

What you can do to support the action against *Leptospirosis*

# SD Leptospirosis Diagnostics

**SD** **BIO** **LINE**  
• *Rapid Test*

Leptospira  
Leptospira IgM  
Leptospira IgG/IgM

**SD**  
• *ELISA*

Leptospira IgM ELISA



# Leptospirosis : Hidden Global Disease



## ► Leptospirosis

- Leptospirosis is a **serious bacterial disease** that occurs all over the world.
- Rodents and other animals are common reservoirs of leptospires.
- Transmission to humans occurs when they come **in contact with water, food or soil** that is contaminated with infected animal urine.

## ► Challenge : One of Neglected Disease

Leptospirosis is a **treatable disease** if it is detected and treated with antibiotics in a timely manner.

### ◉ Problems: Leptospirosis is a major, yet under recognized threat to public health.

- The diagnosis is difficult to confirm. (requires trained technicians)
- It may be confused with other diseases. (e.g. Dengue/Hepatitis/Influenza)
- The disease may be mild and not be investigated in the laboratory.
- Laboratory tests may not be available. (especially in remote area)

## ► Immune Response:

- The incubation period is usually 7-10 days, with a range of 2-30 days
- Humans react to an infection by leptospires by producing specific anti-Leptospira antibodies.
- Seroconversion may occur as early as 3-7 days after the onset of infection but sometimes only after 10 days or longer.
- IgM antibodies usually appear somewhat earlier than IgG antibodies, and generally remain detectable for months or even years but at low titre.
- IgG antibodies may sometimes not be detected at all, or be detectable for only relatively short periods of time.

## ► Diagnosis

### Laboratory Criteria (WHO Recommended)

#### Presumptive diagnosis

A positive result of a rapid screening test such as IgM ELISA, latex agglutination test, lateral flow, dipstick etc.

#### Confirmatory diagnosis

- Isolation from blood or other clinical materials through culture of pathogenic leptospires.
- A positive PCR result using a validated method (primarily for blood and serum in the early stages of infection)
- Fourfold of greater rise in titre or seroconversion in microscopic agglutination test (MAT) on paired samples obtained at least 2 weeks apart. A battery of Leptospira reference strains representative of local strains to be used as antigens in MAT.

# Fast and Easy Diagnosis of Leptospirosis

## SD BIO LINE Leptospira Rapid Test

Qualitative detection of antibody to Leptospira interrogans

- **Leptospira**
- **Leptospira IgM**
- **Leptospira IgG/IgM**
- Easy to use: **No need of any equipment**
- Fast test result: **20 minutes**
- Room temperature storage (1-30 °C)
- Specimen: Whole blood, Serum, Plasma  
-Leptospira IgG/IgM : Serum & Plasma



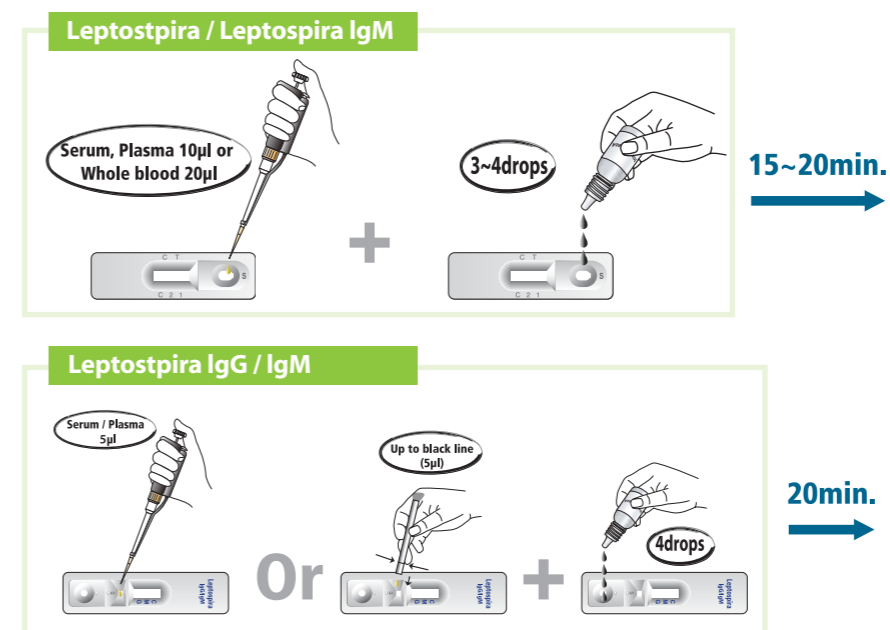
## ► Performance Evaluation

• Used samples : Confirmed by MAT

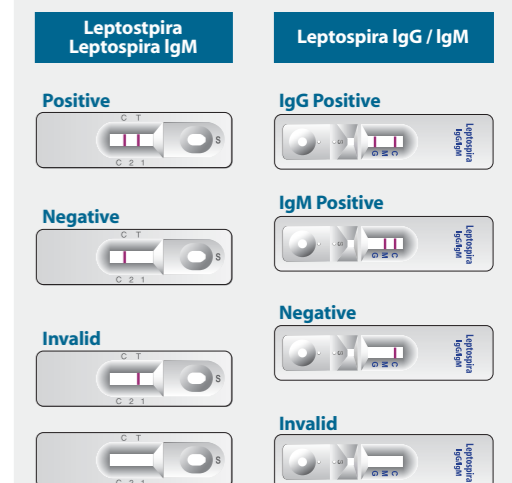
	SD BIOLINE LEPTOSPIRA IgG / IgM			
		Positive	Negative	Total
Samples confirmed by MAT	(+)	44	1	45
	(-)	5	95	100
Total		49	96	145

**Sensitivity : 97.7%**  
**Specificity : 95%**

## ► Test Procedure



## Interpretation



# SD Leptospira IgM ELISA

An enzyme-linked immunosorbent assay for the qualitative detection of IgM antibody against *Leptospira*

- **High Stability** : 12 months at 2-8 °C
- **Simple** assay procedure : Only 2-steps
- **Short** assay time : 30 min - 30min - 10min



## ► Performance Evaluation

• Used samples : Confirmed by MAT

Test Method	Positive samples confirmed by MAT (n=105)		Sensitivity
	Positive	Negative	
SD Leptospira IgM ELISA	102	3	<b>97.2% (102/105)</b>
Commercial Leptospira IgM ELISA	100	5	95.2% (100/105)

Test Method	Negative samples confirmed by MAT (n=347)		Specificity
	Positive	Negative	
SD Leptospira IgM ELISA	3	344	<b>99.1% (344/347)</b>

**Sensitivity : 97.2%**

**Specificity : 99.1%**

## ► Ordering Information

### • Rapid Test

Product	Cat. No.	Description	Type	Test/Kit	Specimen	Storage
Leptospira	16FK10	Leptospira Interrogans antibody test	Device	30T/Kit	S/P/WB	18 months / 1~30 °C
	16FK11		Multi-Device	100T/Kit	S/P/WB	18 months / 1~30 °C
Leptospira IgM	16FK30	Leptospira Interrogans IgM specific test	Device	30T/Kit	S/P/WB	18 months / 1~30 °C
Leptospira IgG/IgM	16FK40	Differential Leptospira IgG/IgM test (3 lines)	Device	30T/Kit	S/P	18 months / 1~30 °C

### • ELISA Kit

Product	Cat. No.	Description	Type	Test/Kit	Specimen	Storage
Leptospira IgM ELISA	16EK10	Leptospira Interrogans IgM specific test	Microplate	96wells/Kit	Serum	12 months / 2~8 °C