



Dengue is one of the most prevalent vector-borne viral diseases.

With more than one-third of the world's population living in areas at risk for transmission, dengue infection is a leading cause of illness and death in the tropics and subtropics. As many as 100 million people are infected yearly.

Dengue is caused by any one of the four related viruses transmitted by mosquitoes. There are not yet any vaccines to prevent infection with Dengue virus (DENV) and the most effective protective measure is to avoid mosquito bites. When infected, early recognition and prompt supportive treatment can substantially lower the risk of developing severe disease.

NS1 (non-structural protein 1) is a highly conserved glycoprotein that is essential for the viability of the Dengue virus and is produced both in membrane-associated and secretory forms by the virus. NS1 antigen is present at a high concentration in the blood of dengue virus-infected patients during the early clinical phase of the disease.

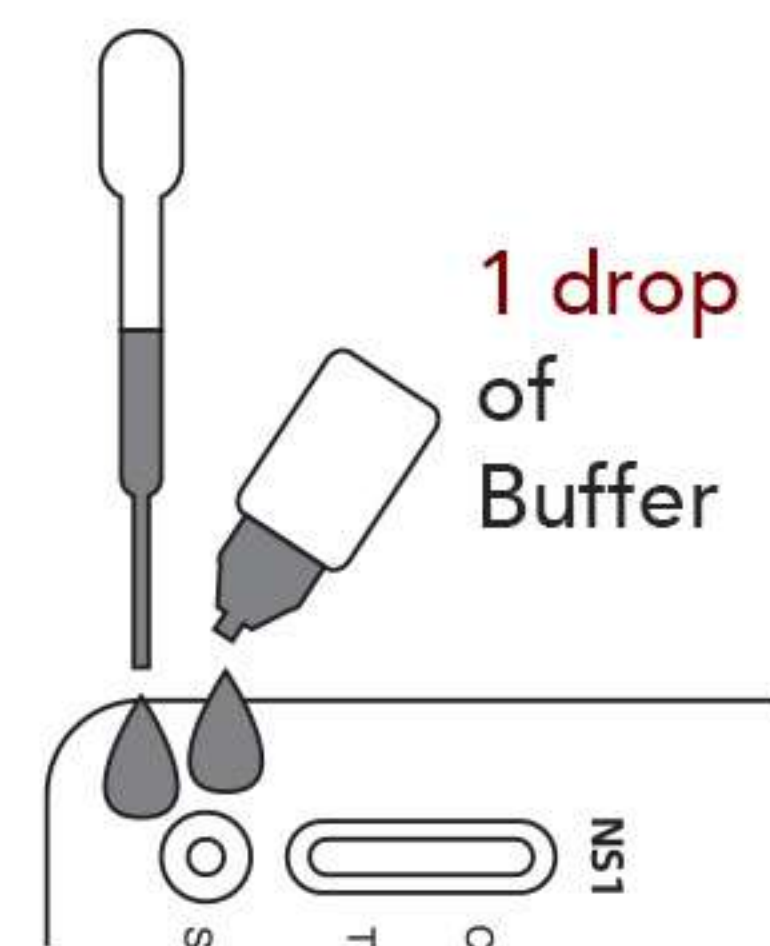
Over half of the world's population is exposed to a potential hazard. The incubation period is usually 4-6 days (up to 3-14 days) followed by abrupt onset of fever, headache, retro-orbital pain, and lumbosacral pain. IgG rises rapidly within 1 to 2 days of symptoms and often exceeds previous levels; IgM may not appear for up to 20 days.

# Dengue NS1/IgG/IgM Test Kit (Colloidal Gold)

## PROCEDURE

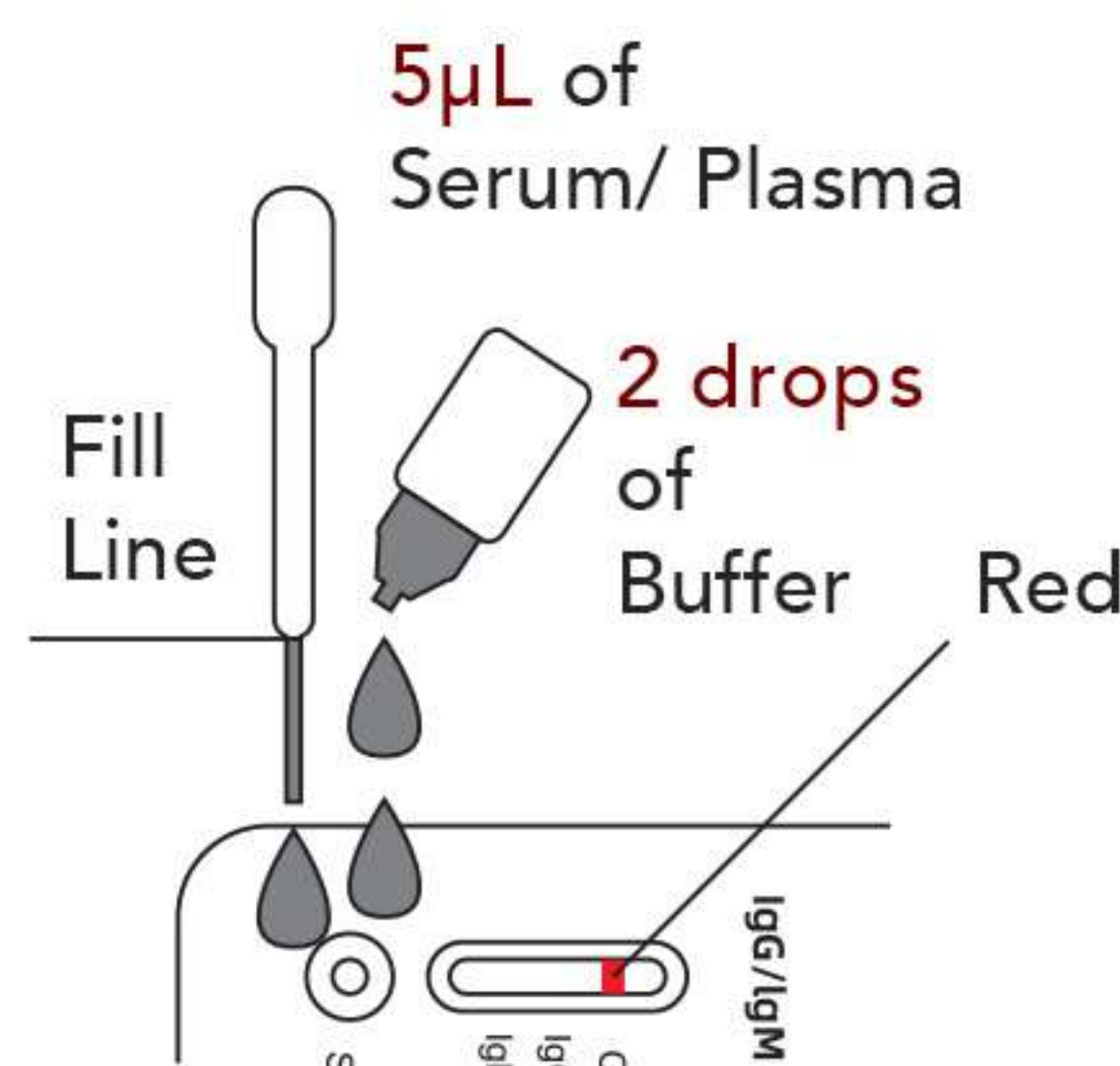
3 drops of Serum/ Plasma/ Whole Blood

Hold the dropper vertically and transfer 3 drops of serum, plasma or whole blood to the specimen well (S) of the test device, then add 1 drop of buffer and start the timer.



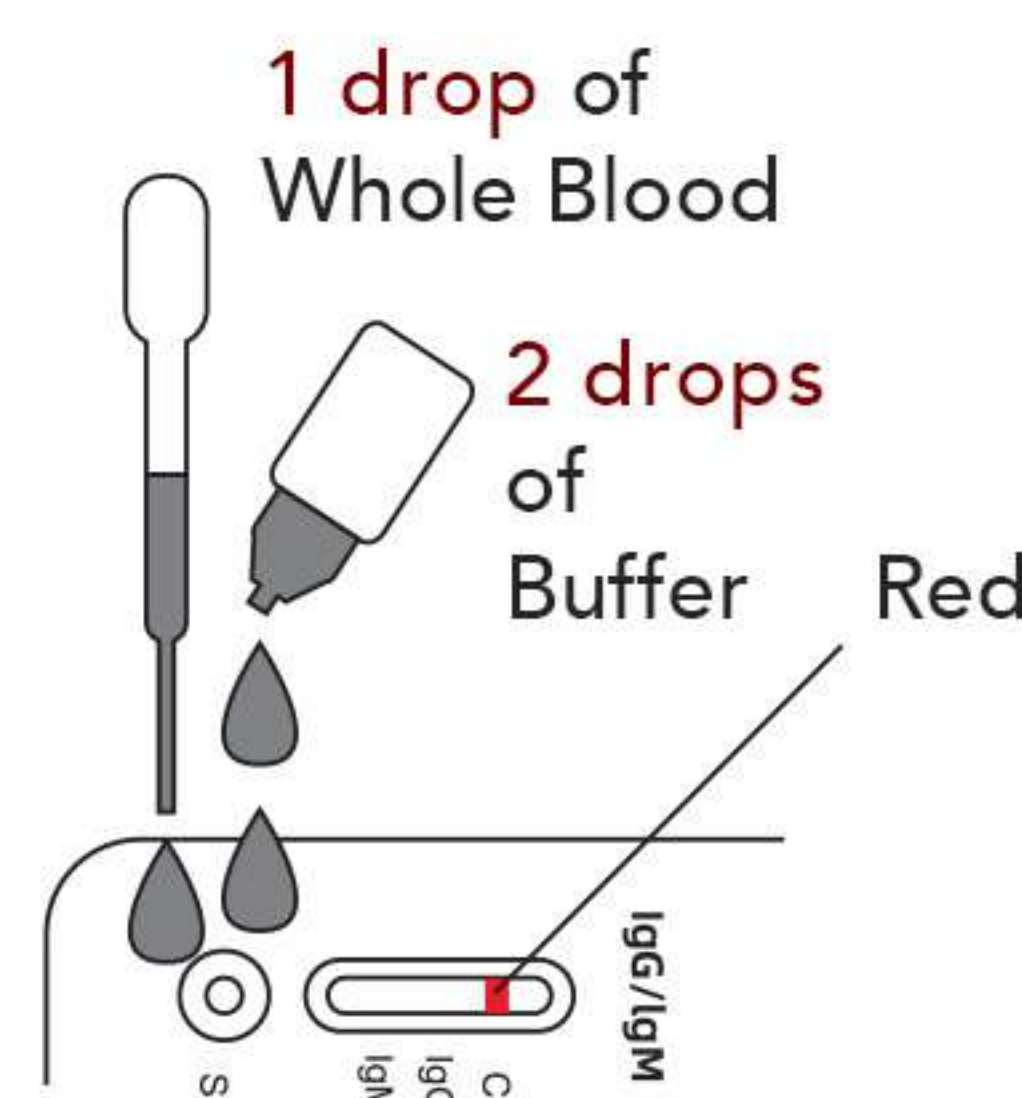
5µL of Serum/ Plasma

Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 5µL), and transfer the specimen to the specimen well (S) of the test device, then add 2 drops of buffer and start the timer. See illustration below. Avoid trapping air bubbles in the specimen well (S).



1 drop of Whole Blood

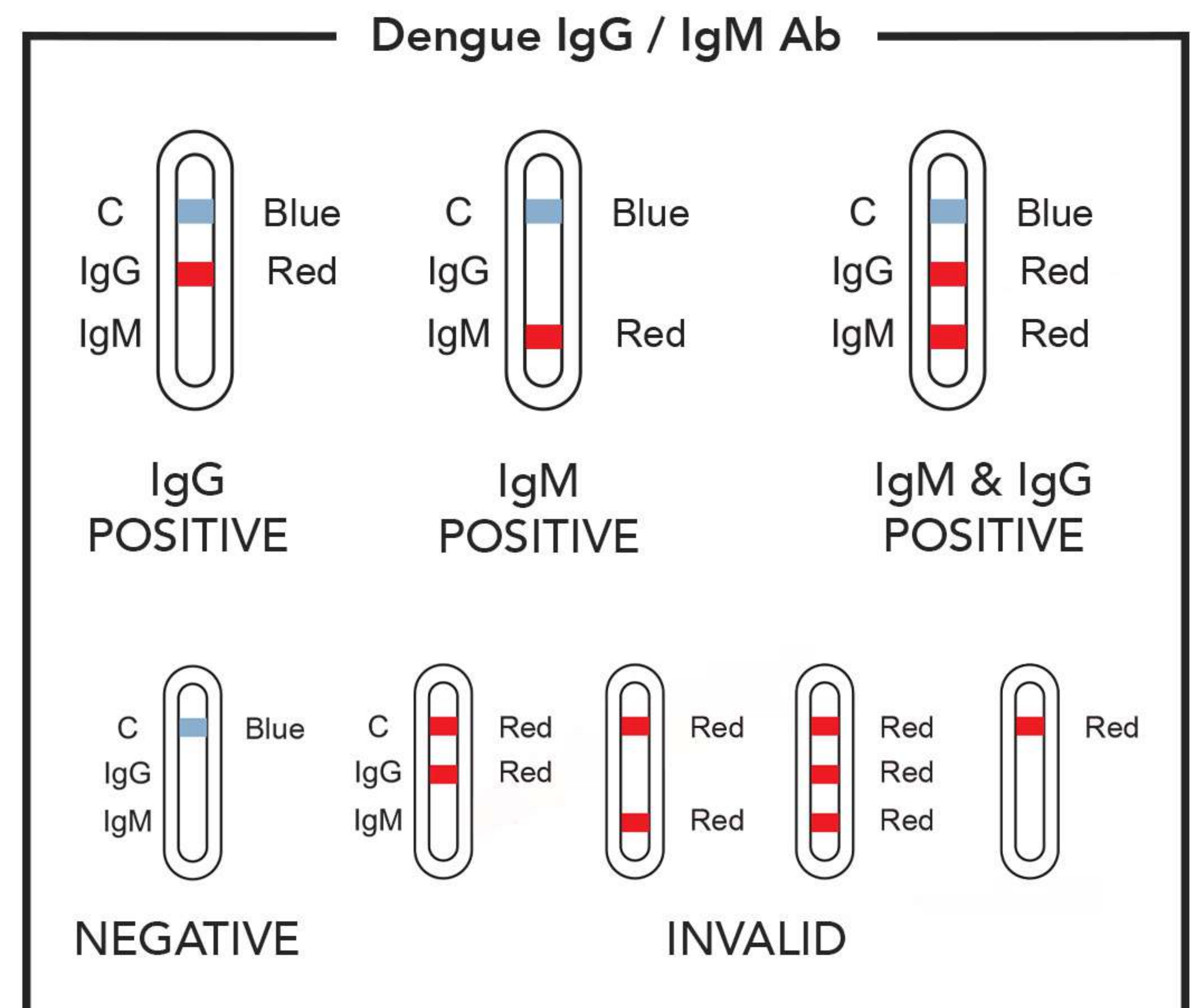
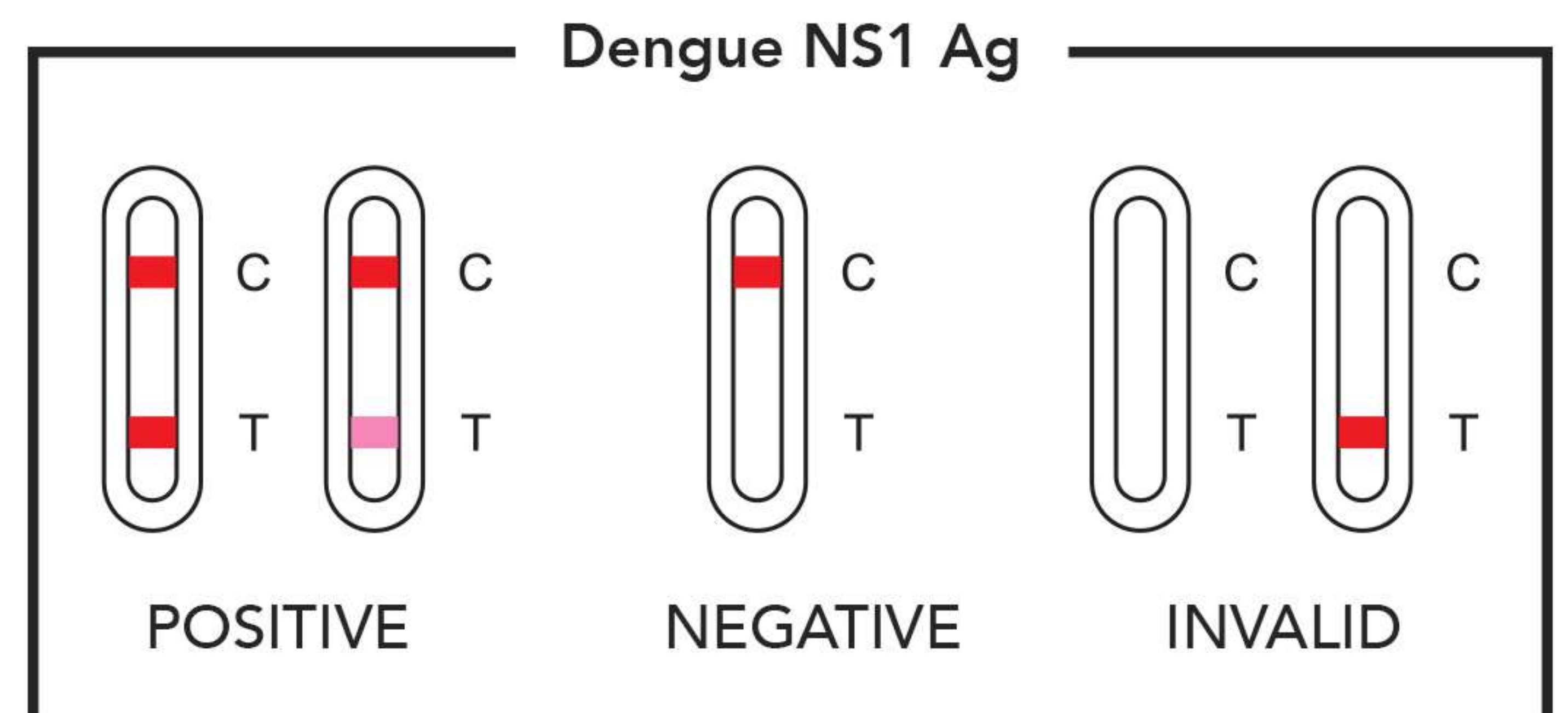
Hold the dropper vertically, draw the specimen 0.5-1cm above the Fill Line, and transfer 1 drop of whole blood to the specimen well (S) of the test device, then add 2 drops of buffer and start the timer.



**15**  
MINUTES

Read results at 15 minutes. Do not interpret the result after 20 minutes.

## INTERPRETATION





# The Dengue Combo Rapid Test

is a rapid chromatographic immunoassay for the qualitative detection of dengue virus NS1 antigen and IgM/ IgG antibodies to dengue virus in whole blood, serum or plasma to aid in the diagnosis of dengue viral infection.

## COMPONENT

TEST DEVICE

DROPPERS

PACKAGE INSERT

BUFFER

STORAGE	SPECIMEN TYPE	TIME TO RESULT	SHELF LIFE
2 - 30°C OR 36 - 86°F	SERUM, PLASMA OR WHOLE BLOOD	15 MINUTES	24 MONTHS

**Dengue  
NS1/ IgG/  
IgM Test Kit  
(Colloidal Gold)**

## ORDERING INFORMATION

TYPE	PACKING SIZE	SPECIMEN
DEVICE	25 TESTS/ BOX	S/P/WB



## PERFORMANCE CHARACTERISTICS

Dengue NS1 Antigen Rapid Test vs EIA

METHOD		DENGUE NS1 EIA		TOTAL RESULTS
DENGUE NS1 ANTIGEN RAPID TEST	RESULTS	POSITIVE	NEGATIVE	
	POSITIVE	66	4	70
	NEGATIVE	3	226	229
TOTAL RESULTS		69	230	299

RELATIVE SENSITIVITY:  
**95.7% (66/69)**  
 RELATIVE SPECIFICITY:  
**98.3% (226/230)**  
 ACCURACY:  
**97.7% (292/299)**

Dengue IgG/ IgM Rapid Test vs ELISA

DENGUE INFECTION	RESULT	IgM	IgG
PRIMARY INFECTION	POSITIVE	14	0
	NEGATIVE	3	17
	TOTAL	17	17
	RELATIVE SENSITIVITY	82.4%	0%
SECONDARY INFECTION	POSITIVE	39	55
	NEGATIVE	16	0
	TOTAL	55	55
	RELATIVE SENSITIVITY	70.9%	>99.0%
NON-DENGUE INFECTION	POSITIVE	0	0
	NEGATIVE	378	378
	TOTAL	378	378
	RELATIVE SENSITIVITY	>99.0%	>99.0%

**PRIMARY &  
SECONDARY  
INFECTION**  
 OVERALL SENSITIVITY:  
**95.8%**  
 OVERALL SPECIFICITY:  
**>99.0%**  
 OVERALL ACCURACY:  
**99.3%**