Abbott

Bioline™
PRODUCT CATALOG

INFECTIOUS DISEASES | TOXICOLOGY
ONCOLOGY | WOMEN'S HEALTH | ELISA

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RAPID DIAGNOSTIC TEST

INFECTIOUS DISEASES

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Bioline™ CHAGAS Ab

ANTIBODIES TO *TRYPANOSOMA CRUZI* TEST

Bioline™ Chagas Ab test is an immunochromatographic 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

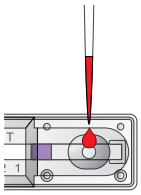
- Test device

SIMPLE PROCEDURE

1 **Add Specimen**

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

Micropipette

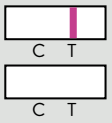


Wait 15 mins.

RESULTS INTERPRETATION

NEGATIVE

POSITIVE



INVALID

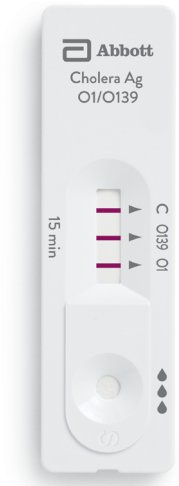
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Chagas Ab	49FK10	Device	Serum/Plasma/Whole Blood	25T/Kit

Bioline™ CHOLERA Ag O1/O139

V. CHOLERAE O1/ O139 ANTIGEN TEST



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

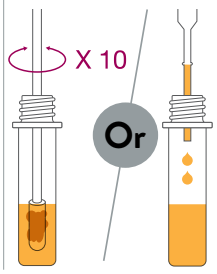
- Test device
- Specimen collection tube with extraction buffer
- Specimen collection swab for solid fecal specimens
- Specimen collection dropper for liquid fecal specimens
- Patient identification label

SIMPLE PROCEDURE

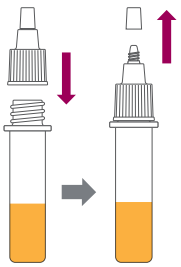
1 Open the cap of the specimen collection tube

2 Insert swab specimen

Insert the swab specimen or transfer liquid specimen.

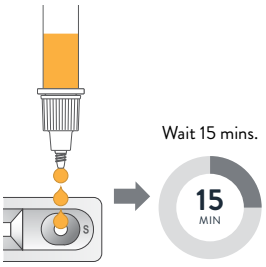


3 Assemble dropping cap and open the nozzle cap

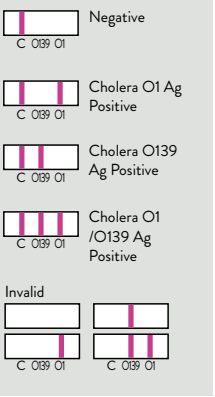


4 Add Specimen

Dispense 3 drops.



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Cholera Ag O1/O139	44FK30	Device	Fecal	20T/Kit

Bioline™ DENGUE DUO

SIMULTANEOUS DENGUE NS1 Ag & IgG/IgM AB TEST

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.

- Ideal diagnostic tool to cover all clinical stages from 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

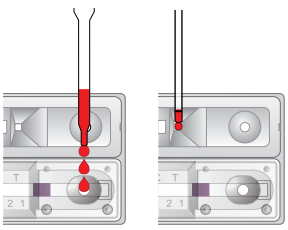
- Test device
- Assay diluent for Dengue IgG/IgM test
- Capillary pipette for dengue IgG/IgM test
- Disposable dropper for dengue NS1 Ag test

SIMPLE PROCEDURE

1 **Add Specimen**

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

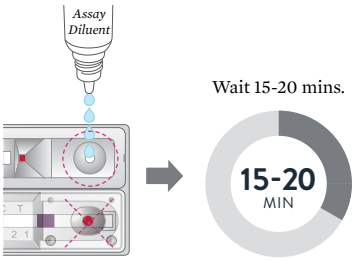
Dengue NS1 Ag *Dengue IgG/IgM*

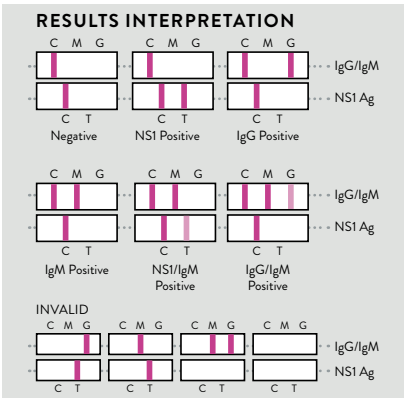


2 **Add Assay Diluent**

Dispense 4 drops of assay diluent into the round well.

Dengue IgG/IgM





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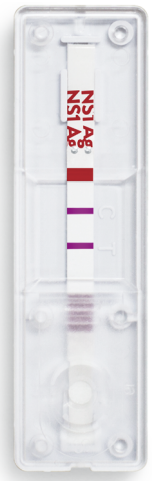
ORDERING INFORMATION

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

Bioline™ DENGUE NS1 Ag

DENGUE NS1 ANTIGEN TEST



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 %

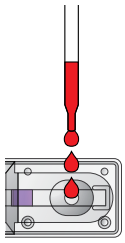
MATERIALS PROVIDED

- Test device
- Disposable dropper

SIMPLE PROCEDURE

1 **Add Specimen**

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

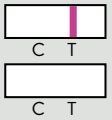


Wait 15-20 mins.

RESULTS INTERPRETATION

NEGATIVE

POSITIVE



INVALID

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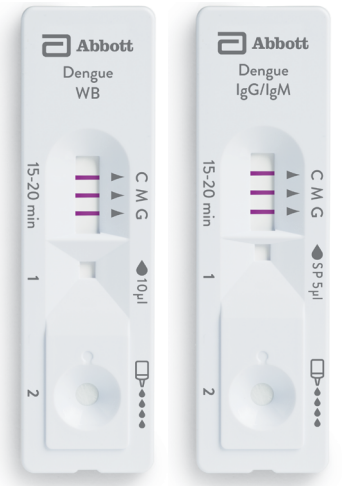
ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Dengue NS1 Ag	11FK50	Device	Serum/Plasma/Whole blood	25T/kit

Bioline™ DENGUE IgG/IgM

DENGUE IgG/IgM ANTIBODY TEST



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 serotypes; 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:
  - Bioline™ Dengue IgG/IgM: Sensitivity 94.6 %, Specificity 96.5 % (vs.ELISA test)
  - Bioline™ Dengue IgG/IgM WB: Sensitivity 94.2 %, Specificity 96.4 % (vs. ELISA test)

MATERIALS PROVIDED

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

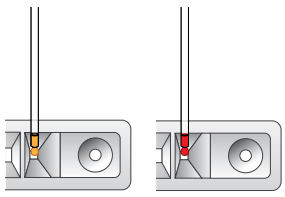
SIMPLE PROCEDURE

1 **Add Specimen**

Add specimen into the specimen well.

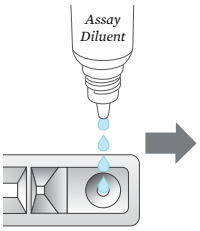
Dengue IgG/IgM (5 µl)

Dengue IgG/IgM WB (10 µl)

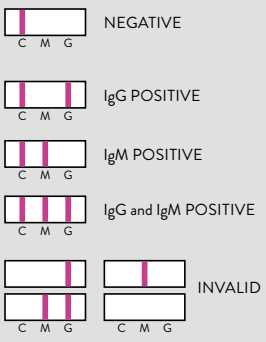


2 **Add Assay Diluent**

Dispense 4 drops of assay diluent into the round well.



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

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

Bioline™ EV71 IgM

IgM ANTIBODIES TO ENTEROVIRUS 71 TEST

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

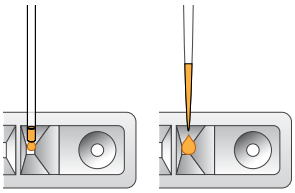
SIMPLE PROCEDURE

1 **Add Specimen**

Dispense 5 µl of serum or plasma into the specimen well "1".

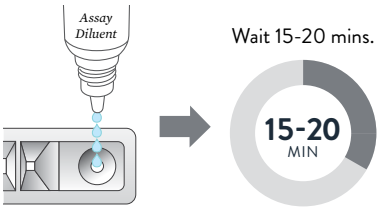
Capillary pipette

Micropipette

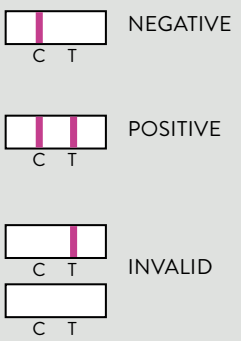


2 **Add Assay Diluent**

Dispense 3-4 drops of the assay diluent.



RESULTS INTERPRETATION



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ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
EV71 IgM	43FK50	Device	Serum/Plasma	25T/Kit

Bioline™ H.PYLORI

H.PYLORI ANTIBODY TEST

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 % (vs. ELISA)
- Specimen : Serum, Plasma

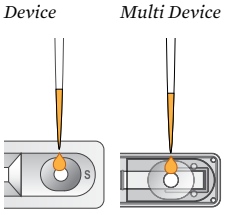
MATERIALS PROVIDED

- Test device/Multi-device
- Assay diluent

SIMPLE PROCEDURE

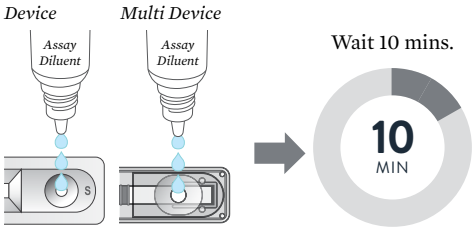
1 **Add Specimen**

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

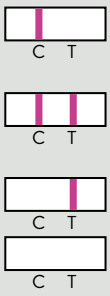


2 **Add Assay Diluent**

Dispense 3 drops of the assay diluent.



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

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

Bioline™ H.PYLORI Ag

H.PYLORI ANTIGEN TEST

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 % (vs. respiratory test and CLO test)
- Specimen: Fecal specimens

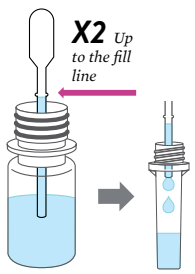
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Assay Diluent

Transfer assay diluent twice.

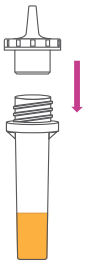


2 Insert swab specimen

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

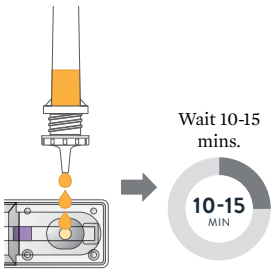
3 Assemble dropping cap

Assemble dropping cap on the specimen collection tube.



4 Add Specimen

Dispense 3 drops.



RESULTS INTERPRETATION

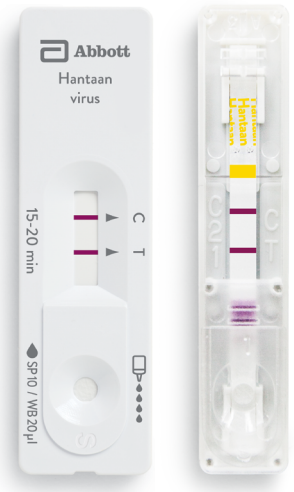
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
H.pylori Ag	04FK20	Device	Fecal	20T/Kit

Bioline™ HANTAANVIRUS

HANTAAN VIRUS ANTIBODY TEST



The Bioline™ Hantaanvirus test is rapid, qualitative detection of IgG, IgM,
IgA antibodies to Hantaan 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 %

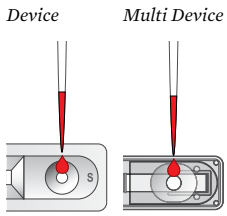
MATERIALS PROVIDED

- Test device
- Assay diluent

SIMPLE PROCEDURE

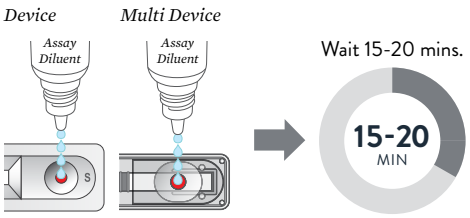
1 **Add Specimen**

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

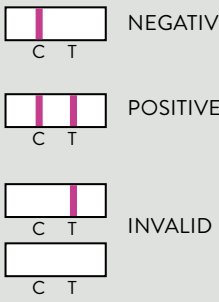


2 **Add Assay Diluent**

Dispense 3-4 drops of the assay diluent.



RESULTS INTERPRETATION



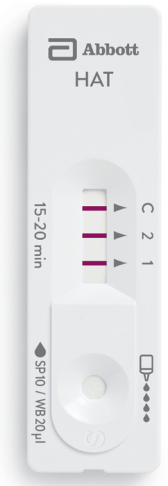
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Hantaanvirus	17FK10	Device	Serum/Plasma/Whole blood	30T/Kit
Hantaanvirus	17FK11	Multi-Device	Serum/Plasma/Whole blood	10Tx10/Kit

Bioline™ HAT

T.B.GAMBIENSE ANTIBODY (VSG) TEST



The Bioline™ HAT is an immunochromatographic test for rapid, qualitative detection of antibodies specific to variable surface glycoprotein (VSG) LiTat 1.3 and 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
- 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)

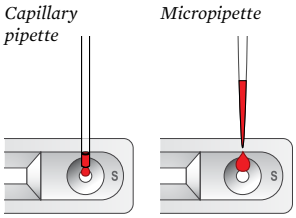
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

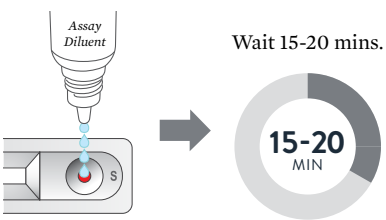
1 Add Specimen

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

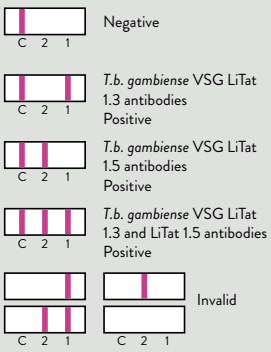


2 Add Assay Diluent

Dispense 4 drops of the assay diluent.



RESULTS INTERPRETATION



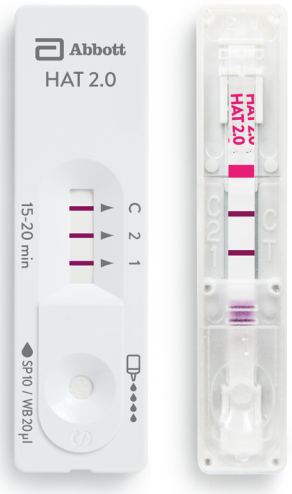
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
HAT	53FK10	Device	Serum/Plasma/Whole Blood	25T/Kit

Bioline™ HAT 2.0

T.B.GAMBIENSE ANTIBODY (ISG&VSG) TEST



Bioline™ HAT 2.0 is an immunochromatographic test for rapid, qualitative detection of antibodies of all isotypes (IgG, IgM, IgA) specific to invariable surface glycoprotein (ISG) or variable surface glycoprotein (VSG) of *Trypanosoma brucei gambiense (T.b. gambiense)* in human serum, plasma or whole blood.

- Affordable, easy and rapid testing of suspected HAT patients
- 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:
  - Device: Sensitivity 97.5 %, Specificity 84.0 % (vs. Microscopic examination)
  - Multi-device: Sensitivity 91.0 %, Specificity 96.5 % (vs. Microscopic examination)

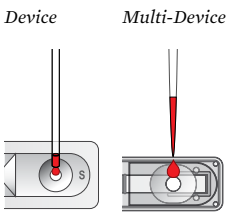
MATERIALS PROVIDED

- Test device / Multi-device
- Assay diluent
- Capillary pipette (20 µl) (for fingerstick)
- Alcohol swab
- Lancet

SIMPLE PROCEDURE

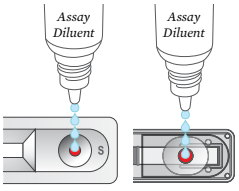
1 **Add Specimen**

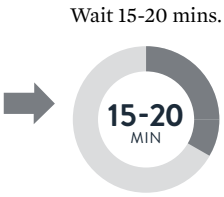
Dispense 10 µl of serum, plasma, or 20 µl of whole blood into the specimen well "S".



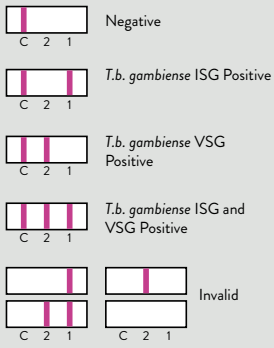
2 **Add Assay Diluent**

Dispense 4 drops of the assay diluent.





RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
HAT 2.0	53FK20	Device	Serum/Plasma/Whole Blood	25T/Kit
HAT 2.0	53FK21	Multi-Device	Serum/Plasma/Whole Blood	10Tx10/Kit

Bioline™ HAV IgG/IgM

HEPATITIS A VIRUS ANTIBODY TEST

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.

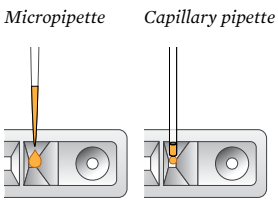
- Differential detection of IgG and IgM antibodies
- Specimen: Serum, plasma (5 µl)
- Test result: 20 minutes
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity 97.6 %, Specificity 98.0 %

MATERIALS PROVIDED

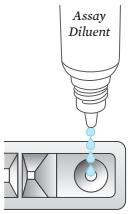
- Test device
- Assay diluent
- Capillary pipette (5 µl)

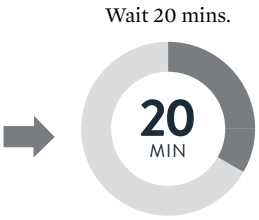
SIMPLE PROCEDURE

1 **Add Specimen**
Dispense 5 µl of specimen into the specimen well.



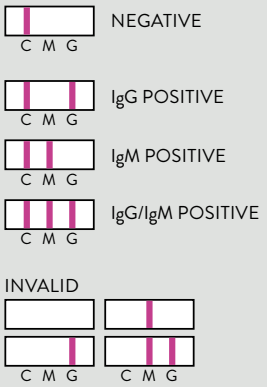
2 **Add Assay Diluent**
Dispense 4 drops of the assay diluent.





The presence of any test line, no matter how faint, the result is considered positive.

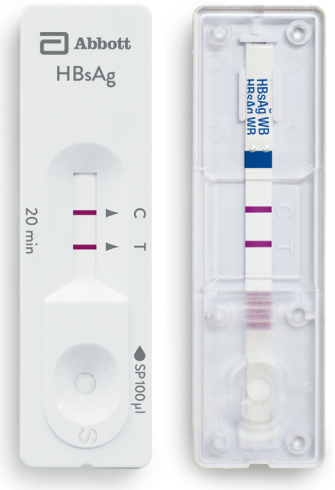
RESULTS INTERPRETATION



ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
HAV IgG/IgM	13FK10	Device	Serum/Plasma	25T/Kit

Bioline™
HEPATITIS B SERIES
HEPATITIS B VIRUS TEST



HBsAg, HBsAg WB

Bioline™ Hepatitis tests are intended for professional use as an aid in the diagnosis of hepatitis B. Highly sensitive, specific immunochromatographic assays for detection of HBsAg.

	HBsAg	HBsAg WB
SPECIMEN	Serum, Plasma	Serum, Plasma, Whole blood
SENSITIVITY	100 %	100 %
SPECIFICITY	100 %	100 %

MATERIALS PROVIDED

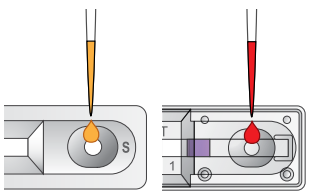
- Test device

SIMPLE PROCEDURE

1 **Add Specimen**

Dispense 100 µl of specimen into the specimen well.

HBsAg *HBsAg WB*



Wait 20 mins.

RESULTS INTERPRETATION

NEGATIVE

POSITIVE

INVALID

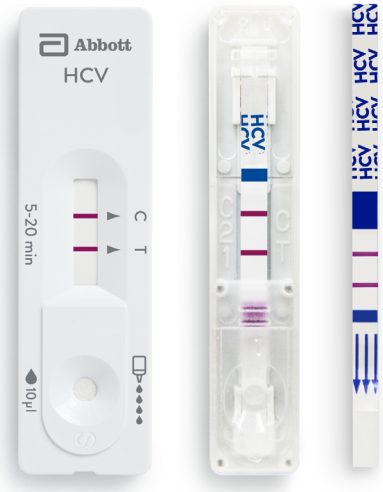
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
HBsAg	01FK10	Device	Serum/Plasma	30T/Kit
HBsAg WB	01FK10W	Device	Serum/Plasma/Whole blood	30T/Kit

Bioline™ HCV

HEPATITIS C VIRUS ANTIBODY TEST



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

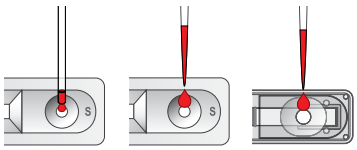
- Test device / Multi-device / Strip
- Assay diluent
- Option : Lancet, alcohol swab, capillary pipette (for fingerstick)

SIMPLE PROCEDURE

1 Add Specimen

Dispense 10 µl of specimen into the specimen well.

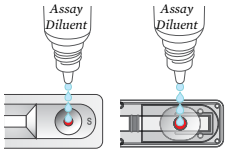
Capillary pipette *Micropipette* *Multi Device*



2 Add Assay Diluent

Dispense 4 drops of the assay diluent.

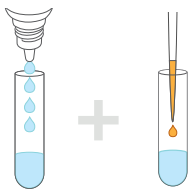
Device *Multi Device*



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.

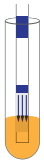
Strip

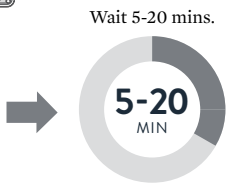


2 Insert Strip

Insert strip into the test tube.

Strip





The presence of any test line, no matter how faint, the result is considered positive.

RESULTS INTERPRETATION

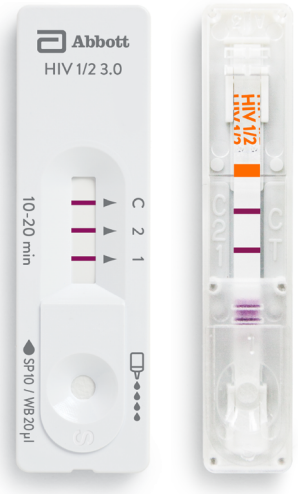
ORDERING INFORMATION

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*	02FK16CE	Device	Serum/Plasma/Whole blood	25T/Kit
HCV**	02FK17CE	Device	Serum/Plasma/Whole blood	25T/Kit
HCV Fast	02FK12	Strip	Serum/Plasma	25T/Kit

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

Bioline™ HIV 1/2 3.0

HIV-1/2 ANTIBODY TEST



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.

- 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 %

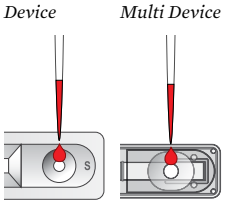
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

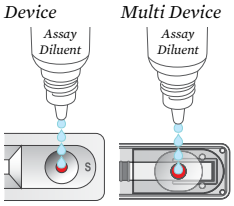
1 Add Specimen

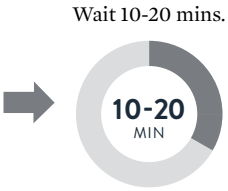
Dispense 10 µl of plasma, serum or 20 µl of whole blood into the specimen well.



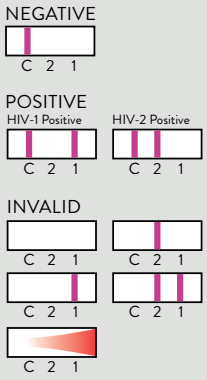
2 Add Assay Diluent

Dispense 4 drops of the assay diluent.





RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

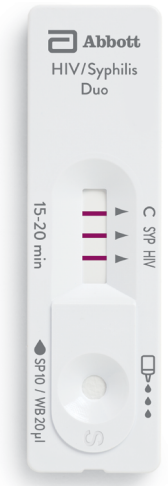
ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
HIV 1/2 3.0	03FK10	Device	Serum/Plasma/Whole blood	30T/Kit
HIV 1/2 3.0	03FK11	Multi-Device	Serum/Plasma/Whole blood	10Tx10/Kit
HIV 1/2 3.0*	03FK16	Device	Serum/Plasma/Whole blood	25T/Kit
HIV 1/2 3.0**	03FK17	Device	Serum/Plasma/Whole blood	25T/Kit
HIV 1/2 3.0	03FK10CE	Device	Serum/Plasma/Whole blood	30T/Kit
HIV 1/2 3.0***	03FK16CE	Device	Serum/Plasma/Whole blood	25T/Kit

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

Bioline™ HIV/SYPHILIS DUO

SIMULTANEOUS DETECTION OF HIV-1/2 AND SYPHILIS ANTIBODIES TEST



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 99.91 %, Specificity 99.67 %
  - Syphilis: Sensitivity 99.67 %, Specificity 99.72 %

MATERIALS PROVIDED

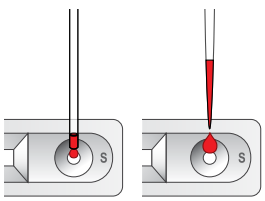
- Test device
- Assay diluent
- Option : Lancet, alcohol swab, capillary pipette

SIMPLE PROCEDURE

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

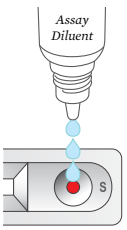
1 Add Specimen

Micropipette *Capillary pipette*



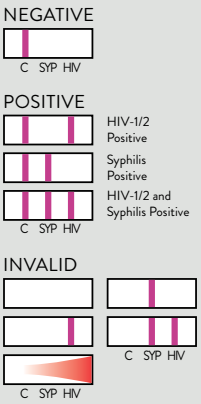
2 Add Assay Diluent

Dispense 3 drops of the assay diluent.



Wait 15-20mins.

RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	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.

Bioline™ INFLUENZA ANTIGEN

INFLUENZA VIRUS TYPE A & B ANTIGEN TEST

Bioline™ Influenza Antigen test is a chromatographic immunoassay for the differential and qualitative detection of influenza virus type A and type B antigens directly from nasal / throat / nasopharyngeal swab or nasal/nasopharyngeal aspirate specimens.

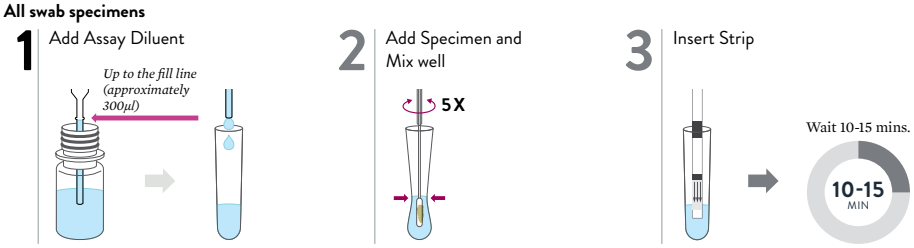
- Detection : Differential detection of Influenza virus type A & B
- Specimen : Human nasal swab, throat swab, nasopharyngeal swab or nasal/ nasopharyngeal aspirate
- Shelf life and storage temperature: 24 months from the date of manufacturing at 1-30 °C
- Performance: Sensitivity : 91.8%, Specificity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

MATERIALS PROVIDED

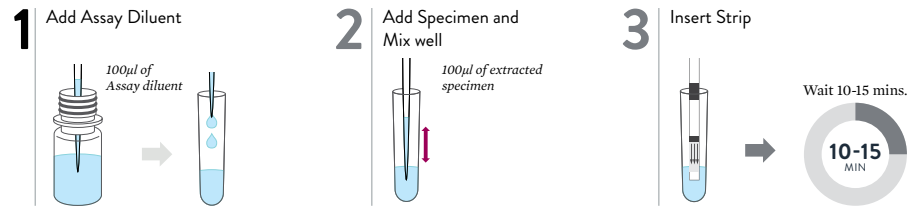
- Test strip
- Disposable tube with rack
- Assay diluent
- Sterilized swab
- Control swabs: Positive and Negative
- Disposable dropper

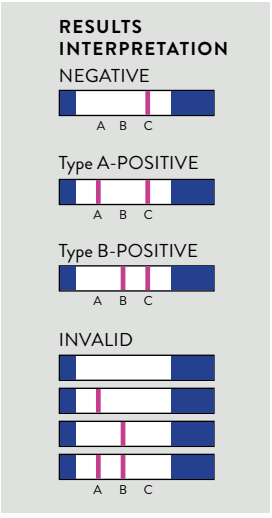
SIMPLE PROCEDURE

All swab specimens



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





The presence of any test line, no matter how faint, the result is considered positive.

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

Bioline™ INFLUENZA Ag A/B/A (H1N1)

INFLUENZA VIRUS TYPE A, B AND A (H1N1) PANDEMIC RAPID TEST

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

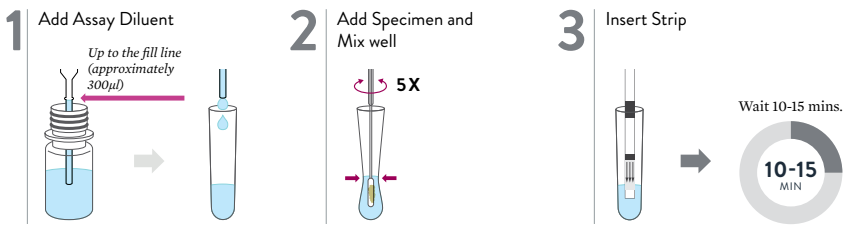
- Detection: Differential detection of Influenza virus type A, type B and A (H1N1) antigen (4 lines)
- Specification: The samples tested POSITIVE can be determined as influenza H1N1 positive without additional confirmation test.
- Shelf life and storage temperature: 24 months from the date of manufacturing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

MATERIALS PROVIDED

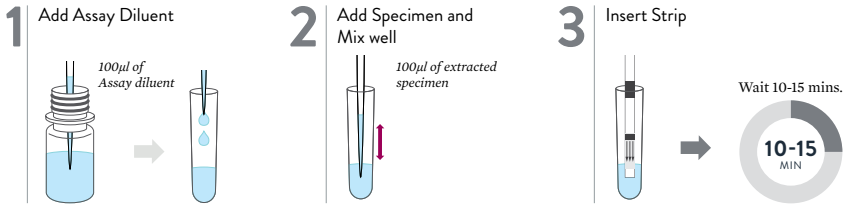
- Test strip
- Disposable tube with rack
- Assay diluent
- Sterilized swab
- Control swab: A positive, B positive, Negative
- Disposable dropper

SIMPLE PROCEDURE

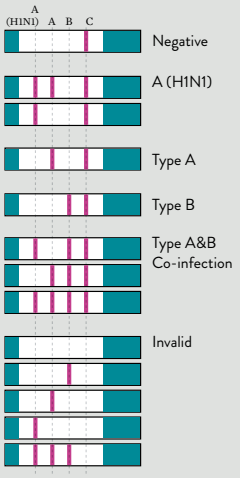
All swab specimens



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



RESULTS INTERPRETATION



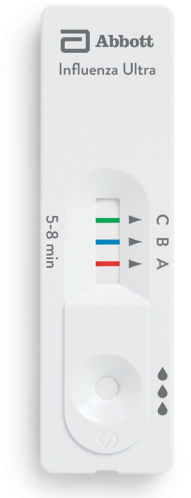
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Influenza Ag A/B/A (H1N1)	19FK31	Strip	Nasal/Throat/Nasopharyngeal swab, Nasal/Nasopharyngeal aspirate	10T/Kit
Influenza Ag A/B/A (H1N1)	19FK32	Strip	Nasal/Throat/Nasopharyngeal swab, Nasal/Nasopharyngeal aspirate	25T/Kit

Bioline™ INFLUENZA ULTRA

INFLUENZA VIRUS TYPE A & B ANTIGEN TEST



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

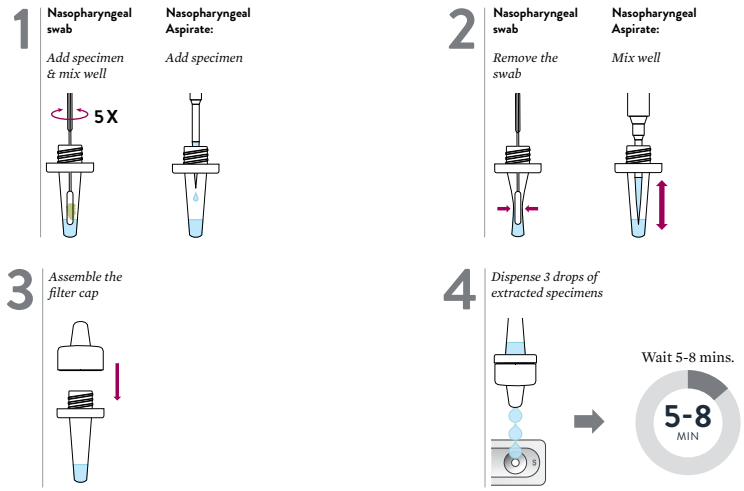
- Differential detection of Influenza virus type A & B
- Positive result as early as 5 mins.
- Easy to interpret results with 3 colors lines – Green, Blue, Red
- Color line and test cassette marking helps to interpret result faster and more confidently
- Cassette test format minimizes contact with potential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

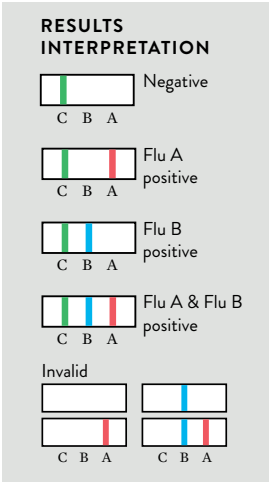
		SENSITIVITY	SPECIFICITY
Nasopharyngeal Swab	Flu A	88.5 %	98.7%
	Flu B	91.5 %	98.7%
Nasopharyngeal Aspirate	Flu A	93.9 %	98.9%
	Flu B	91.7 %	98.9%

MATERIALS PROVIDED

- Test device
- Specimen extraction tube with assay diluent
- Sterilized swab
- Filter cap
- Control swab: A positive, B positive, Negative

SIMPLE PROCEDURE





The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Influenza Ultra	19FK13	Device	Nasopharyngeal swab, Nasopharygeal aspirate	10T/Kit

Bioline™ LEGIONELLA Ag

LEGIONELLA URINARY ANTIGEN TEST

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 %

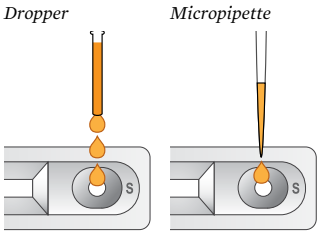
MATERIALS PROVIDED

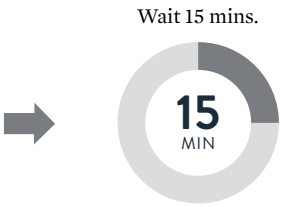
- Test device
- Positive/Negative Control
- Disposable urine dropper

SIMPLE PROCEDURE

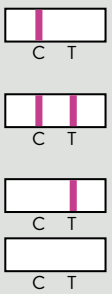
1 **Add Specimen**

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





RESULTS INTERPRETATION



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ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Legionella Ag	58FK10	Device	Urine	25T/Kit

Bioline™ LEISHMANIA Ab

LEISHMANIA ANTIBODY TEST

The Bioline™ Leishmania Ab test kit is rapid immunochromatographic assay for *in vitro* diagnostic use designed to detect *Leishmania* antibodies 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. immune-fluorescent assay)

MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Assay Diluent

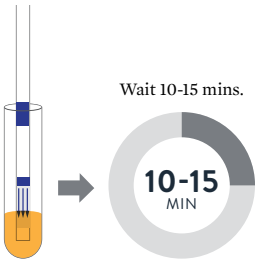
Dispense 3 drops of the assay diluent.

2 Add Specimen

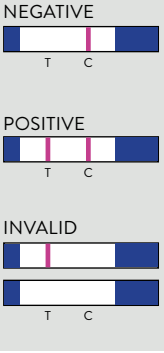
Dispense 20 µl of serum or plasma

Capillary pipette

3 Insert Strip



RESULTS INTERPRETATION



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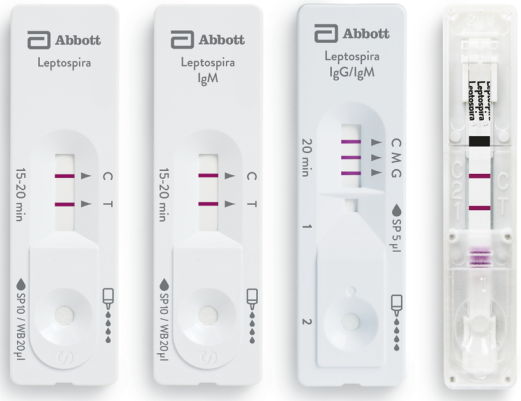
ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Leishmania Ab	47FK12	Strip	Serum/Plsma	25T/Kit

Bioline™
LEPTOSPIRA SERIES
LEPTOSPIRA ANTIBODY TEST



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

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)

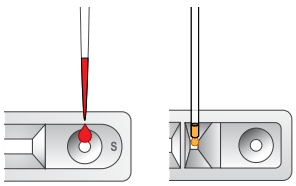
SIMPLE PROCEDURE

1 Add Specimen

Add specimen into the specimen well.

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

Leptospira
IgG/IgM
Serum, plasma 5 µl

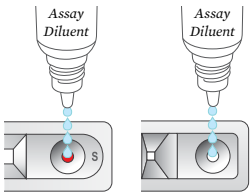


2 Add Assay Diluent

Dispense assay diluent into the round well.

Leptospira
Leptospira IgM
3-4 drops

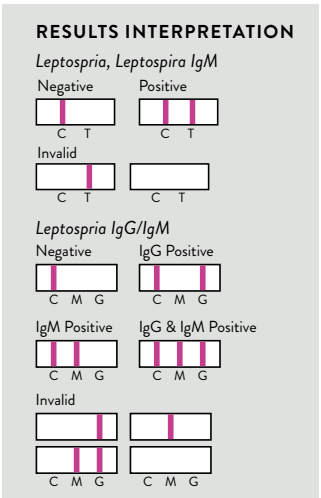
Leptospira
IgG/IgM
4 drops



Leptospira
Leptospira IgM
Wait 15-20 mins.

Leptospira
IgG/IgM
Wait 20 mins.

RESULTS INTERPRETATION



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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

Bioline™
LYMPHATIC FILARIASIS IgG_4
LYMPHATIC FILARIASIS IgG_4 TEST

The Bioline™ Lymphatic Filariasis IgG_4 test is a rapid, qualitative test for the detection of IgG_4 antibodies against the *Wuchereria bancrofti* Wb123 antigen in human serum, plasma or whole blood

- 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)

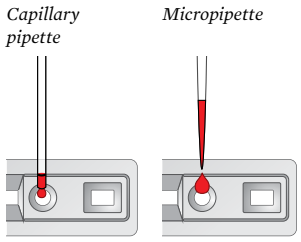
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

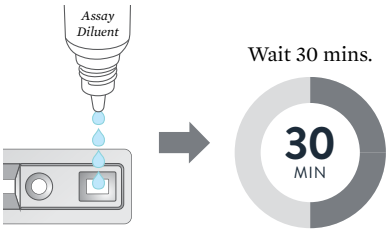
1 Add Specimen

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

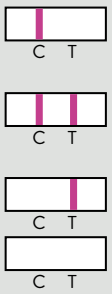


2 Add Assay Diluent

Dispense 4 drops of the assay diluent.



RESULTS INTERPRETATION



NEGATIVE (Nonreactive)

POSITIVE (Reactive)

INVALID

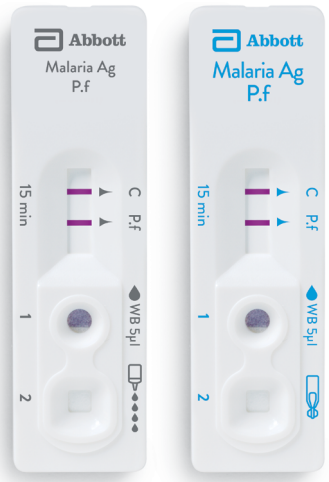
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Lymphatic Filariasis IgG_4	61FK30	Device	Serum/Plasma/Whole Blood	25T/Kit

Bioline™ MALARIA Ag P.F

MALARIA ANTIGEN P.F (HRP2) TEST



Bioline™ Malaria Ag P.f test is rapid, qualitative detection of HRP2 (Histidine-rich protein 2) specific to *P. falciparum* in human blood specimen.

- Specific and accurate diagnosis 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 %

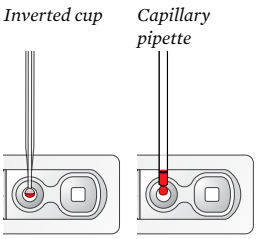
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Specimen

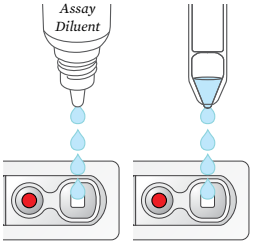
Dispense 5 µl of whole blood into the round specimen well.



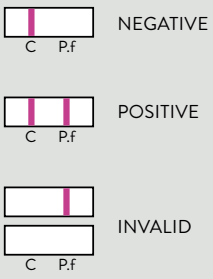
2 Add Assay Diluent

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

Dispense all of the assay diluent from the diluent tube into the square well of test device.



RESULTS INTERPRETATION



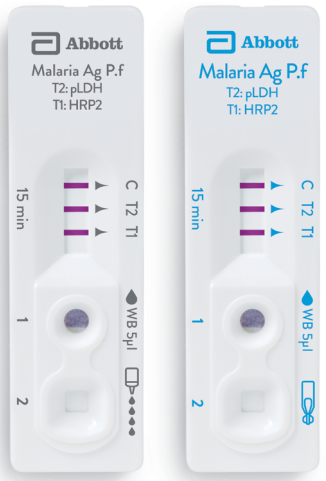
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Malaria Ag P.f	05FK50	Device, Sterile lancet	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), Sterile lancet	Whole blood	1Pack X 25/Kit

Bioline™
MALARIA Ag P.F (HRP2/pLDH)

MALARIA ANTIGEN P.F (HRP2/pLDH) TEST



The Bioline™ Malaria Ag P.f (HRP2/pLDH) test is a rapid, qualitative test for the detection of histidine-rich protein 2 (HRP2) antigen and lactate dehydrogenase (pLDH) from Malaria *P. falciparum* in human whole blood.

- Reduce false positive rates after treatment
- Useful in regions 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 (HRP2) : Sensitivity 99.7 %, Specificity 99.3 %
  - P.f (pLDH) : Sensitivity 97.4 %, Specificity 99.7 %

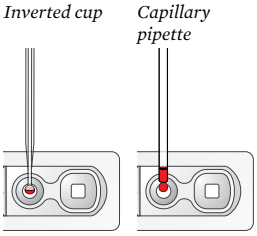
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Specimen

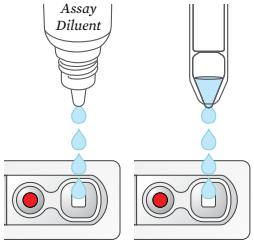
Dispense 5 µl of whole blood into the round specimen well.



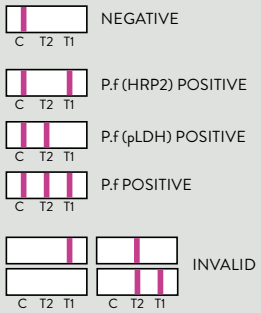
2 Add Assay Diluent

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

Dispense all of the assay diluent from the diluent tube into the square well of test device.



RESULTS INTERPRETATION



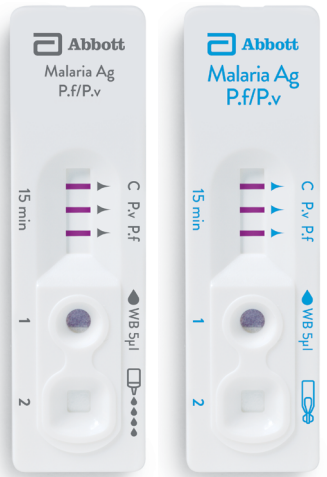
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Malaria Ag P.f (HRP2/pLDH)	05FK90	Device, Sterile lancet	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), Sterile lancet	Whole blood	1Pack X 25/Kit

Bioline™ MALARIA Ag P.F/P.V

MALARIA ANTIGEN P.F/P.V (HRP2/pLDH) TEST



Bioline™ Malaria Ag P.f/P.v test is a rapid, qualitative test for the detection of HRP2 (Histidine-rich protein 2) specific to *Plasmodium falciparum* and Plasmodium lactate dehydrogenase (pLDH) specific to *Plasmodium vivax*.

- Differential diagnosis between *Plasmodium falciparum* and *Plasmodium vivax*
- Useful in regions 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 (HRP2) : Sensitivity 99.7 %, Specificity 99.5 %
  - P.v (pLDH) : Sensitivity 95.5 %, Specificity 99.5 %

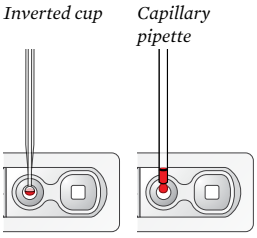
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Specimen

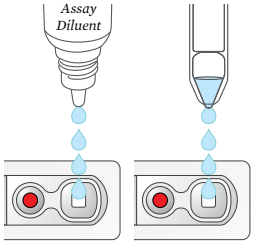
Dispense 5 µl of whole blood into the round specimen well.



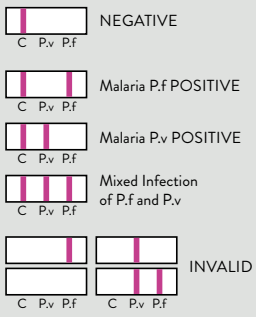
2 Add Assay Diluent

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

Dispense all of the assay diluent from the diluent tube into the square well of test device.



RESULTS INTERPRETATION



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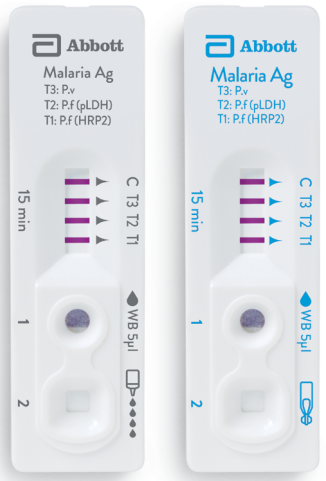
ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Malaria Ag P.f/P.v	05FK80	Device, Sterile lancet	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), Sterile lancet	Whole blood	1Pack X 25/Kit
Malaria Ag P.f/P.v	05FK86	Device, Sterile lancet	Whole blood	10T/Kit

Bioline™ MALARIA Ag P.F/P.F/P.V

MALARIA ANTIGEN P.F (HRP2/pLDH) & P.V (pLDH) TEST



Bioline™ Malaria Ag P.f/P.f/P.v test is rapid, qualitative and differential test for the detection of HRP2 and pLDH from *P. falciparum* and pLDH from *P. vivax* in human whole blood.

- Useful in regions where *P.v* and *P.f* are both dominant
- Identify false positives by *P.f* HRP2 after treatment
- Useful in regions 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 (HRP2) : 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

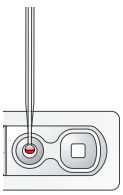
- Test device
- Assay diluent
- Disposable specimen applicator (Inverted cup)
- Lancet, alcohol swab

SIMPLE PROCEDURE

1 Add Specimen

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

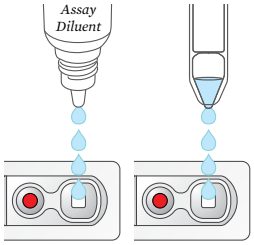
Inverted cup



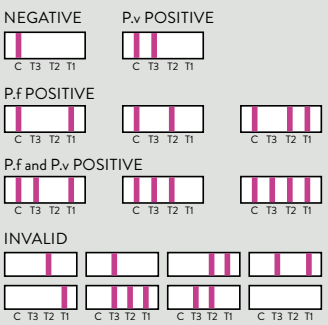
2 Add Assay Diluent

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

Dispense all of the assay diluent from the diluent tube into the square well of test device.



RESULTS INTERPRETATION



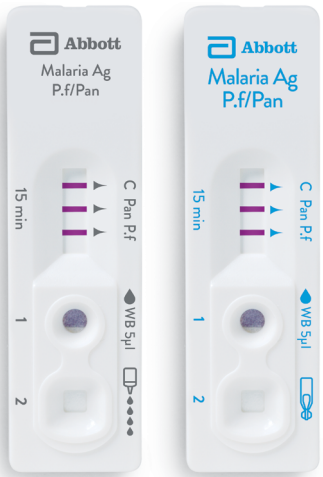
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Malaria Ag P.f/P.f/P.v	05FK120	Device, Sterile lancet	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), Sterile lancet	Whole blood	1Pack X 25/kit

Bioline™ MALARIA Ag P.F/PAN

MALARIA ANTIGEN P.F/PAN (HRP2/pLDH) TEST



Bioline™ Malaria Ag P.f/Pan test is rapid, qualitative and differential test for the detection of HRP2 specific to *P. falciparum* and pLDH specific to Malaria plasmodium (*P.f, P.v, P.m* and *P.o*) in human blood.

- Distinguish *P.f* infection from other species (*P.v, P.m* or *P.o*)
- Useful fin regions where all malaria species are circulating
- 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 (HRP2) : Sensitivity 99.7 %, Specificity 99.5 %
  - Pan (pLDH) : Sensitivity 95.5 %, Specificity 99.5 %

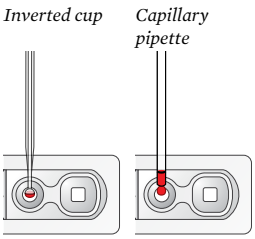
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Specimen

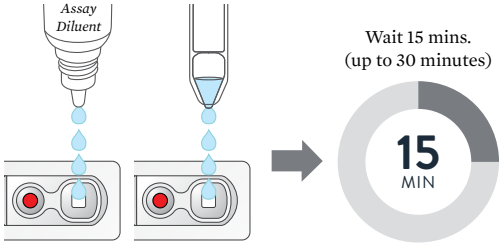
Dispense 5 µl of whole blood into the round specimen well.



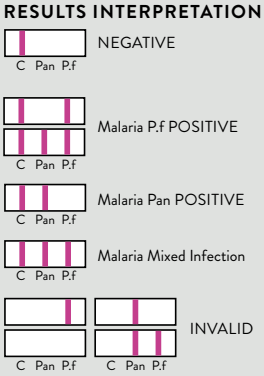
2 Add Assay Diluent

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

Dispense all of the assay diluent from the diluent tube into the square well of test device.



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Malaria Ag P.f/Pan	05FK60	Device, Sterile lancet	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), Sterile lancet	Whole blood	1Pack X 25/kit
Malaria Ag P.f/Pan	05FK67	Device (POCT), Sterile lancet	Whole blood	1Pack X 30/kit

Bioline™ NOROVIRUS

NOROVIRUS ANTIGEN TEST

The Bioline™ Norovirus test is a chromatographic immunoassay 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)

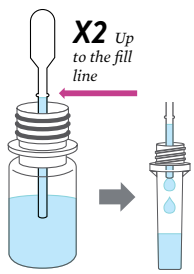
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Assay Diluent

Transfer assay diluent twice.

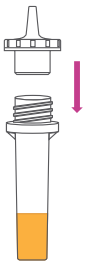


2 Insert swab specimen

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

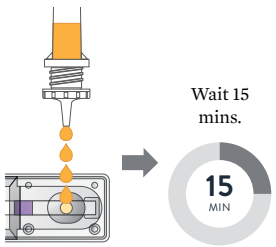
3 Assemble dropping cap

Assemble dropping cap on the specimen collection tube.



4 Add Specimen

Dispense 4 drops.



RESULTS INTERPRETATION

The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Norovirus	52FK10	Device	Fecal	20T/Kit

Bioline™ ONCHOCERCIASIS IgG$_4$

ONCHOCERCIASIS IgG$_4$ TEST

The Bioline™ Onchocerciasis IgG$_4$ test is a rapid, qualitative test for the detection of IgG$_4$ antibody against OV16 antigen in human serum, plasma or whole blood.

- Less invasive and less painful than current diagnostic methods
- Time to results: 30 minutes. (The results are valid from 30 minutes to 24 hours.)
- 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	RDT NEGATIVE
Skin snip	Positive	60	14
	Negative	1	103
Sensitivity		81.1 % (60/74)	
Specificity		99.0 % (103/104)	

PLASMA/SERUM		RDT POSITIVE	RDT 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) (for fingerstick)
- Alcohol swab
- Lancet

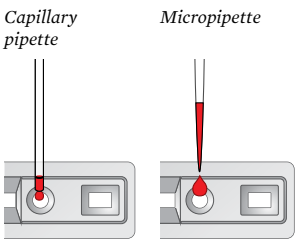
SIMPLE PROCEDURE

1 Add Specimen

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

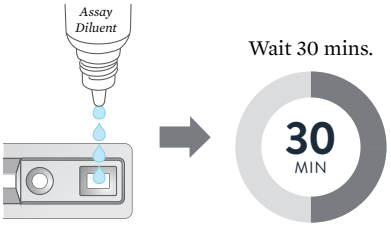
Capillary pipette

Micropipette

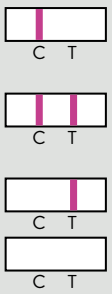


2 Add Assay Diluent

Dispense 4 drops of the assay diluent.



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Onchocerciasis IgG$_4$	61FK10	Device	Serum/Plasma/Whole Blood	25T/Kit

Bioline™ ONCHO/LF IgG_4 BIPLEX

ONCHOCERCIASIS IgG_4 AND LYMPHATIC FILARIASIS IgG_4 TEST

The Bioline™ Oncho/LF IgG_4 biplex test is a rapid, qualitative test for the detection of IgG_4 antibodies against the *Onchocerca volvulus Ov16* and *Wuchereria bancrofti Wb123* antigens in human serum, plasma or whole blood

- 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

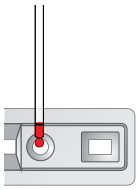
- Test device
- Assay diluent
- Capillary pipette (10 µl) (for fingerstick)
- Alcohol swab
- Lancet

SIMPLE PROCEDURE

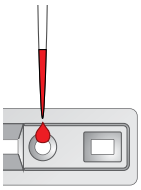
1 **Add Specimen**

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

Capillary pipette



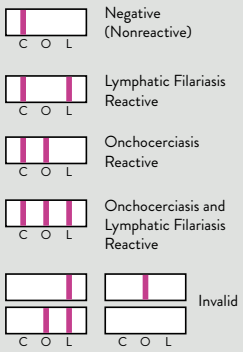
Micropipette



2 **Add Assay Diluent**

Dispense 4 drops of the assay diluent.

RESULTS INTERPRETATION



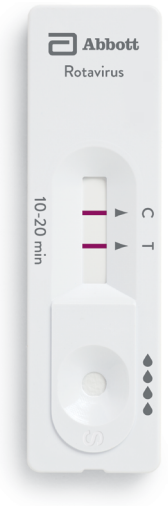
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Oncho/LF IgG_4 biplex	61FK20	Device	Serum/Plasma/Whole Blood	25T/Kit

Bioline™ ROTAVIRUS

ROTAVIRUS ANTIGEN TEST



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)

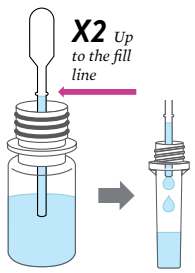
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Assay Diluent

Transfer assay diluent twice.

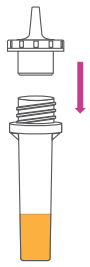


2 Insert swab specimen

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

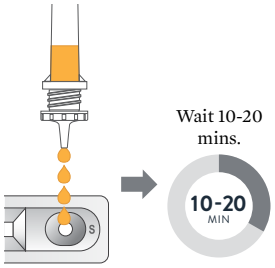
3 Assemble dropping cap

Assemble dropping cap on the specimen collection tube.



4 Add Specimen

Dispense 3-4 drops.



RESULTS INTERPRETATION

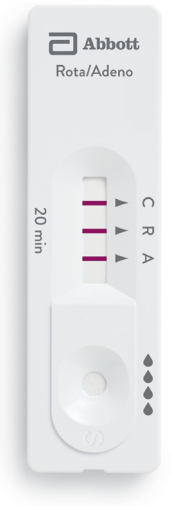
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Rotavirus	14FK10	Device	Fecal	20T/Kit

Bioline™ ROTA/ADENO

ROTA/ADENO VIRUS ANTIGEN TEST



Bioline™ Rota/Adeno 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)

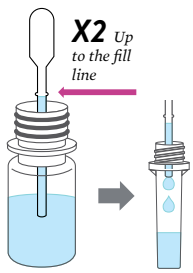
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Assay Diluent

Transfer assay diluent twice.

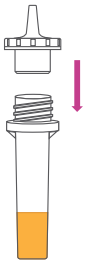


2 Insert swab specimen

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

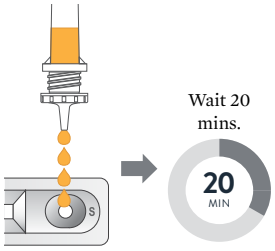
3 Assemble dropping cap

Assemble dropping cap on the specimen collection tube.

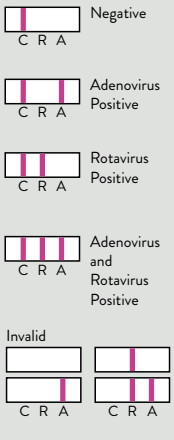


4 Add Specimen

Dispense 3-4 drops.



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Rota/Adeno	14FK20	Device	Fecal	20T/Kit

Bioline™ RSV

RSV (RESPIRATORY SYNCYTIAL VIRUS) ANTIGEN TEST

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)

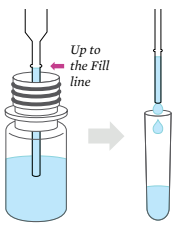
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

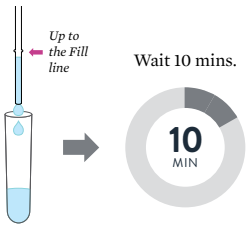
1 Add Assay Diluent

Add 200 - 250 µl of extraction buffer.

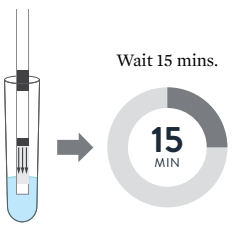


2 Add Specimen & Mix Well

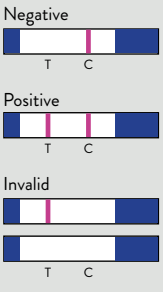
Add 200 - 250 µl of specimen.



3 Insert Strip



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
RSV	40FK12	Strip	Nasopharyngeal Aspirate	25T/Kit

Bioline™
SALMONELLA TYPHI IgG/IgM FAST

SALMONELLA TYPHI IGG/IGM TEST

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.

- Differential antibody detection: IgG and IgM antibodies
- 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: (vs. Blood culture)
  - 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

SIMPLE PROCEDURE

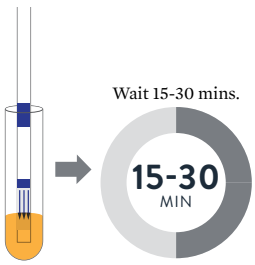
1 Add Assay Diluent

Dispense 4 drops of the assay diluent.

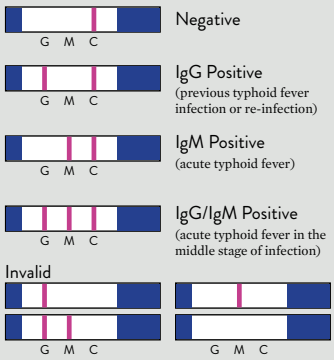
2 Add Specimen

Dispense 1 µl of specimen.

3 Insert Strip



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Salmonella typhi IgG/IgM Fast	15FK12	Strip	Serum/Plasma/Whole blood	25T/Kit

Bioline™ STREP A

GROUP A STREPTOCOCCAL ANTIGEN STRIP TEST

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)

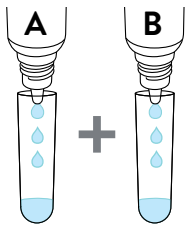
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

1 Add Reagent

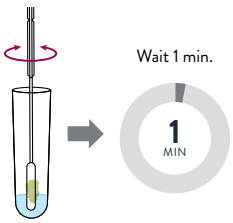
Add 3 drops of reagent A+B



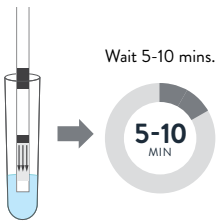
2 Add Specimen & Mix Well

Keep the swab in the test tube for 1 minute. The swab can remain in the test tube for up to 15 minutes.

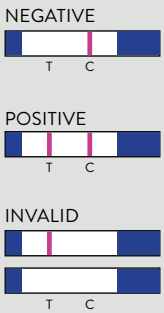
x5-10



3 Insert Strip



RESULTS INTERPRETATION



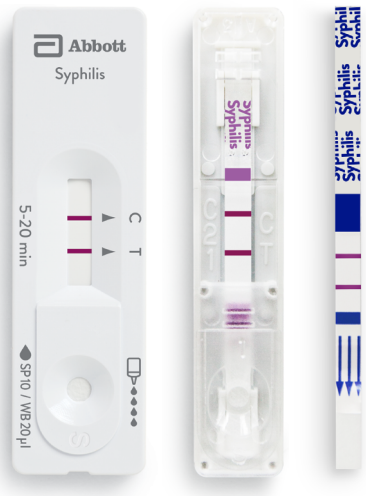
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Strep A	45FK12	Strip	Throat swab	25T/Kit

Bioline™ SYPHILIS 3.0

SYPHILIS ANTIBODY TEST



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
- No need for 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)

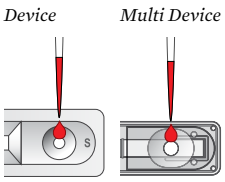
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

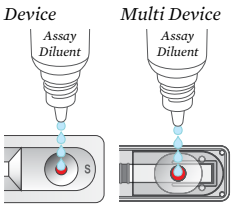
1 Add Specimen

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



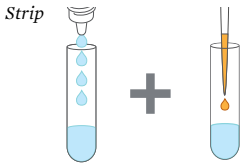
2 Add Assay Diluent

Dispense 4 drops of the assay diluent.



1 Add Assay Diluent and Specimen

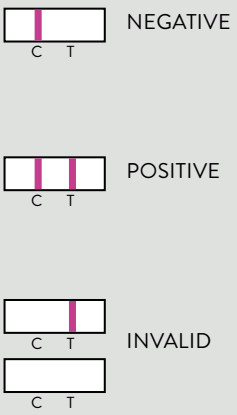
Add 10µl of serum or plasma or 20µl of whole blood and 4 drops of assay diluent to the empty test tube. And then, mix well.



2 Insert Strip

Insert strip into the test tube.

RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

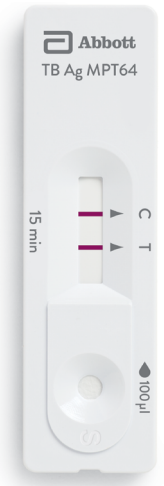
ORDERING INFORMATION

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
Syphilis 3.0*	06FK13	Device	Serum/Plasma/Whole blood	25T/Kit
Syphilis 3.0**	06FK16	Device	Serum/Plasma/Whole blood	25T/Kit
Syphilis 3.0***	06FK17	Device	Serum/Plasma/Whole blood	25T/Kit

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

Bioline™ TB Ag MPT64

IDENTIFICATION OF *MYCOBACTERIUM TUBERCULOSIS* COMPLEX



Bioline™ TB Ag MPT64 is a rapid immunochromatographic test for the identification of the *M.tuberculosis* complex.

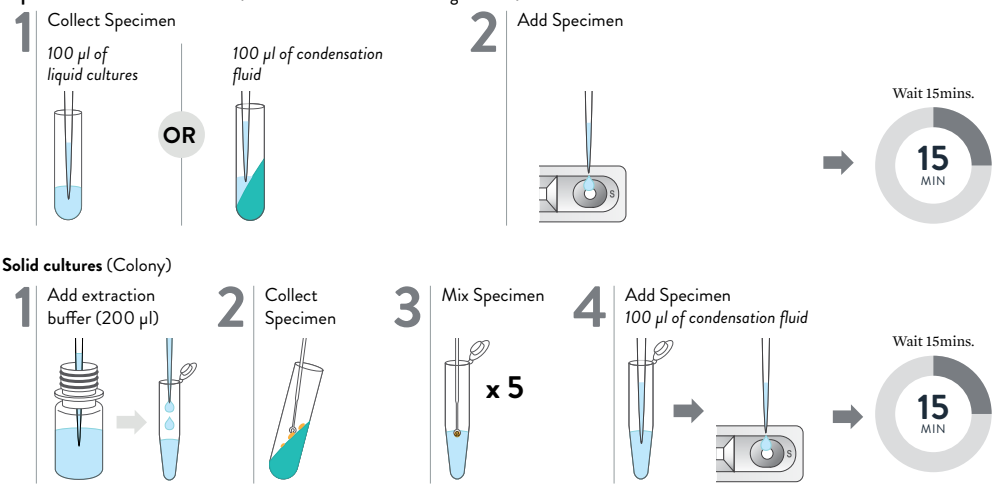
- Simple, rapid assay using mouse monoclonal anti-MPT64
- Rapid discrimination between the *M. tuberculosis* complex and other mycobacterium
- Identification of the *M. tuberculosis* complex in combination with culture systems based on liquid media
- Specimen : Solid cultures (colony, condensation fluid) 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)

SIMPLE PROCEDURE

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



Solid cultures (Colony)

RESULTS INTERPRETATION

The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
TB Ag MPT64	08FK50	Device	Liquid cultures / Solid cultures	25T/Kit

Bioline™ TETANUS

TETANUS ANTIBODY TEST

Bioline™ Tetanus test is a 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 in the 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 : Bioline™ Tetanus vs ELISA
  - Sensitivity : Serum 96.5 %, Whole blood 94.8 %
  - Specificity : Serum 87 %, Whole blood 89.1 %

MATERIALS PROVIDED

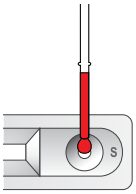
- Test device
- Disposable droppers or Microsafe tube (30 µl)
- Assay diluent

SIMPLE PROCEDURE

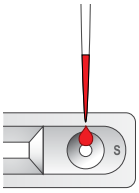
1 **Add Specimen**

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

Microsafe tube or dropper (whole blood)

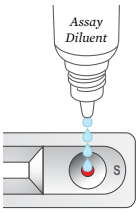


Micropipette (whole blood, plasma or serum)

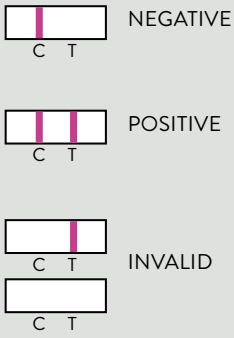


2 **Add Assay Diluent**

Dispense 3-4 drops of the assay diluent.



RESULTS INTERPRETATION



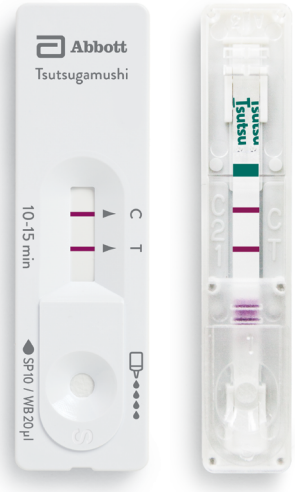
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Tetanus (Disposable droppers)	42FK10	Device	Serum/Plasma/Whole Blood	25T/Kit
Tetanus (Microsafe tubes)	42FK20	Device	Serum/Plasma/Whole Blood	25T/Kit

Bioline™ TSUTSUGAMUSHI

SCRUB TYPHUS ANTIBODY TEST



The Bioline™ Tsutsugamushi test is a solid phase, immunochromatographic assay for the rapid, qualitative detection of IgG, IgM or 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

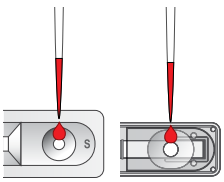
- Test device
- Assay diluent

SIMPLE PROCEDURE

1 **Add Specimen**

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

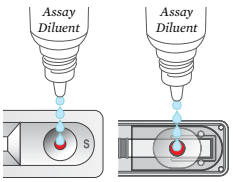
Device *Multi Device*



2 **Add Assay Diluent**

Dispense 3-4 drops of the assay diluent.

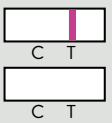
Device *Multi Device*



RESULTS INTERPRETATION

NEGATIVE

POSITIVE



INVALID

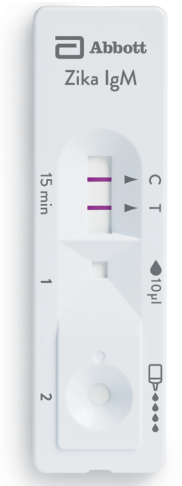
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Tsutsugamushi	18FK10	Device	Serum/Plasma/Whole blood	30T/Kit
Tsutsugamushi	18FK11	Multi-Device	Serum/Plasma/Whole blood	10Tx10/Kit

Bioline™ ZIKA IgM

ZIKA IgM ANTIBODY TEST



The 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 90.8 %, Specificity 98.3 % (vs. ELISA)

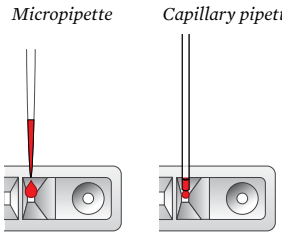
MATERIALS PROVIDED

- Test device
- Capillary pipette (10 µl)
- Assay diluent
- Alcohol swabs
- Lancets

SIMPLE PROCEDURE

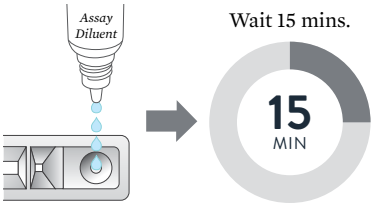
1 **Add Specimen**

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

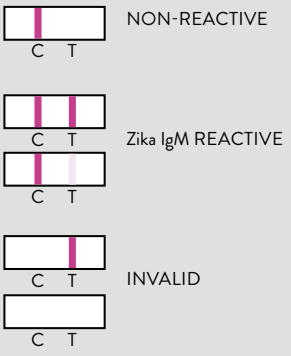


2 **Add Assay Diluent**

Dispense 4 drops of assay diluent into the round well.



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Bioline™ Zika IgM	12FK21	Device, Safety lancet	Serum/Plasma/Whole Blood	25T/Kit
Bioline™ Zika IgM	12FK26	Device, Sterile lancet	Serum/Plasma/Whole Blood	25T/Kit

Bioline™

TOXICOLOGY

AMP

COC

DOA MULTI 5

DOA MULTI 6

MDMA

MET

MET/THC

MOP

THC

Bioline™ DOA

DRUG OF ABUSE TEST

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

SIMPLE PROCEDURE

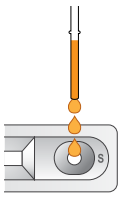
1 **Add Specimen**

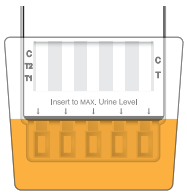
Dropper method

Dispense 3-4 drops (MDMA, DOA 5 and DOA6: 3 drops) of urine into the specimen well "S".

Dipping method

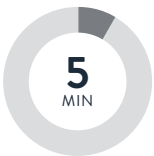
Immerse the test device vertically into the urine specimen for 10 seconds. After 10 seconds, bring out the test device, place on flat surface.



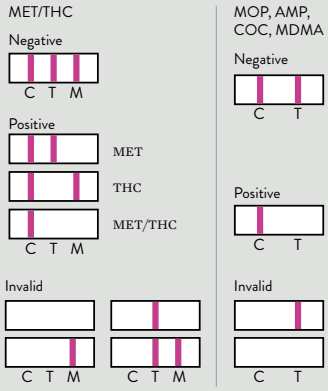


MAX.urine level

Wait 5 mins.



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

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

Bioline™

ONCOLOGY

FOB

SD BIOLINE FOB

FECAL OCCULT BLOOD TEST

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

- 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 %

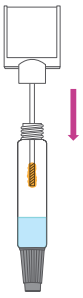
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

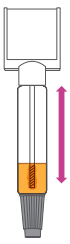
1 Insert swab specimen

Insert the applicator stick into the specimen collection tube



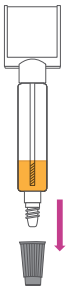
2 Mix well

Shake and mix well



3 Open the cap

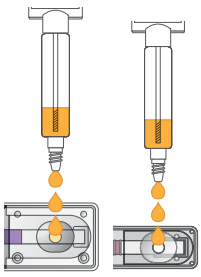
Loosen green cap the lower part of the specimen collection tube



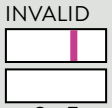
4 Add specimen

Dispense 3 drops of the assay diluent.

Device *Multi-Device*



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
SD BIOLINE FOB (Fecal Occult Blood)	25FK10	Device	Fecal	25T/Kit
SD BIOLINE FOB (Fecal Occult Blood)	25FK12	Multi-Device	Fecal	10Tx5/Kit

Bioline™

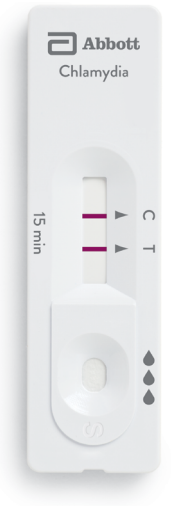
WOMEN' S HEALTH

CHLAMYDIA

RUBELLA IgG/IgM

Bioline™ CHLAMYDIA

CHLAMYDIA ANTIGEN TEST



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, with 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)

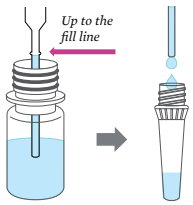
MATERIALS PROVIDED

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

SIMPLE PROCEDURE

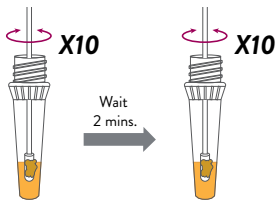
1 Add Reagent A

Transfer 300 µl of Reagent A.



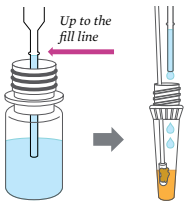
2 Add Specimen and Extraction

Insert the patient swab into the tube.



3 Add Reagent B

Transfer 600 µl of Reagent B.



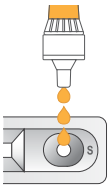
4 Mix Specimen

5 Assemble dropping cap

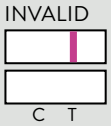
Assemble dropping cap on the specimen collection tube.

6 Add Specimen

Dispense 3 drops of the extracted specimen.



RESULTS INTERPRETATION



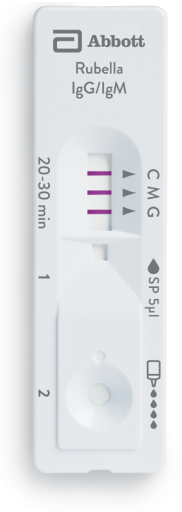
The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Chlamydia	09FK10	Device	Endocervical swab, Cytology brush	25T/Kit

Bioline™ RUBELLA IgG/IgM

RUBELLA IgG/IgM TEST



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

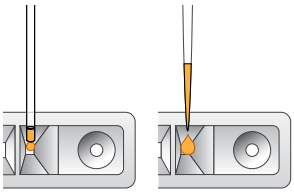
SIMPLE PROCEDURE

1 Add Specimen

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

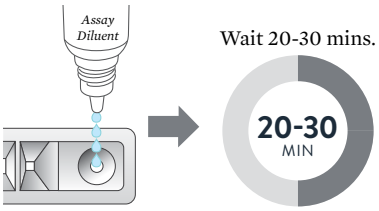
Capillary pipette

Micropipette

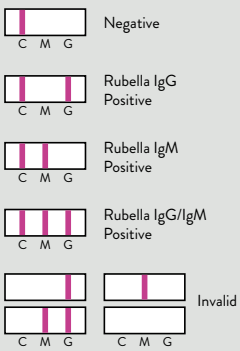


2 Add Assay Diluent

Dispense 3-4 drops of the assay diluent.



RESULTS INTERPRETATION



The presence of any test line, no matter how faint, the result is considered positive.

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Rubella IgG/IgM	07FK20	Device	Serum/Plasma	25T/Kit

Bioline™

ELISA KIT

ENZYME LINKED IMMUNOSORBENT ASSAY KIT

DENGUE IgG CAPTURE ELISA

DENGUE IgM CAPTURE ELISA

DENGUE NS1 Ag ELISA

ONCHOCERCIASIS IgG_4 ELISA

Bioline™
DENGUE IgG CAPTURE ELISA

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

Bioline™
DENGUE IgM CAPTURE ELISA

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 levels 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

Bioline™
DENGUE NS1 Ag ELISA

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.

- 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 % (87.4 - 96.6 %), Specificity 98.9 % (96.0 - 99.7 %)

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Dengue NS1 Ag ELISA	11EK50	Microplate	Serum	96 wells/Kit

Bioline™
ONCHOCERCIASIS IgG4 ELISA

Bioline™ Onchocerciasis IgG4 ELISA is an Enzyme-linked immunosorbent assay for the qualitative detection of human onchocerciasis IgG4 antibody against Ov16 antigen.

- 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 86.9 % , Specificity 100.0 %

ORDERING INFORMATION

PRODUCT	CAT. NO.	TYPE	SPECIMEN	PACK SIZE
Onchocerciasis IgG_4 ELISA	61EK11	Microplate	Serum, Plasma, and DBS	480 wells/Kit

MEMO

MEMO

Reference
1. Sensitivity and Specificity are extracted from the Instruction for use of each product.

Product not available in all countries, and is subject to regulatory approval in regulated countries. Please check with your local sales representative regarding availability in your area.

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COL-02941-02, 12/21

Abbott