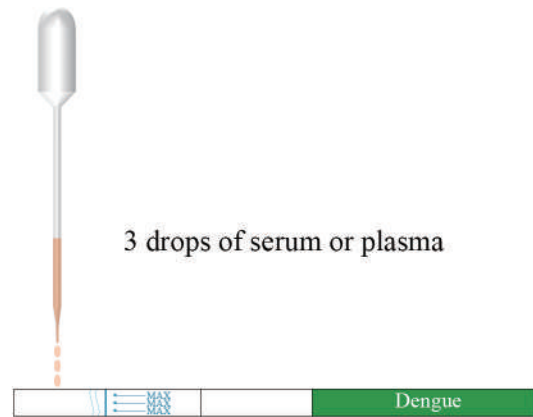
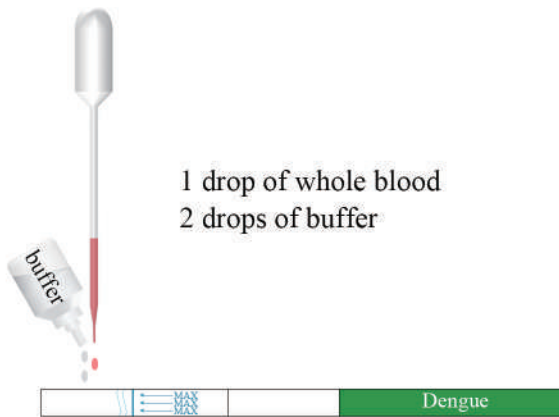
Components



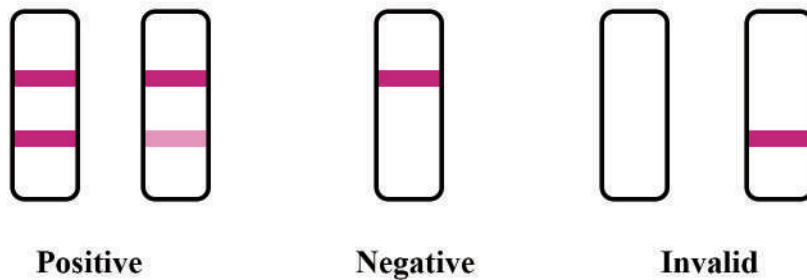
Features



Test Procedure



Interpretation of results



Product Accuracy

1052 clinical specimens from three Professional Point of Care sites were evaluated with the Dengue NS1 Antigen Rapid Test and the commercial kit. The specimens were checked with a commercially available ELISA to confirm the presence of Dengue antigen in the specimens. The summary is as follows:

Agreement with Commercial Dengue Rapid Test

		Commercial Dengue Rapid Test		Total
		Positive	Negative	
CLUNGENE®	Positive	342	1	343
	Negative	2	707	709
Total		344	708	1052

The agreement between these two devices is 99.42% for positive specimens, and 98.86% for negative specimens.

Agreement with ELISA

		ELISA		Total
		Positive	Negative	
CLUNGENE®	Positive	342	1	343
	Negative	2	707	709
Total		344	708	1052

A statistical comparison was made between the results yielding a clinical sensitivity of 99.42%, a clinical specificity of 98.86% and an accuracy of 99.71%.