

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



LYHER®

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.



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.



	Dengue NS1 Test Kit (Colloidal Gold)	Dengue IgG/IgM Test Kit (Colloidal Gold)	Dengue NS1/IgG/IgM Test Kit (Colloidal Gold)
Storage	2 - 30°C / 36-86°F		
Specimen type	Serum , Plasma or Whole blood		
Time to result	15 minutes		
Shelf life	24 months		

## Component

- Test Device
- Droppers
- Package insert
- Buffer

## Performance Characteristics

### Dengue NS1 Antigen Rapid Test vs. EIA

Method	Results	Dengue NS1 EIA		Total results
		Positive	Negative	
Dengue NS1 Antigen Rapid Test	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

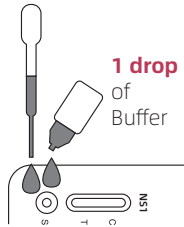
Dengue Infection	Result	IgM	IgG
Primary Infection	Positive	14	0
	Negative	3	17
	Total	17	17
	Relative Sensitivity	82.4%	0%
Secondary Infection	Positive	39	55
	Negative	16	0
	Total	55	55
	Relative Sensitivity	70.9%	>99.0%
Non-Dengue Infection	Positive	0	0
	Negative	378	378
	Total	378	378
	Relative Sensitivity	>99.0%	>99.0%

For the primary and secondary infection, the overall sensitivity is 95.8%, the overall specificity is >99.0% and the overall accuracy is 99.3%.

## Procedure

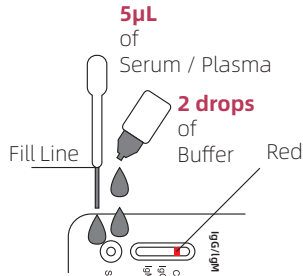
### Dengue NS1 Ag

**3 drops**  
of  
Serum / Plasma / Whole Blood

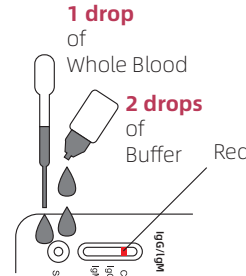


Hold the dropper vertically and transfer 3 drops of serum, plasma or whole blood to the specimen well (S) of the test device, then add 1 drop of buffer and start the timer.

### Dengue IgG / IgM Ab



Hold the dropper vertically, draw the specimen up to the Fill Line (approximately 5 µL), 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).



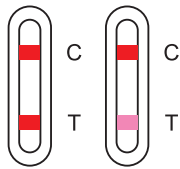
Hold the dropper vertically, draw the specimen 0.5-1 cm above the Fill Line, and transfer 1 drop of whole blood to the specimen well (S) of the test device, then add 2 drops of buffer and start the timer.

**15 minutes**

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

## Interpretation

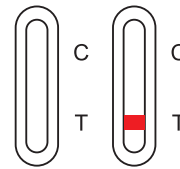
### Dengue NS1 Ag



**POSITIVE**



**NEGATIVE**



**INVALID**

### Dengue IgG / IgM Ab



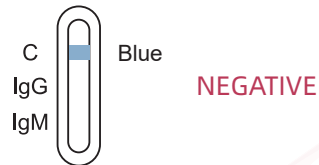
**IgG POSITIVE**



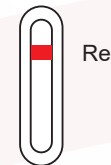
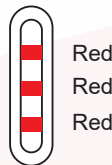
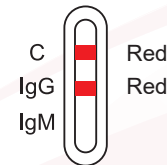
**IgM POSITIVE**



**IgM AND IgG POSITIVE**



**NEGATIVE**



**INVALID**

## Ordering Information

Product	Type	Tests/Kit	Specimen
Dengue NS1 Test Kit (Colloidal Gold)	Device	1T×25/Kit	S/P/WB
Dengue IgG/IgM Test Kit (Colloidal Gold)	Device	1T×25/Kit	S/P/WB
Dengue NS1/IgG/IgM Test Kit (Colloidal Gold)	Device	1T×25/Kit	S/P/WB