Abbott

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SD PRODUCT CATALOG

Ordering

When you place an order, please inform us of full description, product catalog number, unit size, quantity required including any special instructions with the correct billing and shipping address.

Please note that individual products may have different specifications in various markets. Also, some products may not be available in all markets worldwide, only in selected markets.

Cancellation

Any order cancellation should be informed to us within 2 days after placing purchase order. Special custom or large volume orders can not be cancelled at our sole discretion.

Pricing

Prices will be quoted upon request in US Dollars and are subject to change without prior notice. Quantity discounts are available for bulk.

Payment Terms

All orders are prepaid unless prior credit arrangements have been made with our Finance Department. All orders are F.O.B. from our factory. Freight charges and insurance charges are the responsibility of the customer. Prices are subject to change without prior notice.

Shipping

Shipments are made on FCA basis unless otherwise specified. The cost of courier service and special handling if requested shall be the customer's responsibility. Please specify your shipping requirements when placing your order.

Returned Goods Policy

No returns shall be accepted without prior approval from SD in the form of an assigned Return Goods Authorization (RGA) Number. To return unused products in error sent to you, please contact us for a RGA Number and further details.

Product Information and General Enquiries

Further information can be obtained from your distributor
Website: www.abbott.com/poct

SD BIOLINE RAPID DIAGNOSTIC TEST

Item	Product	Cat. No.	Type	Tests /Kit	Specimen	Shelf life	Ref.**	Page
Hepatitis & Blood Borne Diseases	HBsAg	01FK10	Device	30T	S/P	24M		6
		01FK11	Multi-device	100T				
	HBsAg WB	01FK10W	Device	30T	S/P/WB	24M	WHO	
		01FK11W	Multi-device	100T	S/P/WB			
	HBsAg Fast	01FK12	Strip	100T	S/P			
	Anti-HBs	01FK20	Device	30T	S/P			
		01FK21	Multi-device	100T				
	Anti-HBs Fast	01FK22	Strip	100T				
	HBeAg	01FK30	Device	30T	S/P	14M		
	HCV	02FK10	Device	30T	S/P/WB	24M	WHO	7
		02FK11	Multi-device	100T	S/P/WB	24M		
		02FK16	Device	25T	S/P/WB	24M	WHO	
		02FK17	Device	25T	S/P/WB	24M	WHO	
		02FK10CE	Device	30T	S/P/WB	24M	CE	
	HCV Fast	02FK12	Strip	25T	S/P			
	HAV IgG/IgM	13FK10	Device	25T	S/P	24M	CE	8
	HIV-1/2 3.0	03FK10	Device	30T	S/P/WB	24M	WHO	9
		03FK10S	Device	30T	S/P			
		03FK11	Multi-device	100T	S/P/WB			
		03FK12	Strip	25T				
		03FK16	Device	25T			WHO	
		03FK17	Device	25T			WHO	
		03FK10CE	Device	30T			CE	
		03FK10LCE	Device	30T				
		03FK11CE	Multi-Device	100T				
		03FK16CE	Device	25T				
STD (Sexually Transmitted Diseases)	HIV/Syphilis Duo	06FK30	Device	25T	S/P/WB	24M	WHO	10
		06FK35	Device	25T				
		06FK30CE	Device	25T			CE	
		06FK35CE	Device	25T				
	Syphilis 3.0	06FK10	Device	30T	S/P/WB	24M	CE	11
		06FK11	Multi-device	100T			CE	
		06FK12	Strip	25T			CE	
	Chlamydia	09FK10	Device	25T	Endocervical Swab	18M		12
Malaria	Malaria P.f/P.v	05FK30	Device	30T	S/P/WB	18M	CE	13
	Malaria Ag P.f	05FK50	Device	25T	WB	24M	CE/WHO	14
		05FK51	Device, Safety lancet	25T				
		05FK52	POCT, Safety lancet	25T				
		05FK53	POCT	25T				
	Malaria Ag P.f (HRP2/pLDH)	05FK90	Device	25T	WB	24M	CE/WHO	15
		05FK91	Device, Safety lancet	25T				
		05FK92	POCT, Safety lancet	25T				
		05FK93	POCT	25T				
	Malaria Ag P.f/P.v	05FK80	Device	25T	WB	24M	CE/WHO	16
		05FK81	Device, Safety lancet	25T				
		05FK82	POCT, Safety lancet	25T				
		05FK83	POCT	25T				
		05FK86	Device	10T				
	Malaria Ag P.f/P.f/P.v	05FK120	Device	25T	WB	24M	CE/WHO	17
		05FK121	Device, Safety lancet	25T				
		05FK122	POCT, Safety lancet	25T				
		05FK123	POCT	25T				
	Malaria Ag P.f/Pan	05FK60	Device	25T	WB	24M	CE/WHO	18
		05FK61	Device, Safety lancet	25T				
		05FK62	POCT, Safety lancet	25T				
		05FK63	POCT	25T				
		05FK67	POCT	30T				
Dengue	Dengue Duo (NS1 Ag+Ab Combo)	11FK45	Combo-device	10T	S/P/WB	24M	CE	19
		11FK46	Combo-device	25T				
	Dengue NS1 Ag	11FK50	Device	25T	S/P/WB	24M	CE	20
	Dengue IgG/IgM	11FK10	Device	25T	S/P	24M	CE	21
	Dengue IgG/IgM WB	11FK20	Device	25T	S/P/WB	24M		

Item	Product	Cat. No.	Type	Tests /Kit	Specimen	Shelf Life	Ref.**	Page
Other Vector borne Diseases	Zika IgM	12FK20	Device	25T	S/P/WB	18M	CE	22
	Leptospira	16FK10	Device	30T	S/P/WB	18M	CE	23
		16FK11	Multi-device	100T				
	Leptospira IgM	16FK30	Device	30T	S/P/WB	18M	CE	
	Leptospira IgG/IgM	16FK40	Device	30T	S/P	18M	CE	
	Hantaan virus	17FK10	Device	30T	S/P/WB	18M	CE	24
		17FK11	Multi-device	100T				
	Tsutsugamushi (Scrub typhus)	18FK10	Device	30T	S/P/WB	18M	CE	25
		18FK11	Multi-device	100T				
	Chikungunya IgM	46FK10	Device	25T	S/P/WB	24M	CE	26
	JEV IgM	48FK10	Device	25T	S/P	24M	CE	27
	Chagas Ab Rapid	49FK10	Device	25T	S/P/WB	24M	CE	28
	Onchocerciasis IgG_4	61FK10	Device	25T	S/P/WB	24M	CE	29
	Oncho/LF IgG_4 biplex	61FK20	Device	25T	S/P/WB	24M	CE	30
	Lymphatic Filariasis IgG_4	61FK30	Device	25T	S/P/WB	24M	CE	31
	HAT	53FK10	Device	25T	S/P/WB	24M	CE	32
	Leishmania Ab	47FK12	Strip	25T	S/P	24M	CE	33
Respiratory Diseases	Influenza Ag	19FK11	Strip	10T	Nasal/Throat swab, Nasal/ Nasopharyngeal aspirate	24M	CE	34
		19FK12	Strip	25T				
	Influenza Ag A/B/A(H1N1) Pandemic	19FK31	Strip	10T	Nasal/Throat swab, Nasal/ Nasopharyngeal aspirate	24M	CE	35
		19FK32	Strip	25T				
	Influenza Ultra	19FK13	Device	10T	Nasopharyngeal swab, Nasopharyngeal aspirate	24M	CE	36
	RSV	40FK12	Strip	25T	Nasopharygeal aspirate	21M	CE	37
	Strep A	45FK12	Strip	25T	Throat swab	24M	CE	38
	Legionella Ag	58FK10	Device	25T	Urine	24M	CE	39
Tuberculosis	TB Ag MPT64 Rapid	08FK50	Device	25T	Liquid/ Solid cultures	18M	CE	40
Enteric Diseases	H.pylori	04FK10	Device	30T	S/P	24M	CE	41
		04FK11	Multi-device	100T	S/P			
	H.pylori Ag	04FK20	Device	20T	Fecal	24M	CE	42
	Rotavirus	14FK10	Device	20T	Fecal	18M	CE	43
	Rota/Adeno Rapid	14FK20	Device	20T	Fecal	24M	CE	44
	Norovirus	52FK10	Device	20T	Fecal	24M	CE	45
	Salmonella typhi IgG/IgM Fast	15FK12	Strip	25T	S/P/WB	24M	CE	46
	Cholera Ag O1/O139	44FK30	Device	20T	Fecal	24M	CE	47
Other Diseases	Rubella IgG/IgM	07FK20	Device	25T	S/P	24M		48
	EV71 IgM	43FK50	Device	25T	S/P	18M	CE	49
	Tetanus	42FK10	Device	25T	S/P/WB	24M	CE	50
Tumor Marker	AFP	20FK10	Device	30T	S/P	24M	CE	51
		20FK11	Multi-device	100T	S/P	24M	CE	
	CEA	21FK10	Device	30T	S/P	24M	CE	
		21FK11	Multi-device	100T	S/P	24M	CE	
	FOB	25FK10	Device	25T	Fecal	24M	CE	52
		25FK12	Multi-device	50T				
Cardiac Marker	Troponin I	90FK10	Device	25T	S/P/WB	24M	CE	53
	TnI/Myo Duo	95FK10	Device	25T	S/P/WB	18M	CE	54
Women Health	hCG(urine)	30FK10	Device	25T	Urine	24M	CE	55
		30FK12	Strip	100T				
	hCG(urine/serum)	30FK20	Device	25T	Urine/Serum	24M	CE	
	LH	31FK10	Device	25T	Urine	18M		56
DOA (Drug of Abuse)	MOP	50FK10	Device	25T	Urine	24M	CE	57
	MET	50FK20	Device	25T	Urine	24M	CE	
	AMP	50FK30	Device	25T	Urine	24M	CE	
	COC	50FK40	Device	25T	Urine	24M	CE	
	THC	50FK50	Device	25T	Urine	24M	CE	
	MDMA	50FK100	Device	25T	Urine	24M	CE	
	MET/THC	50FK60	Device	25T	Urine	24M	CE	
	DOA Multi-5	50FK150	Multi-device	10T	Urine	24M	CE	
	DOA Multi-6	50FK130	Multi-device	10T	Urine	24M	CE	

S = Serum P = Plasma WB = Whole Blood
** = CE (CE mark) & WHO (Evaluated at WHO or Procurement contract with WHO)

SD ELISA KITS

Item	Product	Cat. No.	Tests/Kit	Specimen	Shelf life	Ref.	Page
Hepatitis	HBsAg ELISA 3.0	01EK10	96T	S/P	12M		59
		01EK11	480T				
	HCV ELISA 3.0	02EK10	96T	S/P	12M		
		02EK11	480T				
Infectious Disease	HIV 1/2 ELISA 3.0	03EK10	96T	S/P	12M		60
		03EK11	480T				
	Malaria Ag ELISA	05EK40	96T	WB	12M	CE	60
		05EK41	480T				
	Dengue IgG Capture ELISA	11EK10	96T	S	18M	CE	61
	Dengue IgM Capture ELISA	11EK20	96T	S	18M	CE	61
	Dengue NS1 Ag ELISA	11EK50	96T	S	18M	CE	62
	Chikungunya IgM ELISA	46EK10	96T	S	12M	CE	62
	Leptospira IgM ELISA	16EK10	96T	S	12M	CE	63
	H.pylori Ag ELISA	04EK20	96T	Fecal	18M	CE	63

SD URINE STRIPS & ANALYZER

Item	Product	Cat. No.	Type	Tests/Kit	Shelf life	Ref.	Page
UroColor	UroColor1G	10UK01G	Strip	100T/bottle	24M	CE	64
	UroColor2 UroColor2K	10UK02 10UK02K	Strip	100T/bottle	24M		
	UroColor3	10UK03	Strip	100T/bottle	24M		
	UroColor4 UroColor4S	10UK04 10UK04S	Strip	100T/bottle	24M		
	UroColor5K	10UK05K	Strip	100T/bottle	24M		
	UroColor10	10UK10	Strip	100T/bottle	24M		
	UroColor11	10UK11	Strip	100T/bottle	24M		
Control	UroColor Control	11UC11	Strip	25T	12M	CE	64
UroMeter	UroMeter 720	UM0720	Instrument	Unit	-		65
	UroMeter 120	UM0120	Instrument	Unit	-		66

SD BIOLINE
RAPID DIAGNOSTIC TEST

Immunochromatographic Assay

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE Hepatitis B series
Hepatitis B Virus Test

HBsAg, Anti-HBs, HBeAg

Hepatitis B is a widespread and serious liver disease. Hundreds of millions of people, most of them in regions with poor medical care, are chronically infected with the virus and face an elevated risk of acquiring liver cancer. The hepatitis B virus (HBV) is made up of an inner core surrounded by an outer capsule. The outer capsule contains the HBsAg (surface antigen). HBeAg is also found within the core. The detection of anti-HBs has become important in the follow up of patients with the Hepatitis B virus (HBV). It is also important when monitoring the recipients of vaccination with recombinant and natural anti-HBs.

General Information

SD BIOLINE Hepatitis tests are intended for professional use as an aid in the diagnosis of hepatitis B. Highly sensitive, specific immunochromatographic assay for detection of HBsAg, Anti-HBs, HBeAg.

	HBsAg	HBsAg WB	Anti-HBs	HBeAg
Specimen	Serum, Plasma	Serum, Plasma, Whole blood	Serum, Plasma	Serum, Plasma
Sensitivity	100 %	100 %	91.7 %	95.5 %
Specificity	100 %	100 %	98.9 %	98.6 %

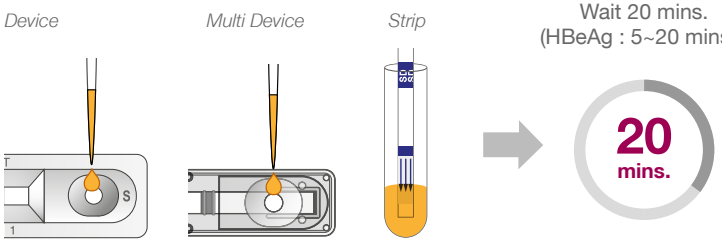
Materials Provided

Test device / Multi-device / Strip

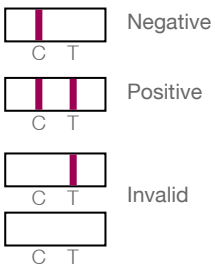
Test Procedure

1 **Add Specimen**

Dispense 100 µl of specimen into the specimen well.



2 **Read Results**



Ordering Information

Product	Cat. No.	Type	Pack Size
HBsAg	01FK10	Device	30T/Kit
HBsAg	01FK11	Multi-Device	10Tx10/Kit
HBsAg Fast	01FK12	Strip	25Tx4/Kit
HBsAg WB	01FK10W	Device	30T/Kit
HBsAg WB	01FK11W	Multi-Device	10Tx10/Kit

Product	Cat. No.	Type	Pack Size
Anti-HBs	01FK20	Device	30T/Kit
Anti-HBs	01FK21	Multi-Device	10Tx10/Kit
Anti-HBs Fast	01FK22	Strip	25Tx4/Kit
HBeAg	01FK30	Device	30T/Kit

SD BIOLINE HCV

Hepatitis C Virus Antibody Test

The Hepatitis C virus (HCV) is recognized as a major agent of chronic hepatitis, transfusion acquired non-A, non-B hepatitis and liver disease throughout the world. HCV diagnostic kits detect the presence of HCV antibodies in human serum, plasma or whole blood by immunoassay. For diagnosis of HCV infection, recombinant proteins (Core, NS3, NS4 and NS5 protein) were used as capture materials and coated on the membrane of an immunochromatographic (rapid) test.

General Information

SD BIOLINE HCV test is a immunochromatographic rapid test for the qualitative detection of antibodies specific to HCV in human serum, plasma or whole blood.

- Recombinant HCV Core, NS3, NS4, NS5 Ag used as capture materials
- Specimen: Serum, Plasma, Whole blood
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity-99.3 %, Specificity-98.1 %

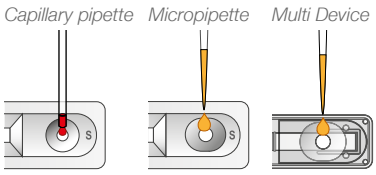
Materials Provided

- Test device / Multi-device / Strip
- Assay diluent
- Option : Lancet, alcohol swab, capillary pipette (for fingerstick)

Test Procedure

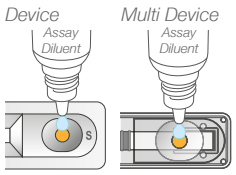
1 Add Specimen

Dispense 10 µl of specimen into the specimen well.



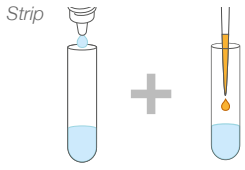
2 Add Assay Diluent

Dispense 4 drops of the assay diluent.



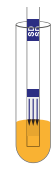
1 Add Assay Diluent and Specimen

Dispense 4 drops of assay diluent to the empty test tube, and then dispense 10µl of serum or plasma to the test tube.



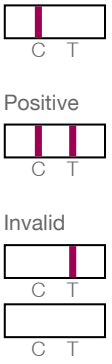
2 Insert Strip

Insert strip into the test tube.



Wait 5-20 mins.

3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
HCV	02FK10	Device	Serum/Plasma/Whole blood	30T/Kit
HCV	02FK11	Multi-Device	Serum/Plasma/Whole blood	10Tx10/Kit
HCV*	02FK16	Device	Serum/Plasma/Whole blood	25T/Kit
HCV**	02FK17	Device	Serum/Plasma/Whole blood	25T/Kit
HCV	02FK10CE	Device	Serum/Plasma/Whole blood	30T/Kit
HCV Fast	02FK12	Strip	Serum/Plasma	25T/Kit

(*) Lancet, Capillary pipette, Alcohol swab included.
(**) Safety lancet, Capillary pipette, Alcohol swab included.

SD BIOLINE HAV IgG/IgM

Hepatitis A Virus Antibody Test

Hepatitis A, one of the oldest diseases known to humankind, is a self-limited disease which results in fulminant hepatitis and death in only a small proportion of patients. However, it is a significant cause of morbidity and socio-economic losses in many parts of the world. Transmission of HAV is typically by the fecal-oral route. Infections occur early in life in areas where sanitation is poor and living conditions are crowded. With improved sanitation and hygiene, infections are delayed and consequently the number of persons susceptible to the disease increases. Under these conditions explosive epidemics can arise from fecal contamination from a single source.

General Information

SD BIOLINE HAV IgG/IgM rapid test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to Hepatitis A virus in human serum or plasma.

- Differential detection of IgG and IgM antibodies
- Specimen: Serum, plasma (5 µl)
- Test result: 20 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity-97.6 %, Spcificity-98.0 %

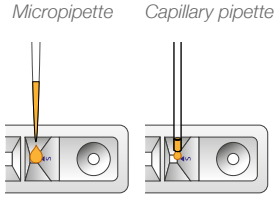
Materials Provided

- Test device
- Assay diluent
- Capillary pipette (5 µl)

Test Procedure

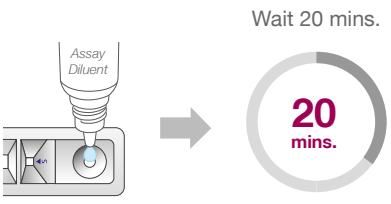
1 **Add Specimen**

Dispense 5 µl of specimen into the specimen well.

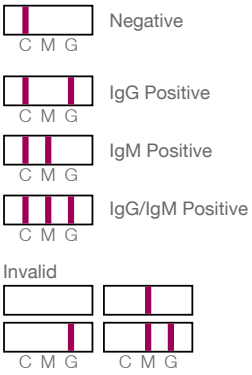


2 **Add Assay Diluent**

Dispense 4 drops of the assay diluent.



3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
HAV IgG/IgM	13FK10	Device	Serum/Plasma	25T/Kit

SD BIOLINE HIV-1/2 3.0

HIV-1/2 Antibody Test

HIV (human immunodeficiency virus) is the virus that causes AIDS. This virus may be passed from one person to another when infected blood, semen or vaginal secretions come in contact with an uninfected person's broken skin or mucous membrane. In addition, infected pregnant women can pass HIV to their baby during pregnancy or delivery as well as through breast-feeding.

General Information

SD BIOLINE HIV-1/2 3.0 test is a immunochromatographic test for the differential and qualitative detection of all isotypes (IgG, IgM, IgA) antibodies specific to HIV-1 including subtype O and HIV-2 simultaneously, in human serum, plasma or whole blood.

- The 3rd Generation Method
- Differentiated test result between HIV type I and II by clear band formation (3-lines)
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30°C
- Performance: Sensitivity-100 %, Specificity-99.8 %

Materials Provided

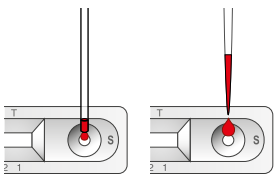
- Test device / Multi-device / Strip
- Assay diluent
- Option : Lancet, alcohol swab and capillary pipette (for whole blood)

Test Procedure

- Dispense plasma, serum (10 µl) or whole blood (20 µl) into the specimen well "S".
- Interpret test results at 10-20 minutes.

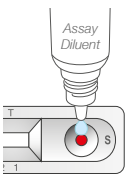
1 **Add Specimen**

Capillary pipette *Micropipette*

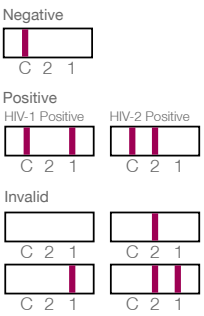


2 **Add Assay Diluent**

Dispense 4 drops of the assay diluent.



3 **Read Results**



Ordering Information

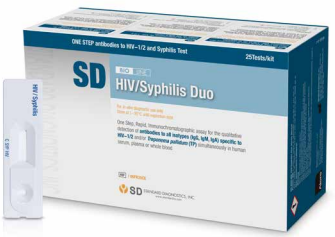
Product	Cat. No.	Type	Pack Size
HIV-1/2 3.0	03FK10	Device	30T/Kit
HIV-1/2 3.0	03FK11	Multi-Device	10Tx10/Kit
HIV-1/2 Fast 3.0	03FK12	Strip	25T/Kit
HIV-1/2 3.0***	03FK16	Device	25T/Kit
HIV-1/2 3.0	03FK10CE	Device	30T/Kit

Product	Cat. No.	Type	Pack Size
HIV-1/2 3.0*	03FK10LCE	Device	30T/Kit
HIV-1/2 3.0	03FK11CE	Multi-Device	10Tx10/Kit
HIV-1/2 3.0**	03FK16CE	Device	25T/Kit
HIV-1/2 3.0	03FK10S	Device	30T/Kit
HIV-1/2 3.0****	03FK17	Device	25T/Kit

(*) Lancet included.
(**) Lancet, Capillary pipette included.
(***) Lancet, Capillary pipette, Alcohol swab included.
(****) Safety lancet, Capillary pipette, Alcohol swab included.

SD BIOLINE HIV/Syphilis Duo

Simultaneous Detection of HIV-1/2 and Syphilis Antibodies Test



HIV and Syphilis are the major public health problems affecting women and their newborn infants in the world. Over a million women and families are having to face the trauma of repeated pregnancy loss, stillbirth, or child born infected with and suffering from HIV and Syphilis

General Information

SD BIOLINE HIV/Syphilis Duo test is a solid phase immunochromatographic assay for the qualitative detection of antibodies to all isotypes (IgG, IgM, and IgA) specific to HIV-1/2 and/or *Treponema pallidum (TP)* simultaneously in human serum, plasma or whole blood.

- Optimal screening test for HIV and syphilis during antenatal care
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance:
  - HIV: Sensitivity-100 % / Specificity-100 %
  - Syphilis: Sensitivity-100 % / Specificity-99.1 %

Materials Provided

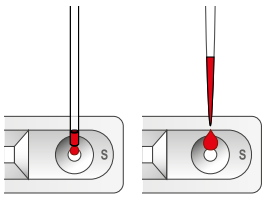
- Test device
- Assay diluent
- Option : Lancet, alcohol swab, capillary pipette

Test Procedure

- Dispense plasma, serum (10 µl) or whole blood (20 µl) into the specimen well "S".

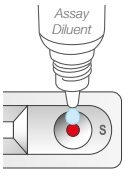
1 Add Specimen

Micropipette *Capillary pipette*



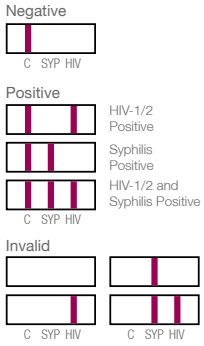
2 Add Assay Diluent

Dispense 3 drops of the assay diluent.



Wait 15-20mins.

3 Read Results



Ordering Information

Procduct	Cat. No.	Type	Specimen	Pack Size
HIV/Syphilis Duo	06FK30	Device	Serum/Plasma/Whole blood	25T/Kit
HIV/Syphilis Duo*	06FK35	Device	Serum/Plasma/Whole blood	25T/Kit
HIV/Syphilis Duo	06FK30CE	Device	Serum/Plasma/Whole blood	25T/Kit
HIV/Syphilis Duo*	06FK35CE	Device	Serum/Plasma/Whole blood	25T/Kit

(*) Lancet, Capillary pipette, Alcohol swab included.

SD BIOLINE Syphilis 3.0

Syphilis Antibody test

Syphilis is a curable sexually transmitted disease caused by the *Treponema pallidum* spirochete The route of transmission of syphilis is almost always by sexual contact. However, there are examples of congenital syphilis via transmission from mother to child in utero.

General Information

SD BIOLINE Syphilis 3.0 test is a solid phase immunochromatographic assay for the qualitative detection of antibodies of all isotypes (IgG, IgM, IgA) against *Treponema pallidum (TP)* in human serum, plasma or whole blood.

- Qualitative immunochromatographic assay
- The optimal choice for mass screening program
- No need preprocessing and equipment
- Shelf life and storage temperature: 24 months from the date of manufacturing at 2-30 °C
- Performance: Sensitivity-99.3 %, Specificity-99.5 % (vs TPHA)

Materials Provided

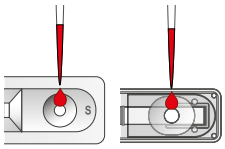
- Test device / Multi-device / Strip
- Assay diluent
- Option: Lancet, alcohol swab, capillary pipette

Test Procedure

1 Add Specimen

Device *Multi Device*

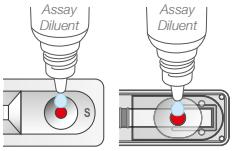
Dispense 10 µl of plasma, serum or 20 µl of whole blood into the specimen well.



2 Add Assay Diluent

Device *Multi Device*

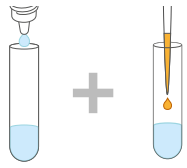
Dispense 4 drops of the assay diluent.



1 Add Assay Diluent and Specimen

Add 10µl of serum or plasma or 20µl of whole blood to the empty test tube, and then add 4 drops of assay diluent to the test tube.

Strip



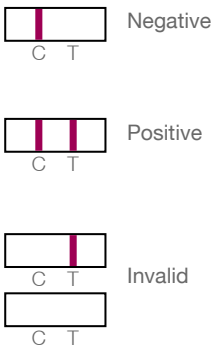
2 Insert Strip

Insert strip into the test tube.

Strip

Wait 5-20 mins.

3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Syphilis 3.0	06FK10	Device	Serum/Plasma/Whole blood	30T/Kit
Syphilis 3.0	06FK11	Multi-Device	Serum/Plasma/Whole blood	10Tx10/Kit
Syphilis Fast 3.0	06FK12	Strip	Serum/Plasma/Whole blood	25T/Kit

SD BIOLINE Chlamydia

Chlamydia Antigen Test

Chlamydia trachomatis is a bacterium which causes a sexually transmitted infection(STI). Chlamydia is a very common disease, which should be taken very seriously. The most worrying effect of a chlamydial infection in women is that of potential fertility problems (PID, infertility, etc.), due to inflammation of the fallopian tubes or cervix. The disease is particularly common among young people.

General Information

SD BIOLINE Chlamydia test is a solid phase immunochromatographic assay for the rapid, qualitative detection of Chlamydia antigen directly from endocervical swab, cytology brush specimens.

- All materials provided, Ready to use reagent
- Shelf life and storage temperature: 18 months from the date of manufacturing at 2-30 °C
- Performance: Sensitivity-93.1 %, Specificity-98.8 % (vs. culture)

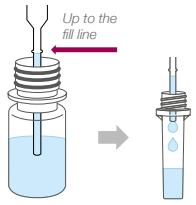
Materials Provided

- Test device
- Reagent A (Extraction solution)
- Reagent B (Neutralization solution)
- Sterile swab and transport tube
- Disposable dropper

Test Procedure

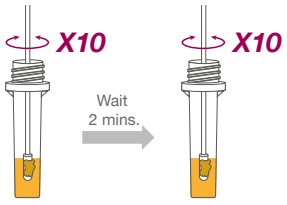
1 Add Reagent A

Transfer 300 µl of Reagent A.



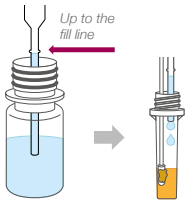
2 Add Specimen and Extraction

Insert the patient swab into the tube.



3 Add Reagent B

Transfer 600 µl of Reagent B.



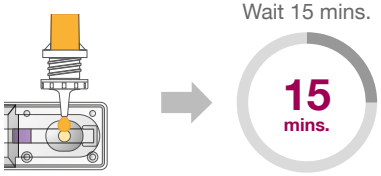
4 Mix Specimen

5 Assemble dropping cap

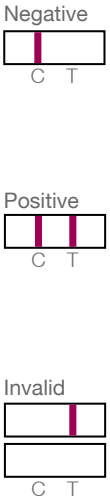
Assemble dropping cap on the specimen collection tube.

6 Add Specimen

Dispense 3 drops of the extracted specimen.



7 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Chlamydia	09FK10	Device	Endocervical swab, Cytology brush	25T/Kit

SD BIOLINE Malaria P.f/P.v

Malaria P.f/P.v Antibody Test

Malaria is a serious and sometimes fatal parasitic disease characterized by fever, chills and anemia. The disease is caused by a parasite that is transmitted from one human to another through the bite of infected *Anopheles* mosquitoes. The disease now occurs in 95 countries worldwide, and it is estimated that there are over 214 million clinical cases and 438,000 malaria-caused deaths in 2015, 95 % of them are African children. The infection with *P. falciparum,* if not promptly treated, may be fatal.

General Information

SD BIOLINE Malaria P.f/P.v test is a qualitative immunochromatographic rapid test for detection of antibodies of all isotypes (IgG, IgM, IgA) specific to *Plasmodium falciparum* and *Plasmodium vivax* simultaneously in human serum, plasma or whole blood.

- Differentiated test results between *P. falciparum* and *P. vivax*
- Specimen : Serum, Plasma, Whole Blood
- Shelf life and storage temperature: 18 months from the date of manufacturing at 2-30 °C
- Performance:
  - Malaria P.f: Sensitivity-87 %, Specificity-99.5 %
  - Malaria P.v: Sensitivity-86 %, Specificity-99.5 %

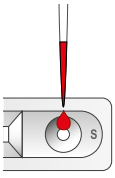
Materials Provided

- Test device
- Assay diluent

Test Procedure

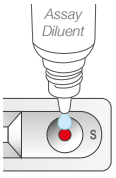
1 Add Specimen

Dispense serum, plasma (10 µl) or whole blood (20 µl) into the specimen well "S".



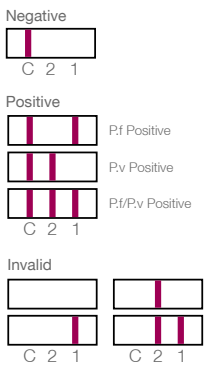
2 Add Assay Diluent

Dispense 3-4 drops of the assay diluent.



Wait 5-20 mins.

3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Malaria P.f/P.v	05FK30	Device	Serum/Plasma/Whole blood	30T/Kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE Malaria Ag P.f
Malaria Antigen P.f (HRP-II) Test

Malaria is a serious and sometimes fatal parasitic disease characterized by fever, chills and anemia. The disease is caused by a parasite that is transmitted from one human to another through the bite of infected *Anopheles* mosquitoes. The disease now occurs in 95 countries worldwide, and it is estimated that there are over 214 million clinical cases and 438,000 malaria-caused deaths in 2015, 95 % of them are African children. The infection with *P. falciparum,* if not promptly treated, may be fatal.

General Information
SD BIOLINE Malaria Ag P.f test is rapid, qualitative detection of HRP-II (Histidine-rich protein II) specific to *P. falciparum* in human blood specimen.

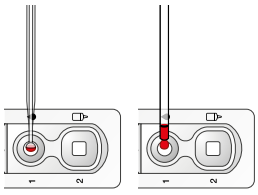
- Specific and accurate diagnosis specific for *P. falciparum*
- WHO prequalified
- Specimen : Whole blood (5 µl)
- Test result : 15 minutes (up to 30 minutes)
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-40 °C
- Performance: Sensitivity-99.7 %, Specificity-99.5 %

Materials Provided
- Test device
- Assay diluent
- Disposable specimen applicator (Capillary Pipette, Inverted cup)
- Option : Lancet, alcohol swab

Test Procedure
1 **Add Specimen**

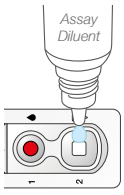
Dispense 5 µl of whole blood into the round specimen well.

Inverted cup *Capillary pipette*



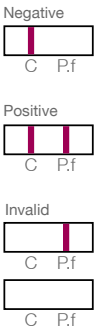
2 **Add Assay Diluent**

Dispense 4 drops of assay diluent into the square assay diluent well.



Wait 15 mins.
(up to 30 minutes)

3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Malaria Ag P.f	05FK50	Device	Whole blood	25T/Kit
Malaria Ag P.f	05FK51	Device, Safety lancet	Whole blood	25T/Kit
Malaria Ag P.f	05FK52	Device (POCT), Safety lancet	Whole blood	1Pack X 25/Kit
Malaria Ag P.f	05FK53	Device (POCT)	Whole blood	1Pack X 25/Kit

SD BIOLINE Malaria Ag P.f (HRP2/pLDH)

Malaria Antigen P.f (HRP2/pLDH) Test

Malaria is a serious and sometimes fatal parasitic disease characterized by fever, chills and anemia. The disease is caused by a parasite that is transmitted from one human to another through the bite of infected *Anopheles* mosquitoes. The disease now occurs in 95 countries worldwide, and it is estimated that there are over 214 million clinical cases and 438,000 malaria-caused deaths in 2015, 95 % of them are African children. The infection with *P. falciparum,* if not promptly treated, may be fatal.

General Information

The SD BIOLINE Malaria Ag P.f (HRP2/pLDH) test is a rapid, qualitative test for the detection of histidine-rich protein II (HRP-II) antigen and lactate dehydrogenase (pLDH) from Malaria *P. falciparum* in human whole blood.

- Reducing the false positive rates after treatment
- Useful for the region where *P.f* HRP2 gene deletion suspected
- WHO prequalified
- Specimen : Whole blood (5 µl)
- Test result : 15 minutes (up to 30 minutes)
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-40 °C
- Performance:
  - P.f (HRP-II) : Sensitivity-99.7 %, Specificity-99.3 %
  - P.f (pLDH) : Sensitivity-97.4 %, Specificity-99.7 %

Materials Provided

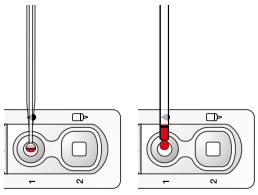
- Test device
- Assay diluent
- Disposable specimen applicator (Capillary Pipette, Inverted cup)
- Option : Lancet, alcohol swab

Test Procedure

1 **Add Specimen**

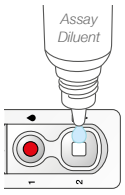
Dispense 5 µl of whole blood into the round specimen well.

Inverted cup *Capillary pipette*



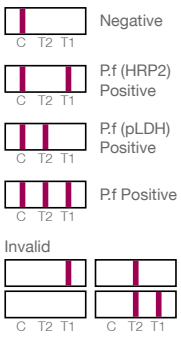
2 **Add Assay Diluent**

Dispense 4 drops of assay diluent into the square assay diluent well.



Wait 15 mins.
(up to 30 minutes)

3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Malaria Ag P.f (HRP2/pLDH)	05FK90	Device	Whole blood	25T/Kit
Malaria Ag P.f (HRP2/pLDH)	05FK91	Device, Safety lancet	Whole blood	25T/Kit
Malaria Ag P.f (HRP2/pLDH)	05FK92	Device (POCT), Safety lancet	Whole blood	1Pack X 25/Kit
Malaria Ag P.f (HRP2/pLDH)	05FK93	Device (POCT)	Whole blood	1Pack X 25/Kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE Malaria Ag P.f/P.v
Malaria Antigen P.f/P.v(HRP-II/pLDH) Test

Malaria is a serious and sometimes fatal parasitic disease characterized by fever, chills and anemia. The disease is caused by a parasite that is transmitted from one human to another through the bite of infected *Anopheles* mosquitoes. The disease now occurs in 95 countries worldwide, and it is estimated that there are over 214 million clinical cases and 438,000 malaria-caused deaths in 2015, 95 % of them are African children. The infection with *P. falciparum,* if not promptly treated, may be fatal.

General Information
SD BIOLINE Malaria Ag P.f/P.v test is a rapid, qualitative test for the detection of HRP-II (Histidine-rich protein II) specific to *Plasmodium falciparum* and Plasmodium lactate dehydrogenase (pLDH) specific to *Plasmodium vivax*.

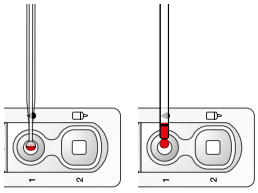
- Differential diagnosis between *Plasmodium falciparum* and *Plasmodium vivax*
- Useful for the region where *P.v* and *P.f* are both dominant
- Differentiate *P.f* mono infection from *P.f/P.v* co-infection
- WHO prequalified
- Specimen : Whole blood (5 µl)
- Test result : 15 minutes (up to 30 minutes)
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-40 °C
- Performance:
  - P.f (HRP-II) : Sensitivity-99.7 %, Specificity-99.5 %
  - P.v (pLDH) : Sensitivity-95.5 %, Specificity-99.5 %

Materials Provided
- Test device
- Assay diluent
- Disposable specimen applicator (Capillary Pipette, Inverted cup)
- Option : Lancet, alcohol swab

Test Procedure
1 Add Specimen

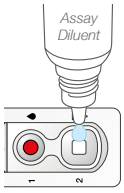
Dispense 5 µl of whole blood into the round specimen well.

Inverted cup *Capillary pipette*



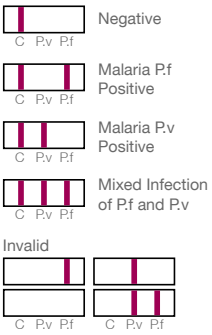
2 Add Assay Diluent

Dispense 4 drops of assay diluent into the square assay diluent well.



Wait 15 mins.
(up to 30 minutes)

3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Malaria Ag P.f/P.v	05FK80	Device	Whole blood	25T/Kit
Malaria Ag P.f/P.v	05FK81	Device, Safety lancet	Whole blood	25T/Kit
Malaria Ag P.f/P.v	05FK82	Device (POCT), Safety lancet	Whole blood	1Pack X 25/Kit
Malaria Ag P.f/P.v	05FK83	Device (POCT)	Whole blood	1Pack X 25/Kit
Malaria Ag P.f/P.v	05FK86	Device	Whole blood	10T/Kit

SD BIOLINE Malaria Ag P.f/P.f/P.v

Malaria Antigen P.f(HRP-II/pLDH) & P.v (pLDH) Test

Malaria is a serious and sometimes fatal parasitic disease characterized by fever, chills and anemia. The disease is caused by a parasite that is transmitted from one human to another through the bite of infected *Anopheles* mosquitoes. The disease now occurs in 95 countries worldwide, and it is estimated that there are over 214 million clinical cases and 438,000 malaria-caused deaths in 2015, 95 % of them are African children. The infection with *P. falciparum,* if not promptly treated, may be fatal.

General Information

SD BIOLINE Malaria Ag P.f/P.f/P.v test is rapid, qualitative and differential test for the detection of HRP-II and pLDH from *P. falciparum* and pLDH from *P. vivax* in human whole blood.

- Useful for the region where *P.v* and *P.f* are both dominant
- Identify false positive by *P.f* HRP-II after treatment
- Useful for the region where *P.f* HRP2 gene deletion suspected
- Differentiate *P.f* mono infection from *P.f/P.v* co-infection
- WHO prequalified
- Specimen : Whole blood (5 µl)
- Test result : 15 minutes (up to 30 minutes)
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-40 °C
- Performance:
  - P.f (HRP-II) : Sensitivity-99.7 %, Specificity-99.3 %
  - P.f (pLDH) : Sensitivity-97.4 %, Specificity-99.3 %
  - P.v (pLDH) : Sensitivity-95.5 %, Specificity-99.3 %

Materials Provided

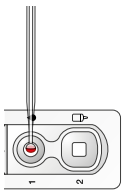
- Test device
- Assay diluent
- Disposable specimen applicator (Inverted cup)
- Option : Lancet, alcohol swab

Test Procedure

1 Add Specimen

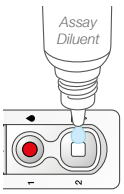
Dispense 5 µl of whole blood into the round specimen well.

Inverted cup



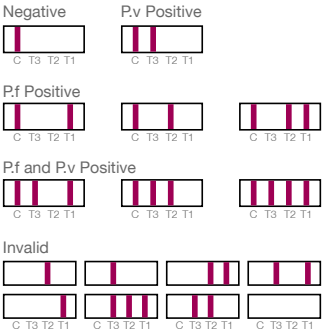
2 Add Assay Diluent

Dispense 4 drops of assay diluent into the square assay diluent well.



Wait 15mins.
(up to 30 minutes)

3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Malaria Ag P.f/P.f/P.v	05FK120	Device	Whole blood	25T/Kit
Malaria Ag P.f/P.f/P.v	05FK121	Device, Safety lancet	Whole blood	25T/Kit
Malaria Ag P.f/P.f/P.v	05FK122	Device (POCT), Safety lancet	Whole blood	1Pack X 25/kit
Malaria Ag P.f/P.f/P.v	05FK123	Device (POCT)	Whole blood	1Pack X 25/kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE Malaria Ag P.f/Pan
Malaria Antigen P.f/Pan (HRP-II/pLDH) Test

Malaria is a serious and sometimes fatal parasitic disease characterized by fever, chills and anemia. The disease is caused by a parasite that is transmitted from one human to another through the bite of infected *Anopheles* mosquitoes. The disease now occurs in 95 countries worldwide, and it is estimated that there are over 214 million clinical cases and 438,000 malaria-caused deaths in 2015, 95 % of them are African children. The infection with *P. falciparum,* if not promptly treated, may be fatal.

General Information
SD BIOLINE Malaria Ag P.f/Pan test is rapid, qualitative and differential test for the detection of HRP-II specific to *P. falciparum* and pLDH specific to Malaria plasmodium (*P.f, P.v, P.m* and *P.o*) in human blood.

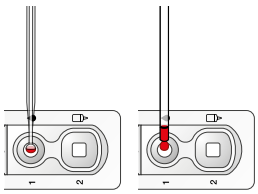
- Distinguish the *P.f* infection from other species (*P.v, P.m* or *P.o*)
- Useful for the region where all malaria species are circulated
- WHO prequalified
- Specimen : Whole blood (5 µl)
- Test result : 15 minutes (up to 30 minutes)
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-40 °C
- Performance:
  - P.f (HRP-II) : Sensitivity-99.7 %, Specificity-99.5 %
  - Pan (pLDH) : Sensitivity-95.5 %, Specificity-99.5 %

Materials Provided
- Test device
- Assay diluent
- Disposable specimen applicator (Capillary Pipette, Inverted cup)
- Option : Lancet, alcohol swab

Test Procedure
1 Add Specimen

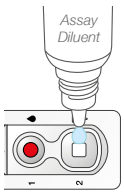
Dispense 5 µl of whole blood into the round specimen well.

Inverted cup *Capillary pipette*



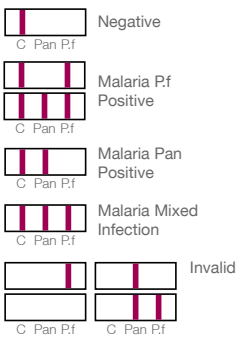
2 Add Assay Diluent

Dispense 4 drops of assay diluent into the square assay diluent well.



Wait 15 mins.
(up to 30 minutes)

3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Malaria Ag P.f/Pan	05FK60	Device	Whole blood	25T/Kit
Malaria Ag P.f/Pan	05FK61	Device, Safety lancet	Whole blood	25T/Kit
Malaria Ag P.f/Pan	05FK62	Device (POCT), Safety lancet	Whole blood	1Pack X 25/kit
Malaria Ag P.f/Pan	05FK63	Device (POCT)	Whole blood	1Pack X 25/kit
Malaria Ag P.f/Pan	05FK67	Device (POCT)	Whole blood	1Pack X 30/kit

SD BIOLINE Dengue Duo

Simultaneous Dengue NS1 Ag & IgG/IgM Ab Test

Dengue is a mosquito-borne viral disease that has rapidly spread in all regions of WHO in recent years. Dengue virus is transmitted by female mosquitoes mainly of the species *Aedes aegypti* and, to a lesser extent, *Ae. albopictus*. Today, severe dengue affects most Asian and Latin American countries and has become a leading cause of hospitalization and death among children and adults in these regions. The incidence of dengue has grown dramatically around the world in recent decades; 390 million dengue infections per year of which 96 million manifest clinically.

General Information

SD BIOLINE Dengue Duo is immunochromatographic assay designed to detect both dengue virus NS1 antigen and IgG/IgM antibodies against dengue virus in human whole blood, serum or plasma.

- The most perfect diagnostic tool to cover all clinical stage form acute phase to convalescence phase
- Presumptive differentiation between primary & secondary dengue infections
- Easy to use rapid test (Test result : 15~20 minutes)
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C

Item	Dengue NS1 Ag test	Dengue IgG/IgM test
Position	Left side	Right side
Use	Detection of dengue virus NS1 antigen	Detection of IgG and IgM antibodies to dengue virus
Purpose	Diagnosis of early acute dengue infection	The presumptive diagnosis between primary and secondary dengue infection.
Sensitivity	92.4 %	94.2 %
Specificity	98.4 %	96.4 %
Compared method	RT-PCR	ELISA

Materials Provided

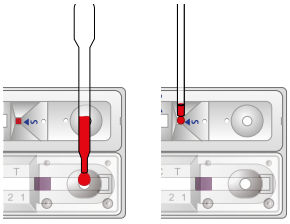
- Test device
- Assay diluent for Dengue IgG/IgM test
- Capillary pipette for dengue IgG/IgM test
- Disposable dropper for dengue NS1 Ag test

Test Procedure

1 Add Specimen

Add specimen (NS1 Ag-3 drops, IgG/IgM-10 µl) into the specimen well "S".

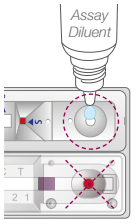
Dengue NS1 Ag *Dengue IgG/IgM*



2 Add Assay Diluent

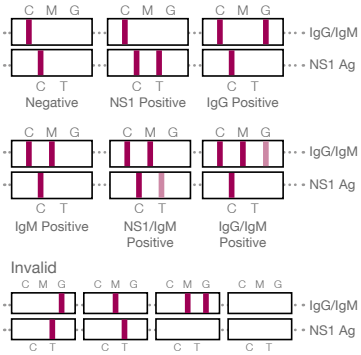
Dispense 4 drops of assay diluent into the round well.

Dengue IgG/IgM



Wait 15-20 mins.

3 Read Results



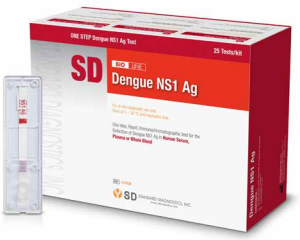
Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Dengue Duo	11FK45	Combo-Device	Serum/Plasma/Whole Blood	10T/Kit
Dengue Duo	11FK46	Combo-Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE Dengue NS1 Ag

Dengue NS1 Antigen Test

Dengue is a mosquito-borne viral disease that has rapidly spread in all regions of WHO in recent years. Dengue virus is transmitted by female mosquitoes mainly of the species *Aedes aegypti* and, to a lesser extent, *Ae. albopictus*. Today, severe dengue affects most Asian and Latin American countries and has become a leading cause of hospitalization and death among children and adults in these regions. The incidence of dengue has grown dramatically around the world in recent decades; 390 million dengue infections per year of which 96 million manifest clinically.



General Information

SD BIOLINE Dengue NS1 Ag test is an *in vitro* immunochromatographic, assay designed to detect Dengue virus NS1 antigen in human serum, plasma or whole blood.

- Diagnosis of early acute dengue infection from 1 day onset of fever
- Specimen : Serum, plasma or whole blood (100 µl)
- Test result : 15~20 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 92.4 %, Specificity – 98.4 %

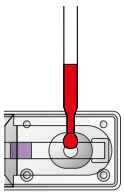
Materials Provided

- Test device
- Disposable dropper

Test Procedure

1 **Add Specimen**

Dispense 3 drops (100 µl) of serum, plasma or whole blood into the round specimen well "S".



Wait 15-20 mins.

2 **Read Results**

Negative

Positive

Invalid

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Dengue NS1 Ag	11FK50	Device	Serum/Plasma/Whole blood	25T/kit

SD BIOLINE Dengue IgG/IgM

Dengue IgG/IgM Antibody Test

Dengue is a mosquito-borne viral disease that has rapidly spread in all regions of WHO in recent years. Dengue virus is transmitted by female mosquitoes mainly of the species *Aedes aegypti* and, to a lesser extent, *Ae. albopictus*. Today, severe dengue affects most Asian and Latin American countries and has become a leading cause of hospitalization and death among children and adults in these regions. The incidence of dengue has grown dramatically around the world in recent decades; 390 million dengue infections per year of which 96 million manifest clinically.

General Information

SD BIOLINE Dengue IgG/IgM test is a solid phase *in vitro* immunochromatographic test for the qualitative and differential detection of IgG and IgM antibodies to dengue virus.

- Differential detection of IgG and IgM antibodies
- Dengue IgG/IgM : Serum / Plasma (5 µl)
- Dengue IgG/IgM WB : Whole blood / Serum / Plasma (10 µl)
- Test result : 15~20 minutes
- Detection of Dengue IgG/IgM Ab against all serotype; DEN-1,2,3 and 4.
- Presumptive differentiation between primary & secondary dengue infections
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance:
  - SD BIOLINE Dengue IgG/IgM: Sensitivity 94.6 %, Specificity 96.5 % (vs. ELISA test)
  - SD BIOLINE Dengue IgG/IgM WB: Sensitivity 94.2 %, Specificity 96.4 % (vs. ELISA test)

Materials Provided

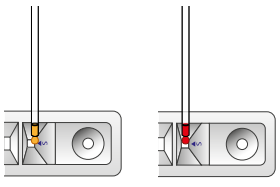
- SD BIOLINE Dengue IgG/IgM : Test device, Assay diluent, Capillary pipette (5 µl)
- SD BIOLINE Dengue IgG/IgM WB : Test device, Assay diluent, Capillary pipette (10 µl)

Test Procedure

1 **Add Specimen**

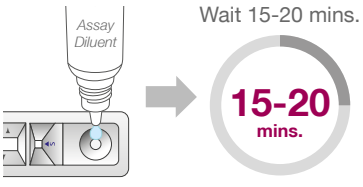
Add specimen into the specimen well "S".

Dengue IgG/IgM (5 µl) *Dengue IgG/IgM WB (10 µl)*



2 **Add Assay Diluent**

Dispense 4 drops of assay diluent into the round well.



3 **Read Results**

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Dengue IgG/IgM	11FK10	Device	Serum/Plasma	25T/Kit
Dengue IgG/IgM WB	11FK20	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE Zika IgM
Zika IgM Antibody Test

Zika virus infection has recently received great scrutiny and clinical attention since the linkages to fetal birth defects such as microcephaly and the linkage to Guillain-Barré syndrome have been observed. Zika virus is a member of the Flaviviridae family and transmitted to humans primarily through the bite of an infected Aedes species mosquito (*A. aegypti* and *A. albopictus*); the same vectors of dengue and chikungunya viruses. Most Zika infections are asymptomatic. However, the symptoms when present are similar to those of dengue and chikungunya, and may include fever, rash, joint pain, conjunctivitis (red eyes), muscle pain and headache. Thus it is difficult to symptomatically differentiate Flavivirus infections including dengue, chikungunya, West Nile, Japanese Encephalitis and yellow fever virus.

General Information
The SD BIOLINE Zika IgM test is an *in vitro* immunochromatographic assay for the qualitative detection of IgM antibodies to Zika virus in human serum, plasma or venous whole blood.

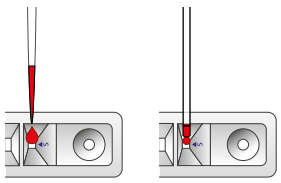
- Specimen : Serum, plasma or whole blood (10 µl)
- Test result : 15 minutes
- Shelf life and storage temperature: 18 months from the date of manufacturing at 2-30 °C
- Performance: Sensitivity 95.6 %, Specificity 98.1 % (vs. ELISA)

Materials Provided
- Test device
- Capillary pipette (10 µl)
- Assay diluent

Test Procedure
1 Add Specimen

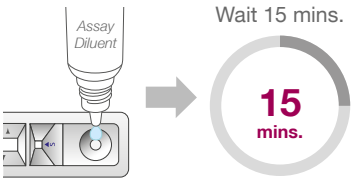
Dispense 10 µl of serum, plasma and whole blood into the specimen well "S".

Micropipette *Capillary pipette*

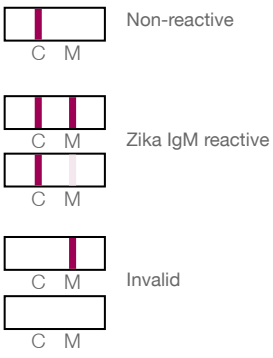


2 Add Assay Diluent

Dispense 4 drops of assay diluent into the round well.



3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
SD BIOLINE Zika IgM	12FK20	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE Leptospira series

Leptospira Antibody Test

Leptospirosis occurs worldwide but is most common in temperate or tropical climates. It is an occupational hazard for many people who work outdoors or with animals such as farmers, sewer workers, veterinarians, fish workers and military personnel. The disease is also a recreational hazard for campers or those who participate in outdoor sports in contaminated areas and has been associated with swimming, wading, and whitewater rafting in contaminated lakes and rivers. The incidence of leptospirosis is increasing among urban children.

General Information

Item	Leptospira	Leptospira IgM	Leptospira IgG/IgM
Detection	Qualitative detection of IgG antibody to *Leptospira interrogans*	Qualitative detection of IgM antibody to *Leptospira interrogans*	Differential detection of IgG & IgM antibodies to *Leptospira interrogans*
Specimen	10 µl of serum or plasma or 20 µl of whole blood	10 µl of serum or plasma or 20 µl of whole blood	5 µl of serum or plasma
Test result	15~20 min	15~20 min	20 min
Interpreter	2 - Line (Control/Test)	2 - Line (Control/Test)	3 - Line (Control/IgG/IgM)

Materials Provided

- Test device
- Capillary pipette for Leptospira IgG/IgM test (5 µl)
- Assay diluent

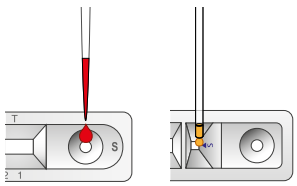
Test Procedure

1 Add Specimen

Add specimen into the specimen well "S".

Leptospira
Leptospira IgM
Serum, plasma 10 µl or whole blood 20 µl

Leptospira IgG/IgM
Serum, plasma 5 µl

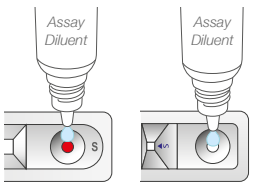


2 Add Assay Diluent

Dispense assay diluent into the round well "S".

Leptospira
Leptospira IgM
3-4 drops

Leptospira IgG/IgM
4 drops

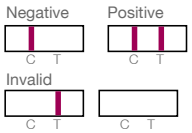


Leptospira
Leptospira IgM
Wait 15-20 mins.

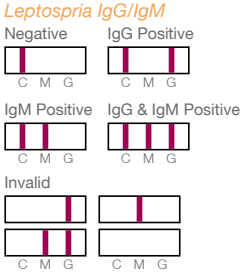
Leptospira IgG/IgM
Wait 20 mins.

3 Read Results

Leptospria, Leptospira IgM



Leptospria IgG/IgM



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Leptospira	16FK10	Device	Serum/Plasma/Whole Blood	30T/Kit
Leptospira	16FK11	Multi-Device	Serum/Plasma/Whole Blood	10Tx10/Kit
Leptospira IgM	16FK30	Device	Serum/Plasma/Whole Blood	30T/Kit
Leptospira IgG/IgM	16FK40	Device	Serum/Plasma	30T/Kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE Hantaan virus
Hantaan virus Antibody Test

Hantaan virus are carried by rodents and are spread to human via inhalation of aerosolized virus particles shed in the rodent feces and urine. Infection with Hantaan virus can range in severity from asymptomatic to a severe, life-threatening illness characterized by fever, hemorrhage, and renal failure.

General Information
The SD BIOLINE Hantaan virus test is rapid, qualitative test for the detection of IgG, IgM, IgA antibodies to genus Hantavirus like Hantaan virus, Seoul virus, Puumula virus, Prospect Hill virus in human serum, plasma or whole blood.

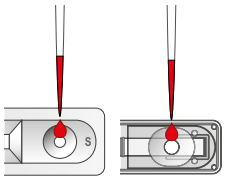
- Disease: Hemorrhagic fever with renal syndrome (HFRS)
- Specimen : Serum, Plasma (10 µl) / Whole blood (20 µl)
- Test result : 15~20 minutes
- Shelf life and storage temperature: 18 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity-96 %, Specificity-94 %

Materials Provided
- Test device
- Assay diluent

Test Procedure
1 **Add Specimen**

Dispense 10 µl of serum, plasma, or 20 µl of whole blood into the specimen well "S".

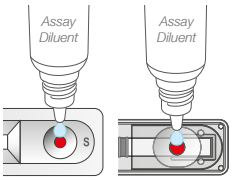
Device *Multi Device*



2 **Add Assay Diluent**

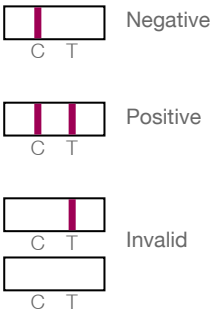
Dispense 3-4 drops of the assay diluent.

Device *Multi Device*



Wait 15-20 mins.

3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Hantaan virus	17FK10	Device	Serum/Plasma/Whole blood	30T/Kit
Hantaan virus	17FK11	Multi-Device	Serum/Plasma/Whole blood	10Tx10/Kit

SD BIOLINE Tsutsugamushi

Scrub Typhus Antibody Test

The causative organism, *Orientia tsutsugamushi*, is transmitted to human by the bite of a larval mite. The disease is characterized by fever, rash, eschar, pneumonitis, menigitis and disseminated intravascular coagulation which leads to severe multiorgan failure in untreated cases.

General Information

The SD BIOLINE Tsutsugamushi test is rapid, qualitative test for the detection of Detection IgG, IgM, IgA antibodies to *Orientia Tsutsugamushi* in human serum, plasma or whole blood.

- Disease: Scrub Typhus
- Specimen : Serum, Plasma (10 µl) / Whole blood (20 µl)
- Test result : 10~15 minutes
- Shelf life and storage temperature: 18 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity-99 %, Specificity-96 %

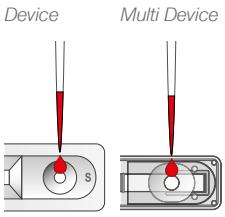
Materials Provided

- Test device
- Assay diluent

Test Procedure

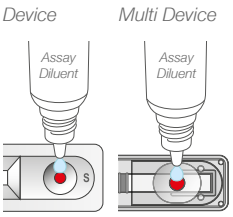
1 **Add Specimen**

Dispense 10 µl of serum, plasma, or 20 µl of whole blood into the specimen well "S".

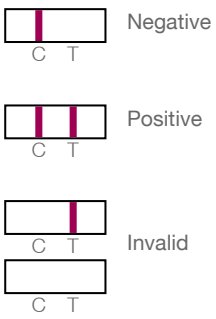


2 **Add Assay Diluent**

Dispense 3-4 drops of the assay diluent.



3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Tsutsugamushi (Scrub typhus)	18FK10	Device	Serum/Plasma/Whole blood	30T/Kit
Tsutsugamushi (Scrub typhus)	18FK11	Multi-Device	Serum/Plasma/Whole blood	10Tx10/Kit

SD BIOLINE Chikungunya IgM

IgM antibodies to Chikungunya virus Test

Chikungunya virus (CHIK) is an insect-borne virus, of the genus, Alphavirus, that is transmitted to humans by virus-carrying Aedes mosquitoes. There have been recent outbreaks of CHIK associated with severe morbidity. CHIK causes an illness with symptoms similar to dengue fever and is characterized by severe, sometimes persistent, joint pain (arthritis), as well as fever and rash.

General Information

SD BIOLINE Chikungunya IgM test is solid phase immunochromatographic assay for the rapid, qualitative detection of IgM antibodies to Chikungunya in human serum, plasma or whole blood.

- Specimen : Serum, plasma (50 µl), whole blood (100 µl)
- Test result : 10 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 97.1 %, Specificity - 98.9 % (vs. ELISA)

Materials Provided

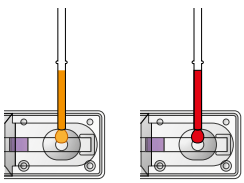
- Test device
- Disposable dropper
- Assay diluent

Test Procedure

1 **Add Specimen**

Dispense 1 drop of serum, plasma, or 2 drops of whole blood into the specimen well "S".

Serum or Plasma *Whole blood*

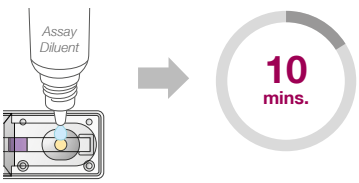


2 **Add Assay Diluent** (for serum, plasam)

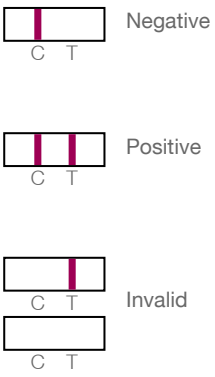
Dispense 1 drop of assay diluent into the specimen well "S".

** The whole blood specimen is not required assay diluent.*

only for Serum or Plasma



3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Chikungunya IgM	46FK10	Device	Serum/Plasma/Whole blood	25T/Kit

SD BIOLINE JEV IgM

IgM antibodies to JE virus Test

Japanese encephalitis is a disease caused by the mosquito-borne Japanese encephalitis virus. The Japanese encephalitis virus is a virus from the family Flaviviridae. Domestic pigs and wild birds are reservoirs of the virus; transmission to humans may cause severe symptoms. One of the most important vectors of this disease is the mosquito Culex tritaeniorhynchus. This disease is the leading cause of viral encephalitis in Asia, with 30,000–50,000 cases reported annually. Casefatality rates range from 0.3 % to 60 % and depends on the population and on age.

General Information

SD BIOLINE JEV IgM test is a solid phase immunochromatographic assay for the rapid, qualitative detection of IgM antibody to JE virus in human serum or plasma.

- Specimen : Serum, plasma(5 µl)
- Test result : 15~20 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 98.9 %, Specificity - 93.5 % (vs. ELISA)

Materials Provided

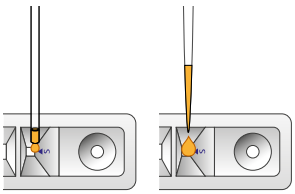
- Test device
- Capillary pipette(5 µl)
- Assay diluent

Test Procedure

1 Add Specimen

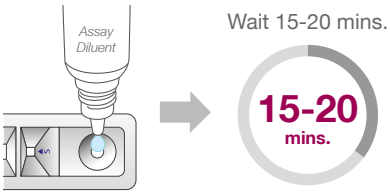
Dispense 5 µl of serum or plasma into the specimen well.

Capillary pipette *Micropipette*

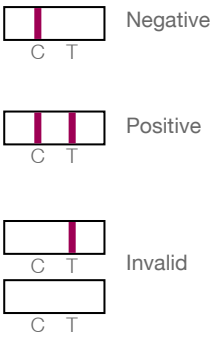


2 Add Assay Diluent

Dispense 3-4 drops of the assay diluent.



3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
JEV IgM	48FK10	Device	Serum/Plasma	25T/Kit

SD BIOLINE Chagas Ab Rapid

Antibodies to *Trypanosoma cruzi* Test

Chagas disease, caused by the protozoan parasite *Trypanosoma cruzi*, is a chronic illness affecting about 24million people in Central and South America. In most cases, after an asymptomatic acute phase with parasitemia, parasite growth is controlled by the host immune response. The infection remains quiescent for many years before entering into a chronic phase during which parasites are hardly detectable in the blood of patients. Consequently, detection of specific antibodies in the patient's serum is important for diagnosis of the disease.

General Information

SD BIOLINE Chagas Ab Rapid test is an immunochromatographic screening test for the detection of antibodies to *Trypanosoma cruzi* test in human serum, plasma or whole blood.

- Serological antibody test for a fast and easy diagnosis of the disease
- Specimen : Serum, plasma or whole blood (100 µl)
- Test result : 15 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 99.3 %, Specificity - 100 % (vs. ELISA)

Materials Provided

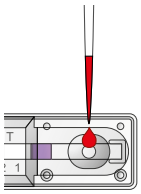
- Test device

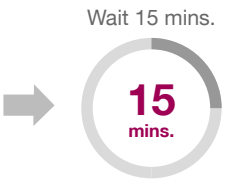
Test Procedure

1 **Add Specimen**

Dispense 100 µl of serum, plasma or whole blood into the specimen well "S".

Micropipette





2 **Read Results**

Negative

Positive

Invalid

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Chagas Ab Rapid	49FK10	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE Onchocerciasis IgG_4

Onchocerciasis IgG_4 test

Onchocerciasis, commonly known as river blindness, is caused by a parasitic worm, *Onchocerca volvulus*, which is transmitted to humans through the bite of the blackfly. It causes itching, skin disfiguration, and, with chronic exposure, permanent blindness. Globally, an estimated 169 million people are at risk for river blindness and 37 million are infected. Of those at risk, 99 percent live in Africa, but in Latin America also exist. Studies have shown that the human IgG4 antibody response to the *O. volvulus* protein Ov16 is a sensitive and specific marker for exposure to onchocerciasis.

General Information

This SD BIOLINE Onchocerciasis IgG_4 test is a rapid, qualitative test for the detection of IgG4 antibody against OV16 antigen in human serum, plasma or whole blood.

- Less invasive and less painful than current diagnostic methods
- Effective toll for mass screening surveillance and decision making of MDA(Mass Drug Administration) stopping and monitoring
- Fast result: 30 minutes
- Specimen: Serum, Plasma, Whole blood
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-40 °C
- Performance:

Whole Blood		RDT	
		Positive	Negative
Skin snip	Positive	60	14
	Negative	1	103
Sensitivity		81.1 % (60/74)	
Specificity		99.0 % (103/104)	

Plasma/Serum		RDT	
		Positive	Negative
Skin snip	Positive	64	11
	Negative	1	101
Sensitivity		85.3 % (64/75)	
Specificity		99.0 % (101/102)	

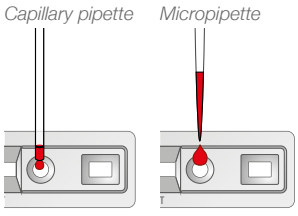
Materials Provided

- Test device
- Assay diluent
- Capillary pipette (10 µl)
- Alcohol swab
- Lancet

Test Procedure

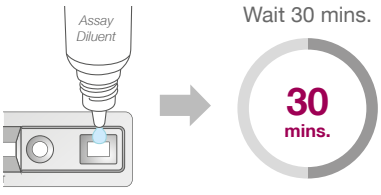
1 Add Specimen

Dispense 10 µl of whole blood, serum or plasma into the specimen well.

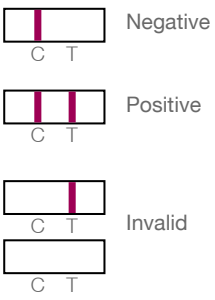


2 Add Assay Diluent

Dispense 4 drops of the assay diluent.



3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Onchocerciasis IgG_4	61FK10	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE Oncho/LF IgG4 biplex

Onchocerciasis IgG4 and Lymphatic Filariasis IgG4 test

Onchocerciasis and lymphatic filariasis have significant geographic overlap in Central Africa. Control and elimination programs may benefit from combining efforts aimed at the individual diseases. In areas where lymphatic filariasis control strategies use mass drug administration with diethylcarbamazine it is important to understand the prevalence of onchocerciasis because severe drug reactions can occur in people infected with *O. volvulus*. This biplex test can also fill these gaps in surveillance data for both diseases' control programs in areas of Africa where the diseases are co-endemic.

General Information

The SD BIOLINE Oncho/LF IgG4 biplex test is a rapid, qualitative test for the detection of IgG4 antibodies against the *Onchocerca volvulus Ov16* and *Wuchereria bancrofti Wb123* antigens in human serum, plasma or whole blood

- A single rapid test for the combined surveillance programs in co-endemic areas
- Specimen: Whole blood, serum, plasma
- Time to results: 30 minutes. (The results are valid from 30 minutes to 24 hours.)
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-40 °C
- Performance (Reference method: ELISA) :
  - Sensitivity: Oncho 92.42 %(WB), 98.48 %(S/P) and LF 81.48 %(WB), 95.06 %(S/P)
  - Specificity: Oncho 100 %(WB), 97.48 %(S/P) and LF 99.31 %(WB), 95.83 %(S/P)

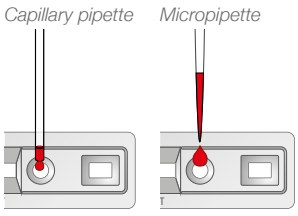
Materials Provided

- Test device
- Assay diluent
- Capillary pipette (10 µl)
- Alcohol swab
- Lancet

Test Procedure

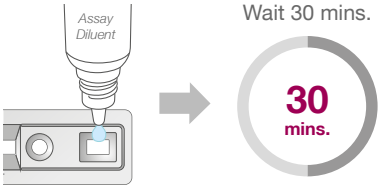
1 Add Specimen

Dispense 10 µl of whole blood, serum or plasma into the specimen well.

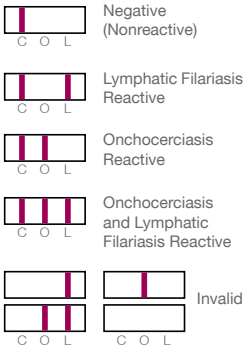


2 Add Assay Diluent

Dispense 4 drops of the assay diluent.



3 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Oncho/LF IgG4 biplex	61FK20	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE Lymphatic Filariasis IgG4

Lymphatic Filariasis IgG4 test

Lymphatic filariasis (LF), the major cause of elephantiasis, is spread by mosquitos and damages the lymphatic system, leading to serious disability, disfigurement, and low quality of life across Africa and some parts of Asia. *Wuchereria bancrofti* (Wb) is one of three species of parasitic worms responsible for LF and accounts for 90 % of the infections globally, including all cases on the African continent. Studies have shown that the human IgG4 antibody response to the *W. bancrofti* protein Wb123 is a sensitive and specific marker for exposure to *W. bancrofti* infection.

General Information

The SD BIOLINE Lymphatic Filariasis IgG4 test is a rapid, qualitative test for the detection of IgG4 antibodies against the *Wuchereria bancrofti* Wb123 antigen in human serum, plasma or whole blood

- Use for endemic areas where MDA(Mass drug administration) has been ongoing for several years
- Specimen: Whole blood, serum, plasma
- Time to results: 30 minutes. (The results are valid from 30 minutes to 24 hours.)
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-40 °C
- Performance (Reference method: ELISA)
  - Sensitivity: 93.33 %(WB), 98.33 %(S/P)
  - Specificity: 98.89 %(WB), 95.56 %(S/P)

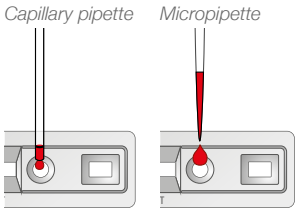
Materials Provided

- Test device
- Assay diluent
- Capillary pipette (10 µl)
- Alcohol swab
- Lancet

Test Procedure

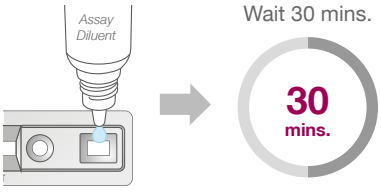
1 Add Specimen

Dispense 10 µl of whole blood, serum or plasma into the specimen well.

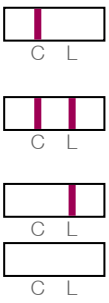


2 Add Assay Diluent

Dispense 4 drops of the assay diluent.



3 Read Results



Negative (Nonreactive)

Positive (Reactive)

Invalid

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Lymphatic Filariasis IgG4	61FK30	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE HAT

T.b.gambiense Antibody Test

Human African Trypanosomiasis (HAT) is a vector-borne parasitic disease, also known as 'sleeping sickness'. It is one of major neglected infectious disease today and is caused by protozoan parasites belonging to the genus Trypanosoma. The small, single-celled pathogens called trypanosomes are transmitted through the bites of tsetse flies.

General Information

The SD BIOLINE HAT is an immunochromatographic test for rapid, qualitative detection of antibodies specific to variable surface glycoprotein (VSG) LiTat 1.3 or LiTat 1.5 of *Trypanosomes brucei gambiense (T.b.gambiense)* in human serum, plasma or whole blood.

- Affordable, easy and rapid testing of suspected HAT patients
- Ideal for both active and passive screening
- Test results: 15 - 20 minutes
- Specimen: Serum, plasma or whole blood
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-40 °C
- Performance: Sensitivity - 98 %, Specificity - 87 % (vs. Microscopic examination)

Materials Provided

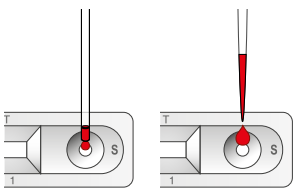
- Test device
- Assay diluent
- Capillary pipette (20 µl)
- Alcohol swab
- Lancet

Test Procedure

1 **Add Specimen**

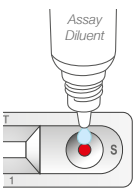
Dispense 10 µl of serum, plasma, or 20 µl of whole blood into the specimen well "S".

Capillary pipette *Micropipette*



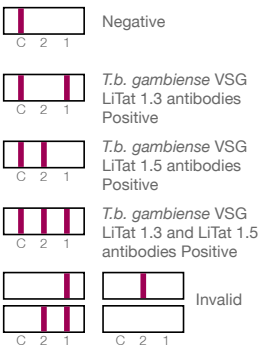
2 **Add Assay Diluent**

Dispense 4 drops of the assay diluent.



Wait 15-20 mins.

3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
HAT	53FK10	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE Leishmania Ab

Leishmania Antibody Test

Leishmaniasis is a vector-borne disease that is transmitted by sandflies and caused by obligate intracellular protozoa of the genus *Leishmania*. Leishmaniasis is found in parts of about 88 countries. Approximately 350 million people live in these areas. Most of the affected countries are in the tropics and subtropics. The settings in which leishmaniasis is found range from rain forests in Central and South America to deserts in West Asia. More than 90 percent of the world's cases of visceral leishmaniasis are in India, Bangladesh, Nepal, Sudan, and Brazil.

General Information

SD BIOLINE Leishmania Ab test is an one-step in vitro immunochromatographic assay designed for the qualitative determination of anti-*Leishmania* in human serum or plasma.

- Easy to use rapid test : All materials provided
- Specimen : Serum, plasma (20 µl)
- Test result : 10~15 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity-98.0 %, Specificity-99.5 % (vs. Immuno-fluorescent method)

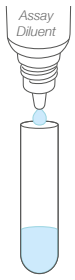
Materials Provided

- Test strip
- Assay diluent
- Capillary pipette (20 µl)
- Disposable test tube

Test Procedure

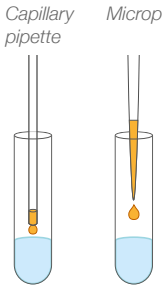
1 Add Assay Diluent

Dispense 3 drops of the assay diluent.

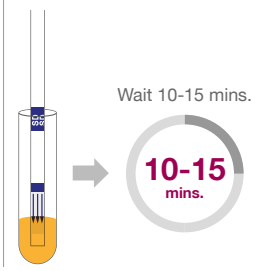


2 Add Specimen

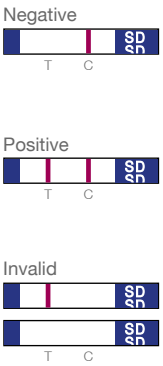
Dispense 20 µl of serum or plasma



3 Insert Strip



4 Read Results



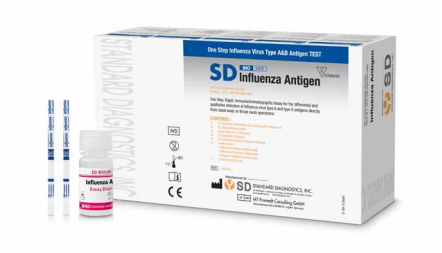
Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Leishmania Ab	47FK12	Strip	Serum/Plsma	25T/Kit

SD BIOLINE Influenza Antigen

Influenza Virus Type A & B Antigen Test

Influenza, commonly known as "flu", is a highly contagious viral infection of the respiratory tract. It affects both sexes and all age groups, but its highest incidence is in children. Outbreaks tend to occur in the winter and early spring when as many as 40% of children can become infected.[2] There are three types of influenza viruses. Type A is usually responsible for the large influenza epidemics. Type A is constantly changing, with new strains appearing regularly. Influenza types A are divided into subtype H (hemagglutinin) and N (neuraminidase). The subtype H has H1~H15 types and the subtype N has N1~N9. Especially H1N1, H3N2, H2N2, H5N1 are important to a human infection.



General Information

SD BIOLINE Influenza Ag test detects Influenza virus type A & B. It also detects all kinds of influenza antigen subtypes including novel influenza H1N1 pandemic.

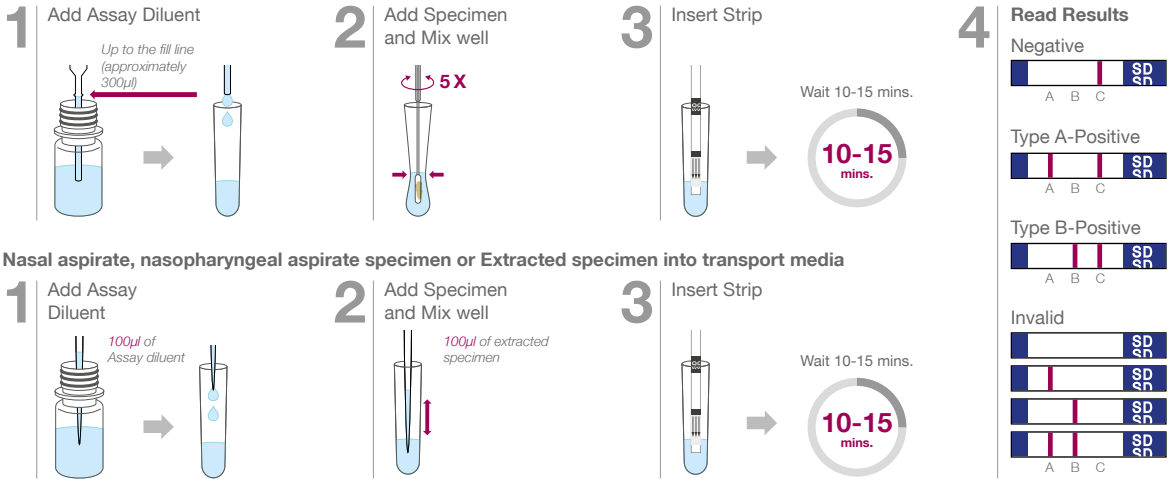
- Detection : Differential detection of Influenza virus type A & B
- Specimen : Human nasal swab, throat swab, nasopharyngeal swab or nasal/nasopharyngeal aspirate
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity : 91.8%, Specificity : 98.9%(vs. Viral Culture and RT-PCR as gold standard)

Materials Provided

- Test strip
- Disposable tube with rack
- Assay diluent
- Sterilized swab
- Control swab
- Disposable dropper

Test Procedure

All swab Specimens



Nasal aspirate, nasopharyngeal aspirate specimen or Extracted specimen into transport media

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Influenza Antigen	19FK11	Strip	Nasal/Throat/Nasopharyngeal swab, Nasal/ Nasopharyngeal aspirate	10T/Kit
Influenza Antigen	19FK12	Strip	Nasal/Throat/Nasopharyngeal swab, Nasal/ Nasopharyngeal aspirate	25T/Kit

SD BIOLINE Influenza Ag A/B/A(H1N1) Pandemic

Influenza virus Type A, B and A (H1N1)Pandemic Rapid Test

The 2009 flu pandemic, or swine flu, is a global outbreak of a new strain of Influenza A virus subtype H1N1, a type of swine Influenza, that was first detected in people in the United States in April 2009. This virus continued to spread globally, On June 11, 2009, the WHO declared the outbreak a pandemic.

General Information

SD BIOLINE Influenza Ag A/ B/ A(H1N1) Pandemic rapid test kit is a chromatographic immunoassay for the differential and qualitative detection of Influenza virus type A, type B and A(H1N1) Pandemic antigens directly from nasal/throat swab, nasal/nasopharyngeal aspirate specimens.

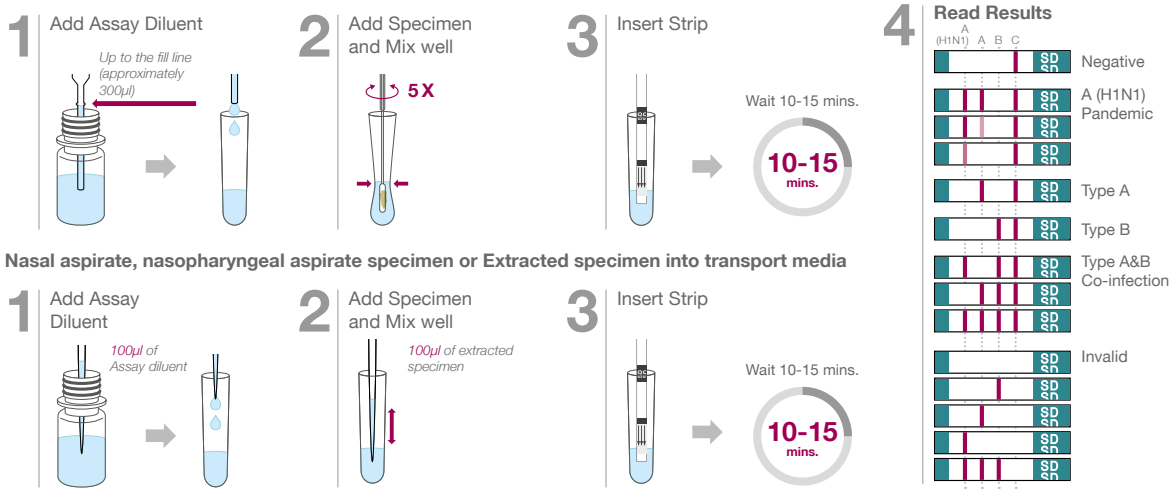
- Detection: Differential detection of Influenza virus type A, type B and A(H1N1) pandemic antigen (4 lines)
- Specification: The samples tested POSITIVE can be determined as influenza H1N1 positive without additional confirmation test.
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C

Materials Provided

- Test strip
- Disposable tube with rack
- Assay diluent
- Strip Holder
- Sterilized swab
- Control swab
- Disposable dropper

Test Procedure

All swab Specimens



Nasal aspirate, nasopharyngeal aspirate specimen or Extracted specimen into transport media

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Influenza Ag A/ B/ A(H1N1) Pandemic	19FK31	Strip	Nasal/Throat/Nasopharyngeal swab, Nasal/Nasopharyngeal aspirate	10T/Kit
Influenza Ag A/ B/ A(H1N1) Pandemic	19FK32	Strip	Nasal/Throat/Nasopharyngeal swab, Nasal/Nasopharyngeal aspirate	25T/Kit

SD BIOLINE Influenza Ultra

Influenza Virus Type A & B Antigen Test

Influenza, commonly known as "flu", is a highly contagious viral infection of the respiratory tract. It affects both sexes and all age groups, but its highest incidence is in children. Outbreaks tend to occur in the winter and early spring when as many as 40% of children can become infected.[2] There are three types of influenza viruses. Type A is usually responsible for the large influenza epidemics. Type A is constantly changing, with new strains appearing regularly. Influenza types A are divided into subtype H (hemagglutinin) and N (neuraminidase). The subtype H has H1~H15 types and the subtype N has N1~N9. Especially H1N1, H3N2, H2N2, H5N1 are important to a human infection.

General Information

SD BIOLINE Influenza Ultra is a rapid assay to detect and distinguish influenza A and B virus, with nasopharyngeal swab or nasopharyngeal aspirate specimens.

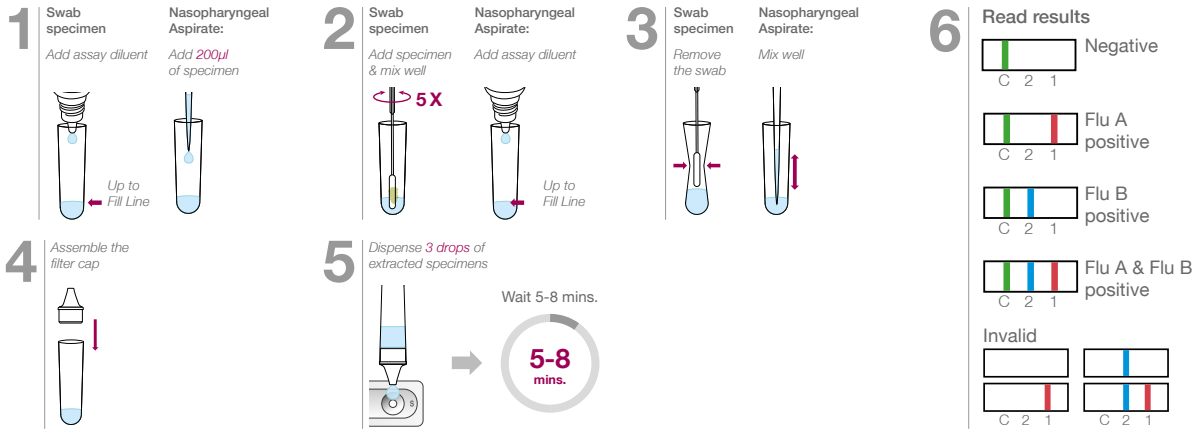
- Differential detection of Influenza virus type A & B
- Positive result as early as 5 mins.
- Easy to interpret results with 3 colors lines – Green, Blue, Red
- Color line and test cassette marking helps to interpret result faster and more confidently
- Cassette test format minimizes contact with potential biohazard material
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance vs Cell Culture

		Sensitivity	Specificity
Nasopharyngeal Swab	Flu A	88.5 %	97.4%
	Flu B	91.5 %	97.4%
Nasopharyngeal Aspirate	Flu A	93.9 %	97.7%
	Flu B	91.7 %	97.7%

Materials Provided

- Test device
- Disposable tube
- Assay diluent
- Sterilized swab
- Control swab
- Filter cap

Test Procedure



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Influenza Ultra	19FK13	Device	Nasopharyngeal swab, Nasopharygeal aspirate	10T/Kit

SD BIOLINE RSV

RSV(Respiratory Syncytial Virus) Antigen Test

RSV is the most common respiratory virus in infants and young children. It infects virtually all infants by the age of two. In most infants, the virus causes symptoms resembling those of the common cold. In infants born prematurely and/or with chronic lung disease, RSV can cause a severe or even life-threatening disease. Prior to the introduction of Synagis, RSV disease resulted in over 125,000 hospitalizations each year. There is a high mortality risk in approximately 2 percent of those infants.[3]

General Information

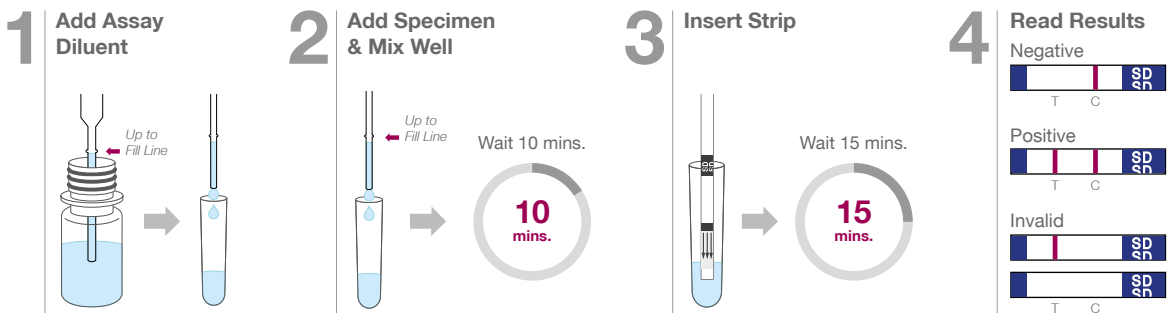
SD BIOLINE RSV test is an immunochromatographic assay for qualitative detection of respiratory syncytial virus (RSV) in NPS (Nasopharyngeal secretion/ aspirations).

- Specimen: NPA(Nasopharyngeal Aspirate)
- Test result in 15 minutes
- Shelf life and storage temperature: 21 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity-92.3 %, Specificity-93.3 % (vs. culture)

Materials Provided

- Test strip
- Disposable test tube, dropper
- Extraction buffer

Test Procedure



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
RSV Test	40FK12	Strip	Nasopharyngeal Aspirate	25T/Kit

SD BIOLINE Strep A

Group A Streptococcal Antigen Strip Test

GAS (Group A streptococcus) is one of the most important causes of acute upper respiratory track infection. Hardly diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and serious compications such as rheumatic fever and glomerulonephritis. Conventional identification procedures for GAS from throat swabs involve the isolation and subsequent identification of viable pathogen techniques that require 24~48 hours or longer for results.

General Information

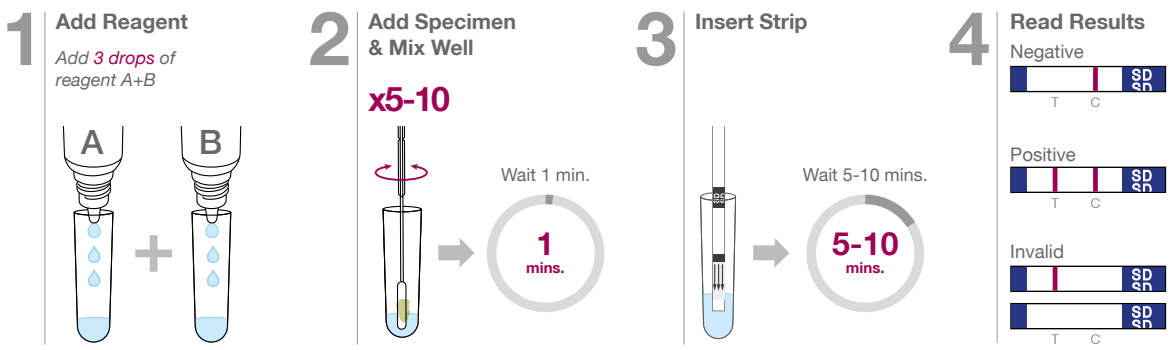
SD BIOLINE Strep A strip test is a immunochromatographic assay for the qualitative detection of group A streptococcal antigens directly from throat swabs or confirmation of presumptive Group A Streptococcal colonies recovered from culture. The assay detects either viable or nonviable organisms directly form throat swabs or culture colonies within 5 ~ 10 minutes.

- Specimen : Throat swab
- Test result : 5~10 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 87.3 %, Specificity - 95.8 % (vs. culture method)

Materials Provided

- Test strip
- Extraction Reagent A, B
- Sterile throat swab
- Disposable test tube
- Positive / Negative control

Test Procedure



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Strep A	45FK12	Strip	Throat swab	25T/Kit

SD BIOLINE Legionella Ag

Legionella Urinary Antigen Test

Legionellosis is a collection of infections that emerged in the second half of the 20th century, and that are caused by *Legionella pneumophila* and related Legionella bacteria. The severity of legionellosis varies from mild febrile illness (Pontiac fever) to a potentially fatal form of pneumonia (Legionnaires' disease). *Legionella pneumophila* is responsible for approximately 90 % of infections, and of these, over 80 % are due to a single serogroup, "Serogroup 1". Water is the major natural reservoir for Legionella, and the bacteria are found worldwide in many different natural and artificial aquatic environments such as cooling towers, water systems.[4]

General Information

SD BIOLINE Legionella Ag test is a rapid immunochromatographic assay for the qualitative detection of *Legionella Pneumophila* Serogroup 1 antigen in urine specimen. It is used as an aid in the presumptive diagnosis of *Legionella pneumophila* infection caused by *L.pneumophila* serogroup 1 and to monitor the effectiveness of targeted treatment.

- Rapid detection of *Legionella pneumophila* serogroup 1 antigen in urine.
- Enables timely targeted treatment with correct antibiotics for *Legionella pneumophila*.
- Faster throughput in lab or Emergency Room
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 95.6 %, Specificity - 99.2 %

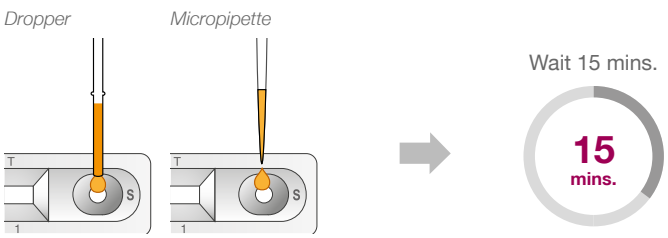
Materials Provided

- Test device
- Positive/Negative Control
- Disposable urine dropper

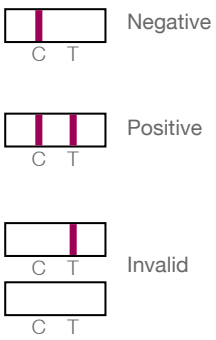
Test Procedure

1 **Add Specimen**

Dispense 3 drops (100 µl) of urine into the specimen well "S".



2 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Legionella Ag	58FK10	Device	Urine	25T/Kit

SD BIOLINE TB Ag MPT64 Rapid

Identification of *Mycobacterium tuberculosis* Complex

Tuberculosis is a highly infectious, potentially fatal disease caused by *Mycobacterium tuberculosis*. Biochemical, immunological and molecular biological characterization of *Mycobacterium tuberculosis* have led to the identification of several antigens which may be useful in the development of improved diagnostic methods in order to discriminate between the *M. tuberculosis* complex and mycobacteria other than *M. tuberculosis* (MOTT bacilli). *M. tuberculosis* has been known to secrete more than 33 different proteins. One of the predominant proteins, MPT64 was found only in the culture fluid of strains of the *M. tuberculosis* complex.

General Information

SD BIOLINE TB Ag MPT64 Rapid is a rapid immunochromatographic test for the identification of the *M.tuberculosis* complex.

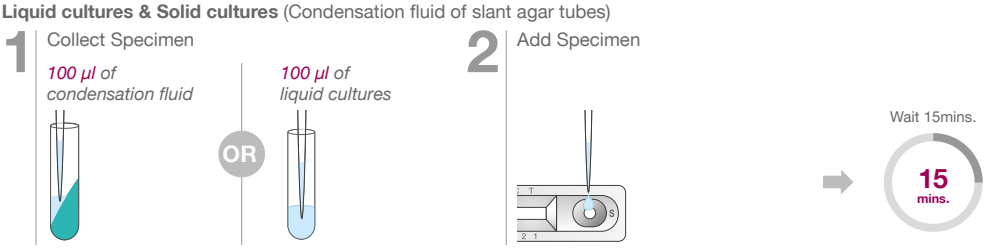
- Simple, rapid assay using mouse monoclonal anti-MPT64
- Rapid discrimination between the *M. tuberculosis* complex and other mycobacterium
- Identification of the *M. tuberculosis* complex in combination with culture systems based on liquid media
- Specimen : Solid cultures(colony, condensation fluid) or liquid cultures
- Shelf life and storage temperature: 18 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 98.6 %, Specificity - 100 % (vs. Isolated culture method)

Materials Provided

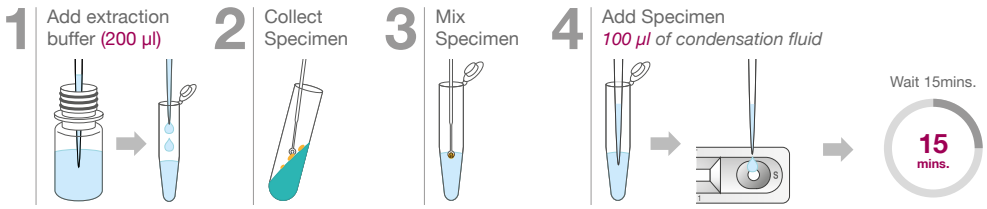
- Test device
- Extraction buffer (for specimen preparation using solid cultures)

Test Procedure

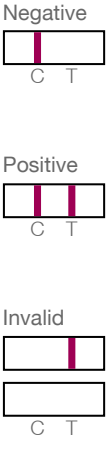
Liquid cultures & Solid cultures (Condensation fluid of slant agar tubes)



Solid cultures (Colony)



Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
TB Ag MPT64 Rapid	08FK50	Device	Liquid cultures / Solid cultures	25T/Kit

SD BIOLINE H.pylori

H.pylori Antibody Test

Helicobacter pylori (H. pylori) is a spiral-shaped bacterium and that is found in the gastric mucous layer or adherent to the epithelial lining of the stomach. *H. pylori* causes more than 90% of duodenal ulcers and up to 80 % of gastric ulcers. Approximately two-thirds of the world's population is infected with H.pylori.[5] SD BIOLINE H.pylori test thanks to its accuracy and the ease of use aids fast and accurate diagnosis of H. pylori infection.

General Information

SD BIOLINE H.pylori test is a rapid test for the qualitative detection of antibodies of all isotypes(IgG, IgM, IgA, etc.) specific to *Helicobacter pylori* in human serum or plasma.

- Detection of all isotypes (IgG, IgM, IgA) antibodies against *H.pylori*
- Shelf life and storage temperature: 24 months from the date of manufacturing at 2-30 °C
- Performance: Sensitivity-95.9 %, Specificity-89.6 %
- **Specimen : Serum, Plasma**

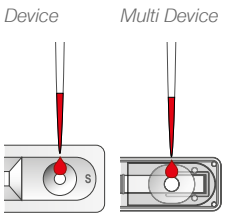
Materials Provided

- Test device/Multi-device
- Assay diluent

Test Procedure

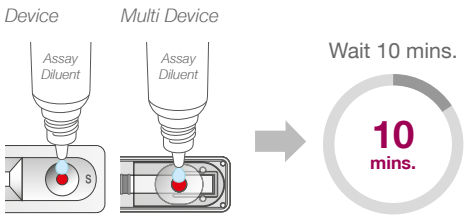
1 **Add Specimen**

Dispense 10 µl of serum or plasma into the specimen well "S".

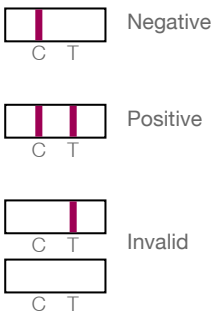


2 **Add Assay Diluent**

Dispense 3 drops of the assay diluent.



3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
H.pylori	04FK10	Device	Serum/Plasma	30T/Kit
H.pylori	04FK11	Multi-Device	Serum/Plasma	10Tx10/Kit

SD BIOLINE H.pylori Ag

H.pylori Antigen Test

Helicobacter pylori (H. pylori) is a spiral-shaped bacterium and that is found in the gastric mucous layer or adherent to the epithelial lining of the stomach. *H. pylori* causes more than 90% of duodenal ulcers and up to 80 % of gastric ulcers. Approximately two-thirds of the world's population is infected with *H.pylori*.[5] SD BIOLINE H.pylori Ag test thanks to its accuracy and the ease of use aids fast and accurate diagnosis of H. pylori infection.

General Information

SD BIOLINE H.pylori Ag kit is a rapid, qualitative test for the detection of *Helicobacter pylori* antigen in human fecal specimens.

- Easy to use
- No need of any equipment
- Test result: 10 -15 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity-98.4 %, Specificity-100 %
- **Specimen: Fecal specimens**

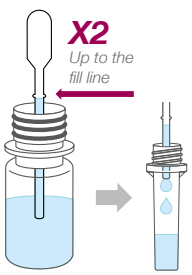
Materials Provided

- Test device
- Specimen collection tube
- Assay diluent
- Specimen collection swab
- Disposable dropper
- Disposable dropping cap

Test Procedure

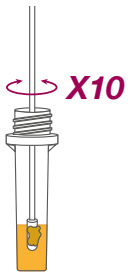
1 Add Assay Diluent

Transfer assay diluent twice.



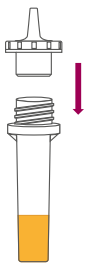
2 Insert swab specimen

Insert the swab into the specimen collection tube and swirl the swab at least 10 times.



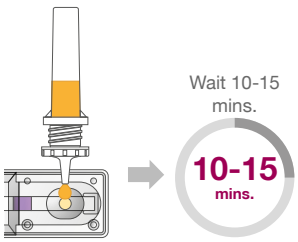
3 Assemble dropping cap

Assemble dropping cap on the specimen collection tube.

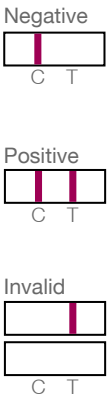


4 Add Specimen

Dispense 3 drops.



5 Read Results



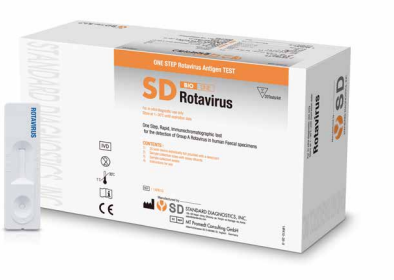
Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
H.pylori Ag	04FK20	Device	Fecal	20T/Kit

SD BIOLINE Rotavirus

Rotavirus Antigen Test

Rotavirus is the most common cause of severe, dehydrating diarrhea among children worldwide. Scientists have described seven rotavirus groups (A to G). Only groups A, B, and C infect humans. Group A, which has multiple strains, causes the majority of childhood infections. Although human of all ages are susceptible to rotavirus infection, children 3 to 24 months of age account for the vast majority of severe infections. A person with rotavirus diarrhea often excretes large amounts of virus, which can spread readily through contaminated hands, contaminated objects, water or food. SD BIOLINE Rotavirus test thanks to its accuracy and the ease of use greatly supports Rotavirus infection control and treatment.



General Information

SD BIOLINE Rotavirus test is an immunochromatographic assay for the detection of Group A rotavirus in human fecal specimens. The test utilizes two kinds of antibody in a solid phase sandwitch immunochromatography to detect group specific proteins, including the major inner capsid protein, present in Group A rotaviruses.

- Early detection of rotavirus antigen group A all serotype
- Convenient and clean test
- Specimen: Fecal specimens
- Shelf life and storage temperature: 18 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity : 94 %, Specificity 98.3 % (vs. RT-PCR)

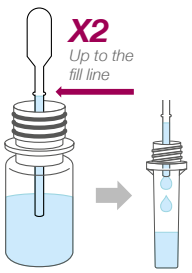
Materials Provided

- Test device
- Specimen collection tube
- Assay diluent
- Specimen collection swab
- Disposable dropper
- Disposable dropping cap

Test Procedure

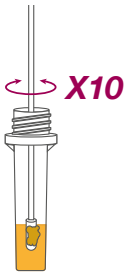
1 Add Assay Diluent

Transfer assay diluent twice.



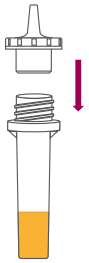
2 Insert swab specimen

Insert the swab into the specimen collection tube and swirl the swab at least 10 times.



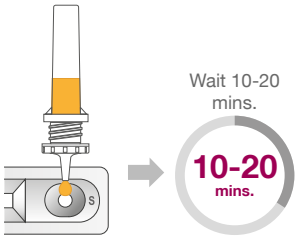
3 Assemble dropping cap

Assemble dropping cap on the specimen collection tube.

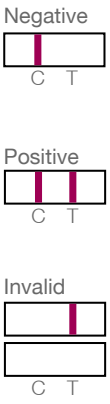


4 Add Specimen

Dispense 3-4 drops.



5 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Rotavirus	14FK10	Device	Fecal	20T/Kit

SD BIOLINE Rota/Adeno Rapid

Rota/Adeno virus Antigen Test

Rotaviruses are one of the major causes of pediatric gastroenteritis and diarrhea. Untreated rotavirus infection may result in severe illness with dehydration and disturbances of the body's normal electrolyte balance, especially in babies and preschool children.

Adenoviruses have been implicated in a wide range of clinical diseases affecting mainly the respiratory, ocular and the gastrointestinal systems of the human. Some adenovirus serotypes are enteric and have emerged as a major source of pediatric gastroenteritis.

SD BIOLINE Rota/Adeno Rapid test detects both viruses with a great accuracy. Its ease of use and short time to result allows fast treatment decisions.

General Information

SD BIOLINE Rota/Adeno Rapid test is a rapid immunochromatographic assay for qualitative detection of the presence of rotavirus or adenovirus antigen in human fecal specimens.

- Differentiation of test result by clear band formation(3-lines)
- Specimen : Fecal specimens
- Test result : 20 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance:
  - Rotavirus: Sensitivity - 99.3 %, Specificity - 99.5 % (vs. RT-PCR)
  - Adenovirus: Sensitivity - 97 %, Specificity - 100 % (vs. RT-PCR)

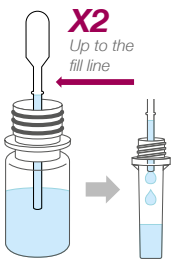
Materials Provided

- Test device
- Specimen collection tube
- Assay diluent
- Specimen collection swab
- Disposable dropper
- Disposable dropping cap

Test Procedure

1 Add Assay Diluent

Transfer assay diluent twice.

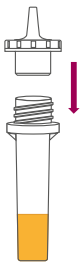


2 Insert swab specimen

Insert the swab into the specimen collection tube and swirl the swab at least 10 times.

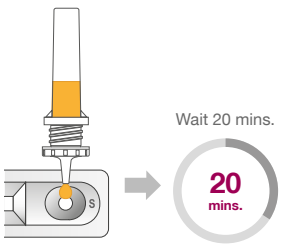
3 Assemble dropping cap

Assemble dropping cap on the specimen collection tube.

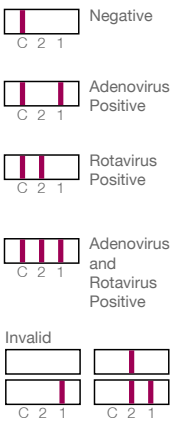


4 Add Specimen

Dispense 3-4 drops.



5 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Rota/Adeno Rapid	14FK20	Device	Fecal	20T/Kit

SD BIOLINE Norovirus

Norovirus Antigen Test

Noroviruses(NoVs) have a leading role in causing gastroenteritis worldwide, causing high morbidity rates among patients of all ages. Since very low doses of viral particles are infectious, rapid spreading through fecal–oral or airborne transmission easily causes an epidemic, especially in institutions such as hospitals and nursing homes. The rapid detection of NoV in stool is essential in both sporadic cases of gastroenteritis and in outbreak prevention and management.

General Information

The SD BIOLINE Norovirus rapid test is a rapid immunochromatographic assay for qualitative detection of the presence of norovirus antigen(Genogroup I(GI) and Genogroup II(GII)) in human fecal specimens. It is used as an aid in the diagnosis of acute gastroenteritis with the symptoms of suspected gastroenteritis caused by Norovirus.

- Easy to use
- Specimen : Fecal specimen(50-100 mg)
- Test result : 15 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 84.1 %, Specificity - 96.1 % (vs realtime RT-PCR)

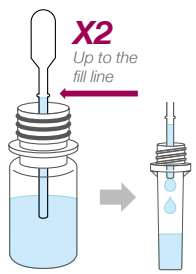
Materials Provided

- Test device
- Specimen collection tube
- Assay diluent
- Specimen collection swab
- Disposable dropper
- Disposable dropping cap

Test Procedure

1 Add Assay Diluent

Transfer assay diluent twice.

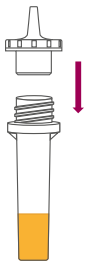


2 Insert swab specimen

Insert the swab into the specimen collection tube and swirl the swab at least 10 times.

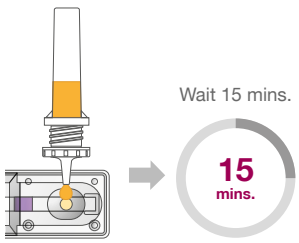
3 Assemble dropping cap

Assemble dropping cap on the specimen collection tube.

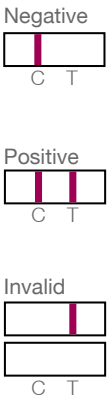


4 Add Specimen

Dispense 4 drops.



5 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Norovirus	52FK10	Device	Fecal	20T/Kit

SD BIOLINE Salmonella typhi IgG/IgM Fast

Salmonella typhi IgG/IgM Test

Typhoid fever is a serious illness caused by a bacteria called *Salmonella typhi*. Symptoms of *Salmonella typhi* infection may be mild to severe and can include fever, headache, loss of appetite, constipation or diarrhea, and nonproductive cough. Typhoid fever is still common in developing countries and affects about 12.5 million persons each year. *Salmonella typhi* bacteria are shed in the urine or stool of infected persons, including chronic carriers. Typhoid fever is spread by eating or drinking contaminated food or water or by direct or indirect contact with fecal material from infected persons.

General Information

SD BIOLINE Salmonella typhi IgG/IgM Fast test is an immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to *Salmonella typhi* in human serum, plasma or whole blood.

- IgM : Perfect alternative of Widal test
- IgG : Examination of past infection
- Specific screening test for *Salmonella typhi*
- Test result : 15 - 30 minutes
- Specimen : Serum, Plasma or Whole blood
- Shelf life and storage temperature: 24 months from the date of manufacturing at 2-30 °C
- Performance:
  - Sensitivity : IgG-64.9 %, IgM-94.6%, IgG+IgM-100 %
  - Specificity : IgG-88.3 %, IgM-92.2%, IgG+IgM-85.7 %

Materials Provided

- Test strip
- Assay diluent
- Disposable loop (1 µl)
- Disposable test tube

Test Procedure

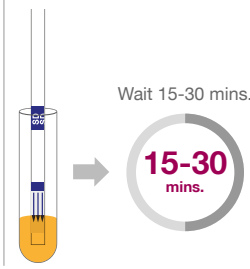
1 Add Assay Diluent

Dispense 4 drops of the assay diluent.

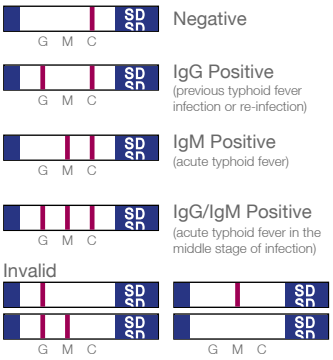
2 Add Specimen

Dispense 1 µl of specimen

3 Insert Strip



4 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Salmonella typhi IgG/IgM Fast	15FK12	Strip	Serum/Plasma/Whole blood	25T/Kit

SD BIOLINE Cholera Ag O1/O139

V. Cholerae O1/ O139 Antigen Test

Cholera is an acute, diarrheal illness caused by infection of the intestine with the bacterium *Vibrio cholerae.* The infection is often mild or without symptoms, but sometimes it can be severe. Approximately one in 20 infected persons has severe disease characterized by profuse watery diarrhea, vomiting, and leg cramps. In these persons, rapid loss of body fluids leads to dehydration and shock. Without treatment, death can occur within hours.[6]

General Information

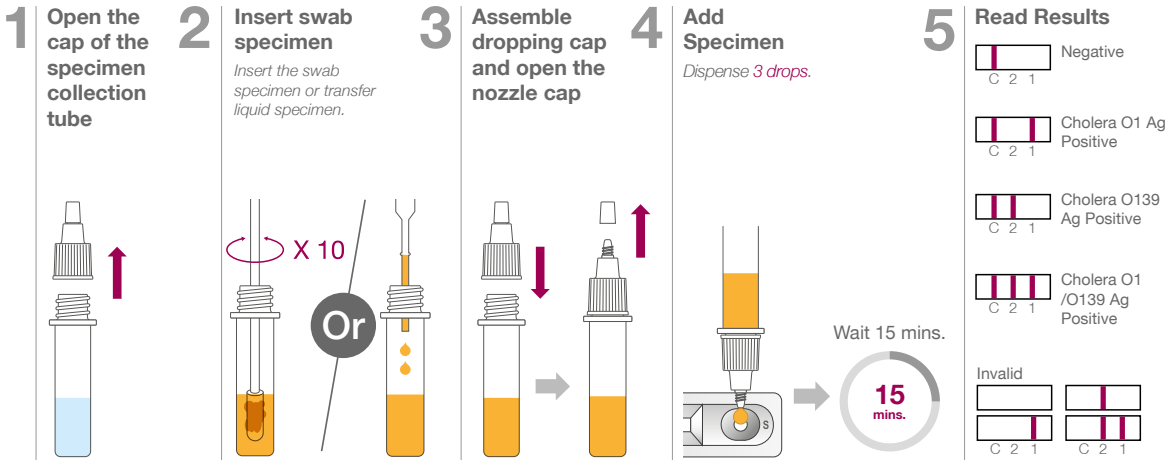
SD BIOLINE Cholera Ag O1/O139 test is a rapid immunochromatographic assay for qualitative detection of *Vibrio cholera* O1/O139 in human fecal specimens.

- Easy to use, convenient and clean test
- Specimen : Solid fecal specimen (about 50 mg) or liquid fecal specimen (300 µl)
- Test result : 15 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 100 %, Specificity - 100 % (vs. Culture)

Materials Provided

- Test device
- Specimen collection tube with extraction buffer
- Specimen collection swab for solid fecal specimens
- Specimen collection dropper for liquid fecal specimens
- Patient identification label

Test Procedure



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Cholera Ag O1/O139	44FK30	Device	Fecal	20T/Kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE Rubella IgG/IgM
Rubella IgG/IgM Test

Rubella (commonly known as German measles or 3-day measles) is an infection that primarily affects the skin and lymph nodes. It is caused by the rubella virus (not the same virus that causes measles), which is usually transmitted by secretions from the nose or throat. It can also pass through a pregnant woman's bloodstream to infect her unborn child. As this is a generally mild disease in children, the primary medical danger of rubella is the infection of pregnant woman, which may cause congenital rubella syndrome in developing babies.

General Information
SD BIOLINE Rubella IgG/IgM test is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to rubella virus in human serum or plasma.

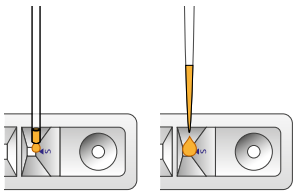
- Indicator of immune status or confirmation of recent rubella infection
- Specimen : Serum or Plasma
- Test result : 20 - 30 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance:
  - Sensitivity : IgG - 99.14 %, IgM - 98.33 %
  - Specificity : IgG - 91.55 %, IgM - 97.64 %

Materials Provided
- Test device
- Capillary pipette (5 µl)
- Assay diluent

Test Procedure
1 **Add Specimen**

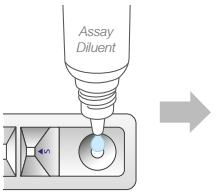
Dispense 5 µl of serum or plasma into the specimen well "S".

Capillary pipette *Micropipette*



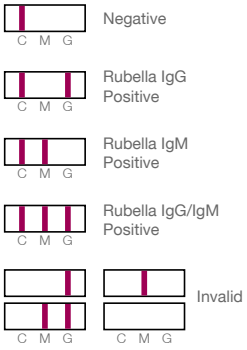
2 **Add Assay Diluent**

Dispense 3-4 drops of the assay diluent.



Wait 20-30 mins.

3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Rubella IgG/IgM	07FK20	Device	Serum/Plasma	25T/Kit

SD BIOLINE EV71 IgM

IgM antibodies to Enterovirus 71 Test

Enteroviruses belong to the Picornaviridae family of viruses and are further organaized into the subgenera polioviruses, coxackieviruses(groups A and B), and echoviruses. Enterovirus 71 (EV71), the newest member of Enteroviridae, is notable for its etioloigical role in epidemics of severe neurological disease in children. It appears to be emerging as an important virulent neurotropic enterovirus in upcoming era of poliomyelitis eradication. The illness usually peaks in June or July.

General Information

SD BIOLINE EV71 IgM test is a rapid, qualitative and differential detection of IgM antibodies to Enterovirus 71 in human serum or plasma.

- Early diagnosis of acute EV 71 infection
- Differential detection of IgM antibody
- Easy to use: No need of any equipment
- Test result: 15~20 minutes
- Specimen: serum, plasma (5 µl)
- Shelf life and storage temperature: 18 months from the date of manufacturing at 1-30 °C

Materials Provided

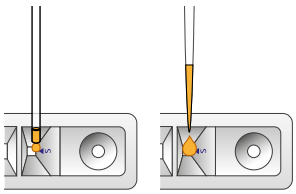
- Test device
- Capillary pipette (5 µl)
- Assay diluent

Test Procedure

1 **Add Specimen**

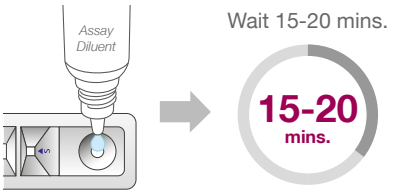
Dispense 5 µl of serum or plasma into the specimen well "S".

Capillary pipette *Micropipette*

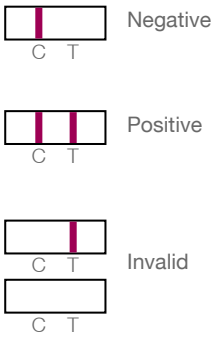


2 **Add Assay Diluent**

Dispense 3-4 drops of the assay diluent.



3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
EV71 IgM	43FK50	Device	Serum/Plasma	25T/Kit

SD BIOLINE Tetanus

Tetanus Antibody Test

Tetanus is an acute and often fatal, disease caused by a neurotoxin produced by *Clostridium tetani*. The toxin causes a high rate of disease outbreak and mortality by invading the nerve system. In cases of infectious exposure from external injuries, an immunization with tetanus toxoid or its immunoglobulin is recommended to prevent tetanus from attacking. Additionally, a sufficient titer level of tetanus antibody in the blood is required because although a person may have a tetanus immunization history in infancy and childhood, the immunization may not have been performed correctly or the antibody titer level may have declined with age.

General Information

SD BIOLINE Tetanus test is rapid immunochromatographic assay for qualitative detection of tetanus antibody in serum, plasma or whole blood.

- Specimen : Serum, Plasma or Whole blood
- Detection limit : 100 mIU/ml (serum, plasma), 200 mIU/ml (whole blood)
- Point of care test at emergency room
- Detection of tetanus antibody (IgG/IgM) before anti-tetanus toxoid immunoglobulin treatment
- No interfering reactivity with hemoglobin, bilirubin or triglyceride
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance : SD BIOLINE Tetanus vs IBL ELISA
  - Sensitivity : Serum - 96.5 %, Whole blood- 94.8 %
  - Specificity : Serum - 87 %, Whole blood - 89.1 %

Materials Provided

- Test device
- Disposable dropper (30 µl)
- Assay diluent

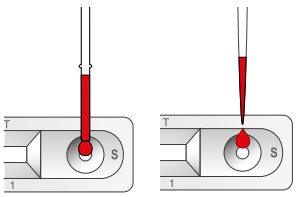
Test Procedure

1 **Add Specimen**

Dispense 30 µl of whole blood, serum or plasma into the specimen well "S".

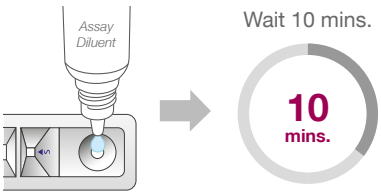
Disposable dropper (whole blood)

Micropipette (whole blood, plasma or serum)

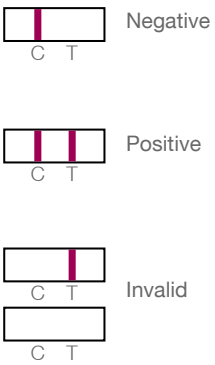


2 **Add Assay Diluent**

Dispense 3-4 drops of the assay diluent.



3 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Tetanus	42FK10	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE AFP/CEA

Tumor Markers Test

Alpha-fetoprotein(AFP) is one of the most well-known carcinofetal antigens.

Carcinoembryonic antigen (CEA) is a tumor-associated antigen, which is expressed largely in gastrointestinal track tumors.

General Information

SD BIOLINE AFP, CEA tests are immunochromatographic assay designed for qualitative detection of AFP, CEA in human serum or plasma.

- Test results : 20 minutes
- Specimen: Serum or plasma

Description	AFP	CEA
Detection	Alpha fetoprotein	Carcinoembryonic antigen
Cut - Off	20 ng/ml	5 ng/ml
Sensitivity	100 %	100 %
Specificity	100 %	99.6 %
Storage temp.	2~30 °C	1~30 °C

Materials Provided

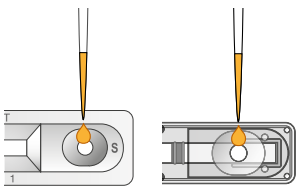
- Test device / Multi-device

Test Procedure

1 **Add Specimen**

Dispense 100 µl of serum or plasma into the specimen well.

Device *Multi Device*



Wait 20 mins.

2 **Read Results**

Negative

Positive

Invalid

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
AFP	20FK10	Device	Serum/Plasma	30T/Kit
AFP	20FK11	Multi-Device	Serum/Plasma	10Tx10/Kit
CEA	21FK10	Device	Serum/Plasma	30T/Kit
CEA	21FK11	Multi-Device	Serum/Plasma	10Tx10/Kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE FOB
Fecal Occult Blood Test

The detection of fecal occult blood is important for the diagnosis of disease that results in gastrointestinal bleeding and to screen for colorectal cancers and large adenomas that bleed. Screening for colorectal cancer probably increases the cancer detection at an early stage, therefore reduces the mortality.

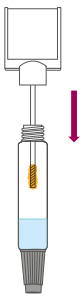
General Information
SD BIOLINE FOB test is a rapid qualitative test for the detection of human blood hemoglobin in human fecal specimens.

- Screening occult blood in fecal
- No cross reaction with animal blood, Vitamin C and Sucrose
- Specimen : Fecal
- Detection Limit : 50 ng/ml of human blood hemoglobin
- Test result in 10 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 2-30 °C
- Performance:
  - Sensitivity : 98 %, Specificity : 98.5 %

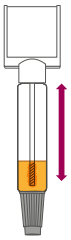
Materials Provided
- Test device / Multi-device
- Specimen collection tube with assay diluent
- Storage and transport bag for specimen container

Test Procedure

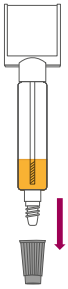
1 Insert swab specimen
Insert the applicator stick into the specimen collection tube



2 Mix well
Shake and mix well

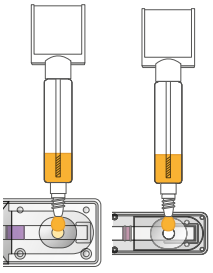


3 Open the cap
Loosen green cap the lower part of the specimen collection tube



4 Add specimen
Dispense 3 drops of the assay diluent.

Device *Multi-Device*



Wait 10 mins.

5 Read Results

Negative
C T

Positive
C T

Invalid
C T

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
FOB(Fecal Occult Blood)	25FK10	Device	Fecal	25T/Kit
FOB(Fecal Occult Blood)	25FK12	Multi-Device	Fecal	10Tx5/Kit

SD BIOLINE Troponin I

Cardiac Troponin I Test

Cardiac markers are substances released from heart muscle when it is damaged as a result of myocardial infarction. Depending on the marker, it can take between 2 to 24 hours for the level to increase in the blood. is released during MI from the cytosolic pool of the myocytes. Its subsequent release is prolonged with degradation of actin and myosin filaments. Because it has increased specificity compared with CK-MB, troponin is a superior marker for myocardial injury.

General Information

SD BIOLINE Troponin I rapid test is rapid immuno-chromatographic assay for the qualitative detection of cardiac troponin I(cTnI) in human serum, plasma or whole blood as an aid in the diagnosis of myocardial infarction in emergency room, critical care, point-of-care, and hospital settings.

- Time to Therapy Reduced
- Length of Stay in ER Reduced
- Patient Satisfaction Increased
- Cost of Care Reduced
- Specimen : Serum, plasma or whole blood (80 µl)
- Test result : 15 minutes
- Cut-off level : 0.5 ng/ml
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity - 96.9 %, Specificity - 97.3 % (vs. Quantitative assay)

Materials Provided

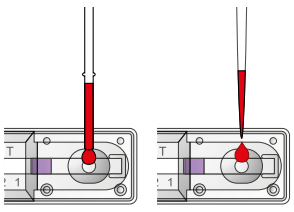
- Test device
- Disposable dropper

Test Procedure

1 **Add Specimen**

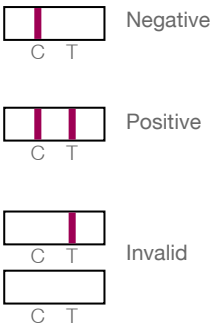
Dispense 80 µl of serum, plasma or whole blood into the specimen well "S".

Dropper *Micropipette*



Wait 15 mins.

2 **Read Results**



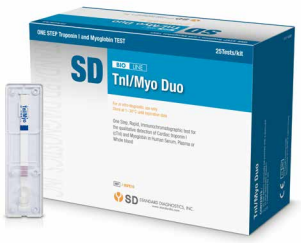
Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Troponin I	90FK10	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE TnI/Myo Duo
Cardiac Troponin I and Myoglobin Test

Cardiac markers are substances released from heart muscle when it is damaged as a result of myocardial infarction. Depending on the marker, it can take between 2 to 24 hours for the level to increase in the blood. is released during MI from the cytosolic pool of the myocytes. Its subsequent release is prolonged with degradation of actin and myosin filaments.



General Information
SD BIOLINE TnI/Myo Duo is an immunochromatographic assay for the qualitative and differential detection of Myoglobin and cardiac troponin I(cTnI) in human serum, plasma or whole blood as an aid in the diagnosis of myocardial infarction(AMI) in emergency room, critical care, point-of-care, and hospital settings.

Myoglobin	When the muscle cells are damaged, it released to the blood rapidly than any other myocardial markers.
Troponin I	The cTnI and its complex are released to blood circulation soon after onset of acute myocardial infarction (AMI). The elevated level could be detected approximately 10-20 hours until 10-15 days after onset of AMI.

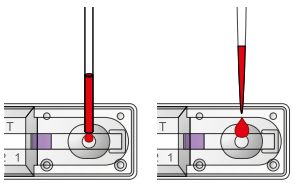
- Time to Therapy Reduced
- Cost of Care Reduced
- Specimen : Serum, plasma or whole blood (80 µl)
- Test result : 15 minutes
- Shelf life and storage temperature: 18 months from the date of manufacturing at 1-30 °C
- Performance:
  - Troponin I : Sensitivity - 97.9 %, Specificity - 100 %
  - Myoglobin : Sensitivity - 100 %, Specificity - 97.6 %

Materials Provided
- Test device
- Disposable dropper (80 µl)

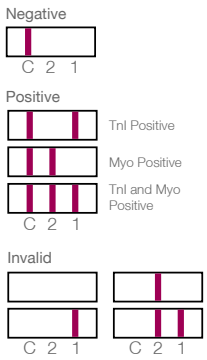
Test Procedure
1 **Add Specimen**

Dispense 80 µl of serum, plasma or whole blood into the specimen well "S".

Dropper *Micropipette*



2 **Read Results**



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
TnI/Myo Duo	95FK10	Device	Serum/Plasma/Whole Blood	25T/Kit

SD BIOLINE hCG, hCG(U/S)

Human chorionic gonadotropin Test

Human chorionic gonadotropin (hCG) is a glycoprotein hormone secreted by the developing placenta shortly after fertilization. When you are pregnant, your body will produce special pregnancy hormone known as hCG.

General Information

SD BIOLINE hCG test is an immunochromatographic assay designed for qualitative detection of hCG in urine.

	hCG	hCG(U/S)
Test result	3 minutes	5 minutes
Detection	25 mIU/ml	25 mIU/ml
Specimen	Urine	Urine, Serum
Storage temperature	2~30 °C	1~30 °C

- Cross reactivity : No cross reactivity with 500 mIU/ml of hLH, 1,000 mIU/ml of hFSH and 1,000μIU/ml of hTSH

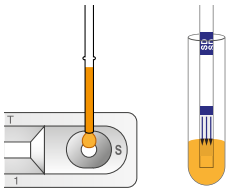
Materials Provided

- Test device / Strip
- Disposable dropper

Test Procedure

1 Add Specimen

Device
Dispense 3-4 drops of urine or serum into the specimen well "S".



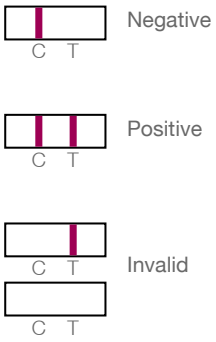
Strip
Insert strip into the test tube.

Urine
Wait 3 mins.

OR

Urine, Serum
Wait 5 mins.

2 Read Results



Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
hCG	30FK10	Device	Urine	25T/Kit
hCG Fast	30FK12	Strip	Urine	25Tx4/Kit
hCG(U/S)	30FK20	Device	Urine, Serum	25T/Kit

SD BIOLINE RAPID DIAGNOSTIC TEST
Immunochromatographic Assay

SD BIOLINE LH
Luteinizing Hormones Test

Human luteinizing hormone (hLH) is a glycoprotein hormone secreted by the anterior pituitary. In view of the characteristic variation of hLH during the menstrual cycle, rapid and sensitive measurement of hLH is an important tool in the diagnosis and management of infertility in females. Approximately 12 ~ 24 hours after the hLH surge, the wall of the enlarged follicle ruptures at ovulation and the mature ovum is extruded. Detection of the hLH surge can aid in predicting the time of ovulation. The onset of the hLH surge precedes ovulation by approximately 30 hours.

General Information
SD BIOLINE LH test is immunochromatographic assay designed for qualitative detection of LH in urine.

- Important tool in the diagnosis and management of infertility in females.
- Test result: 10 minutes
- Specimen: Urine
- No cross reactivity with hFSH, TSH, hCG
- Detection: 20 mIU/ml
- Shelf life and storage temperature: 18 months from the date of manufacturing at 2-30 °C

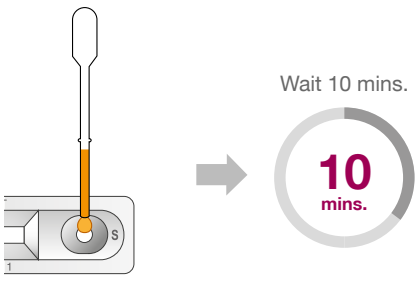
Materials Provided
- Test device
- Disposable dropper

Test Procedure
When to begin testing

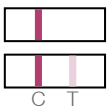
To decide when to begin testing, determine the length of your normal menstrual cycle. The length of your cycle is from the beginning of one period to the beginning of the next (count the first day of bleeding or spotting as day 1).
For example, if your period normally begins every 28 days, you should begin testing 11 days after the first day of your last period.

1 Add Specimen

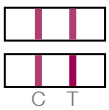
Dispense 3 drop of urine into the specimen well "S".



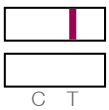
2 Read Results



Negative *(LH is not detected)*
- *One color band*
- *Two color bands on light color "T" band*



Positive *(LH is detected)*
- *Two purple bands of similar color and darkness*
- *The test band ("T") may be darker than the control band ("C")*



Invalid

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
LH	31FK10	Device	Urine	25T/Kit

SD BIOLINE DOA

Drug of Abuse Test

Drug abuse has a wide range of definitions related to taking a psychoactive drug or performance enhancing drug for a non-therapeutic or non-medical effect. Depending on the actual compound, drug abuse may lead to health problems, social problems, physical dependence, or psychological addiction.

General Information

SD BIOLINE DOA test is a rapid and immunochromatographic assay designed for qualitative detection of drug metabolite in human urine at a cut-off concentration.

- Established as a guideline by U.S. NIDA
- No instruments needed
- Shelf life: 24 months from the date of manufacturing
- Storage temperature :
  - 1~30 °C (MDMA, DOA Multi 5, DOA Multi 6), 2-30 °C (MET, MOP, AMP, COC, THC, MET/THC)

Item	MET	THC	MOP	COC	AMP	MDMA
Detection	D-Methamphetamine	11-nor-Δ^9-THC-9-COOH (marijuana)	Morphine , Opiates, Heroin	Benzoylecgonine (cocaine)	D-Amphetamine	3,4-Methylenedioxy-N-Methylamphetamine
Cut-off	1000 ng/ml	50 ng/ml	300 ng/ml	300 ng/ml	1000 ng/ml	500 ng/ml
Sensitivity	100 %	100 %	100 %	100 %	100 %	100 %
Specificity	100 %	100 %	100 %	100 %	100 %	95.2 %

Materials Provided

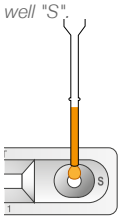
- Test device / Multi-device
- Disposable dropper

Test Procedure

1 Add Specimen

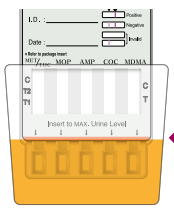
Device

Dispense 3 drop of urine into the specimen well "S".



Multi-Device

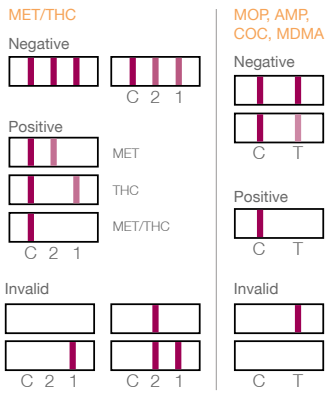
Immerse the test device vertically into the urine specimen for 10 seconds. After 10 seconds, bring out the test device, place on flat surface.



MAX. urine level

Wait 5 mins.

2 Read Results



Ordering Information

Product	Cat. No.	Type	Pack Size
MOP	50FK10	Device	25T/Kit
MET	50FK20	Device	25T/Kit
AMP	50FK30	Device	25T/Kit
COC	50FK40	Device	25T/Kit
THC	50FK50	Device	25T/Kit

Product	Cat. No.	Type	Pack Size
MET/THC	50FK60	Device	25T/Kit
MDMA	50FK100	Device	25T/Kit
DOA Multi-5	50FK150	Multi-Device	1Tx10/Kit
DOA Multi-6	50FK130	Multi-Device	1Tx10/Kit

SD ELISA KIT

Enzyme Linked Immunosorbent Assay Kit

SD ELISA
HBsAg ELISA 3.0
HCV ELISA 3.0

General Information

The ELISA(Enzyme Linked Immunosorbent Assay) is a biochemical technique used mainly in immunology to detect the presence of an antibody or an antigen in a specimen. This a fundamental tool of clinical immunology, and is used as an initial screen. Based on the principle of antibody-antigen interaction, this test allows for easy visualization of results and can be completed without the additional concern of radioactive materials use.

- Shelf life and storage temperature: 12 months from the date of manufacturing at 2-8 °C

Product	HBsAg ELISA 3.0	HCV ELISA 3.0
Capture	Anti-HBs	Rec. HCV Ag (Core, NS3, NS4, NS5)
Method	Double Sandwich	Indirect Sandwich
Sensitivity	100 %	99.5 %
Specificity	100 %	99.5 %
Specimen	Serum or plasma	Serum or plasma

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
HBsAg ELISA 3.0	01EK10	Microplate	Serum or plasma	96 wells/Kit
HBsAg ELISA 3.0	01EK11	Microplate	Serum or plasma	480 wells/Kit
HCV ELISA 3.0	02EK10	Microplate	Serum or plasma	96 wells/Kit
HCV ELISA 3.0	02EK11	Microplate	Serum or plasma	480 wells/Kit

SD ELISA KIT
Enzyme Linked Immunosorbent Assay Kit

SD ELISA
HIV 1/2 ELISA 3.0

General Information
SD HIV-1/2 ELISA 3.0 kit is double sandwich ELISA for the qualitative detection of antibodies to all isotypes(IgG, IgM, IgA) specific to HIV-1 including subtype-O and HIV-2 simultaneously in human serum or plasma.

- Capture antigen: p24, gp41 and gp36
- Shelf life and storage temperature: 12 months from the date of manufacturing at 2-8 °C
- Performance: Sensitivity-100 % / Specificity-99.8 %

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
HIV1/2 ELISA 3.0	03EK10	Microplate	Serum, plasma	96 wells/Kit
HIV1/2 ELISA 3.0	03EK11	Microplate	Serum, plasma	480 wells/Kit

SD ELISA
Malaria Ag ELISA

General Information
SD BIOLINE Malaria Antigen ELISA is qualitative test for the detection of the presence of Plasmodium lactate dehydrogenase(pLDH), an enzyme produced both in the sexual and asexual forms of parasite.

- Detect Plasmodium lactate dehydrogenase(pLDH) of *Plasmodium species*.
- Suitable for mass screening test for Malaria
- Simple and easy to use: All necessary reagents included in the kit
- Shelf life and storage temperature: 12 months from the date of manufacturing at 2-8 °C
- Performance:
  - Sensitivity 98 %(P.f) / Sensitivity 96 %(P.v)
  - Specificity: 100 %

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Malaria Ag ELISA	05EK40	Microplate	Whole blood	96 wells/Kit
Malaria Ag ELISA	05EK41	Microplate	Whole blood	480 wells/Kit

SD ELISA
Dengue IgG Capture ELISA

General Information

In primary infection with the dengue virus, IgG antibody appears a few days after IgM. IgG antibodies are produced at a lower level compared to IgM but will persist for many years after infection.
In secondary infections, IgG response may rise quickly before or simultaneously with an IgM response and will become the predominant immunoglobulin isotype in secondary infections.

- Suitable marker for secondary dengue infection
- High accuracy with all dengue serotypes(DEN1,2,3, and 4)
- Simple and easy to use: All necessary reagents included in the kit
- Shelf life and storage temperature: 18 months from the date of manufacturing at 2-8 °C
- Performance: Sensitivity 98.8 % / Specificity 99.2 %

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Dengue IgG Capture ELISA	11EK10	Microplate	Serum	96 wells/Kit

SD ELISA
Dengue IgM Capture ELISA

General Information

In primary infection with the dengue virus, IgM antibody becomes detectable about five days after disease onset, when circulating virus declines in the blood. IgM level rises quickly to peak at about 2 weeks and declines to undetectable level after 2-3 months
In secondary infections, IgM response is typically at a lower level compared to that in a primary infection.

- Early diagnosis of dengue infection (Especially in primary dengue infection)
- High accuracy with all dengue serotypes(DEN1,2,3, and 4)
- Simple and easy to use: All necessary reagents included in the kit
- Shelf life and storage temperature: 18 months from the date of manufacturing at 2-8 °C
- Included in the WHO Bulk Procurement Scheme
- Performance: Sensitivity 96.4 % / Specificity: 98.9 % (vs. HAI test)

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Dengue IgM Capture ELISA	11EK20	Microplate	Serum	96 wells/Kit

SD ELISA
Dengue NS1 Ag ELISA

General Information

The presence of circulating non-structural glycoprotein (NS1) indicates Viremia. If sufficient virus is present, NS1 can be detectable in a patient's blood from day 0 to day 5 following disease onset. The detection of NS1 antigen is therefore useful as a test of early acute infection.

- Perfect, early diagnosis of dengue infection
- High accuracy with all dengue serotypes(DEN1,2,3, and 4)
- Simple and easy to use: All necessary reagents included in the kit
- Shelf life and storage temperature: 18 months from the date of manufacturing at 2-8 °C
- Performance: Sensitivity 93.3 %(112/120) / Specificity 98.9 %(178/180)

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Dengue NS1 Ag ELISA	11EK50	Microplate	Serum	96 wells/Kit

SD ELISA
Chikungunya IgM ELISA

General Information

SD Chikungunya IgM ELISA is for the qualitative detection of IgM antibodies specific to Chikungunya in human serum.

- Useful to distinguish Chikungunya from dengue virus infection
- To ensure analysis of larger quantities of specimens in the event of large outbreaks or serosurveys
- Simple and easy to use: All necessary reagents included in the kit
- Shelf life and storage temperature: 12 months from the date of manufacturing at 2-8 °C
- Performance: Sensitivity 93.6 % / Specificity 95.9 %

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Chikungunya IgM ELISA	46EK10	Microplate	Serum	96 wells/Kit

SD ELISA
Leptospira IgM ELISA

General Information

SD Leptospira IgM ELISA is for the qualitative detection of IgM antibodies against leptospira antigen in human serum, as an aid in the clinical laboratory diagnosis of Leptospirosis.

- Efficient diagnosis of leptospirosis
- Simple and easy to use: All necessary reagents included in the kit
- Shelf life and storage temperature: 12 months from the date of manufacturing at 2-8 °C
- Performance: Sensitivity 97.2 % / Specificity 99.1 %

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
Leptospira IgM ELISA	16EK10	Microplate	Serum	96 wells/Kit

SD ELISA
H.pylori Ag ELISA

General Information

SD H.pylori Ag ELISA is for the qualitative detection of *Helicobacter pylori* antigen in human fecal specimens, as an aid in the clinical laboratory diagnosis of *H. pylori* infection.

- Optimal choice to confirm treatment efficacy
- Suitable for mass screening test of *H.pylori* infection
- Indicator of active *H. pylori* infection
- Simple and easy to use: All necessary reagents included in the kit
- Shelf life and storage temperature: 18 months from the date of manufacturing at 2-8 °C
- Performance: Sensitivity 100 % / Specificity 100 %

Ordering Information

Product	Cat. No.	Type	Specimen	Pack Size
H. pylori Ag ELISA	04EK20	Microplate	Stool	96 wells/Kit

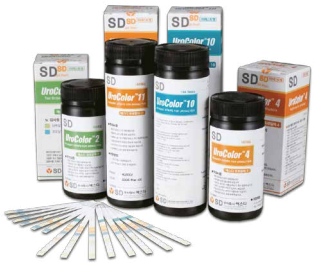
SD URINE CHEMISTRY

UroColor • UroMeter 720 • UroMeter120

SD UroColor

Urine Chemistry Strip

Test for Blood, Bilirubin, Urobilinogen, Ketone, Protein, Nitrite, Glucose, pH, Specific gravity, Leucocytes and Ascorbic acid in urine.



General Information

- Clear positive and negative results
- Checking the interference in Glucose, Blood, Bilirubin, and Nitrite by Vitamin C ingested
- Accurate results in about 60 seconds
- Shelf life : 24 months from the date of manufacturing
- Different color packages by parameters
- Fast result visually or instrumentally
- Packing size : 100's

Ordering Information

Cat No.	Product	Blood	Bilirubin	Urobilinogen	Ketone	Protein	Nitrite	Glucose	pH	Specific gravity	Leukocyte	Vitamin C
10UK01G	UroColor 1G							•				
10UK02	UroColor 2					•		•				
10UK02K	UroColor 2K				•			•				
10UK03	UroColor 3					•		•	•			
10UK04	UroColor 4	•				•		•	•			
10UK04S	UroColor 4S					•		•	•	•		
10UK05K	UroColor 5K	•			•	•		•	•			
10UK10	UroColor 10	•	•	•	•	•	•	•	•	•	•	
10UK11	UroColor 11	•	•	•	•	•	•	•	•	•	•	•

UroColor Control

Product	Cat. No.	Type	Specimen	Pack Size
UroColor Control Strip	11UC11	Positive and Negative Strip	Urine	25T/Kit

SD UroMeter 720

Urine Chemistry Analyzer

Take increased throughput and improved workflow together with precision.

General Information

- High capacity - Max. 720 tests per hour
- Easy to input ID and use data
- Easy to input multiple ID by key board, PC and barcode reader
- Maximum 100,000 test results memory
- Easy software version up (Drag & Drop PC to UroMeter 720) (No memory replacement)
- Applicable to your multi-language by user define method
- Easy to set-up & maintenance
- 4 ~ 11 parameter testing available

Specifications

- Power Adapter : DC 12V 3.33A (100-240V, 50/60Hz)
- Size : 320 x 260 x 178 mm (W x D x H)
- Weight : 2.4 kg (5.3 lb)
- Ambient operating temperature range (18-30ºC)
- Memory : 100,000 results
- Print : Internal line thermal printer
- LCD : 320*240 QVGA color
- RS232C Interface :
  - COM1 : Communication with PC
  - COM2 : Communication with barcode system

Fast result printing
- High speed thermal printer
- Complete data about patient and the result
- Highlightening abnormal result for quick review

LED indicator
- Photo TR module sensor
- Urine color & clarity determination :
- Eliminating the non-specific result from turbid urine

Various testing parameters
- Streamlining operations by immediate start-up
- It works with various urine chemistry dipsticks (parameters 4 ~ 11)

Various interface ports
- RS232C, USB keyboard port, USB port
- Up/Downloading test result by Bidirectional interface
- A handheld bar-code reader identifying specimen

Wide LCD display window
- Bright and clear color LCD
- 320*240 resolution
- Automatic switching to testing mode from standby mode
- Easy to learn and operate

Continuous & automatic dipstick loading conveyor
- Take exact position through moving
- Easy maintenance by dismantling

Ordering Information

Product	Cat. No.	Type
UroMeter 720	UM0720	Unit

SD UroMeter 120

Urine Chemistry Analyzer

Take increased throughput and improved workflow together with precision.

General Information

- Auto calibration with power-on
- Simple and excellent compatibility by USB communication port
- Enhancing user-convenience even for left-hander by ergonomics design
- Enhancing work efficiency by flexible options between quick mode & normal mode
- Easy to input multiple ID by key board, PC and barcode reader
- Applicable to your multi-language by user define method
- 4 ~ 11 parameter testing available
- Maximum 300 tests/hour, Average 120 tests/hour
- Easy to learn and operate

Specifications

- Power Adapter : DC 12V 3.33A (100-240V, 50/60Hz)
- LCD : 320*240 color LCD

Various interface ports

- RS232C, USB keyboard port, USB Port
- Up/Downloading test result by Bidirectional interface
- A handheld bar-code reader identifying specimen

Wide LCD display window

- Bright and clear color LCD
- 320*240 resolution
- Automatic switching to testing mode from standby mode

- RS232C Interface :
  - COM1 : Communication with PC
  - COM2 : Communication with barcode system

Fast result printing

- High speed thermal printer
- Complete data about patient and the result

Compact size, but high capacity

- Light weight : 1.2 kg (2.65 lb)
- Compact size : 252 x 200 x 114mm (W x D x H)

Ergonomic Design

- Design to minimize interference
- Easy to use even left-hander

Ordering Information

Product	Cat. No.	Type
UroMeter 120	UM0120	Unit

Memo

Alere strives to offer the best in quality and technology to our customers, along with better service to meet your diagnostic needs.

abbott.com/poct

Reference

1. Sensitivity and Specificity are extracted from the Instruction for use of each product.
2. Pharmacists planning service, inc.; What is Influenza? Online: http://www.ppsinc.org/flu/flu01.htm
3. Pennsylvania Department of Health. Respiratory Syncytial Virus Fact Sheet ; Online: http://www.health.pa.gov/My%20Health/Diseases%20and%20Conditions/Documents/Fact%20Sheets%202013/Respiratory%20Syncytial%20Virus%20Fact%20Sheet.pdf
4. Legionella and Legionnaires' Disease: 25 Years of Investigation Barry S. Fields,* Robert F. Benson, and Richard E. Besser [CLINICAL MICROBIOLOGY REVIEWS, July 2002, p. 506–526]
5. CDC. Helicobacter pylori. Fact Sheet for Health Care Providers Updated: July 1998. Online: https://www.cdc.gov/ulcer/files/hpfacts.pdf
6. CDC. Cholera General Information - What is cholera? Online: https://www.cdc.gov/cholera/general/index.html

Please consult your regulatory to understand which products are available in your country.

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