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*The Pioneer  
of Point of  
Care Testing*

Developing and manufacturing  
*In Vitro Diagnostics Test (IVDT)*,  
which embodies the cutting-  
edge life science technologies on  
your needs at anywhere.

**BIO FOCUS**

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BFB-008B

## Introduction

Bio Focus is R&D based manufacturer for in vitro diagnostic products from South Korea. We are focusing efforts on Point-of-Care Testing as core strategic business for the new healthcare environment in 21th century.

We are also developing proprietary and unique technologies for world-class rapid immunochromatographic assay and biosensor systems.

Bio Focus has established it's unique position in IVD industry as a total solution provider for a wide range of rapid tests, semi-finished products and raw materials. In addition, we are expanding into more advanced digital POCT systems using our strong background in molecular biology and microfluidics technology.

Our R&D center and factory located in Uiwang city, nearby Seoul, are up-to-dated manufacturing facilities equipped to produce monoclonal antibody, colloidal gold and various rapid tests. Our main factory was built up since 2001 which approved for manufacturing IVD products from KFDA and operated under quality system of ISO 13485. Most of our products are certified with CE or US FDA.

We are currently providing an extensive range of immunochromatography based one-step rapid tests for infectious diseases & STD for HBsAg, HBsAb, HCV, HIV1/2, Syphilis, Norovirus, Rotavirus, Adenovirus, Tumor markers for AFP, CEA, PSA, FOB and Cardiac markers for Troponin I, Myoglobin, CK-MB and other unique rapid tests such as Influenza A&B and HSV-2, Malaria, Dengue, TB and H.Pylori. Beyond that, we also produce highly sensitive urine pregnancy test and ovulation test for professional use and self-testing under our own brand name, BioTracer™ and on an OEM basis.

Our accumulated technologies and experience guarantee the highest quality products at competitive prices. In addition, we are developing new POCT system for quantitative rapid assay using highly specific monoclonal antibody and nano-complex based workstation. We appreciate again for your interest in our products and looking forward more cooperation in near future.

## R&D Center

Bio Focus Co., Ltd has researched and developed lots of in vitro diagnostic products which are approved by KFDA (Korea Ministry of Food and Drug Safety) since it founded it's own institute in 2001.

Under the slogan of "Institute is in charge of our company's future and I am in charge of our institute's future", our researchers are impassioned and innovative with their work. Our objective is to maintain high quality of current products and to develop the new products in order to maximize sales and earnings through the new technology. We have the core technology of immunochromatography as following:

1. Manufacturing colloidal gold of various size
2. Conjugating the colloidal gold with protein (antigen or antibody)
3. Production of monoclonal antibodies
4. Production of recombinant protein
5. Optimizing the immunochromatography system. Final products with high quality have been maintained through manufacturing ability of this core material and strict quality control
6. Nano complex ultra sensitive diagnostic workstation research

We got certificate of international standard "ISO 13485" and applied the system in overall manufacturing process. And we also have CE certificates in the most products.

## Bio Focus Co., Ltd Product List

Item	Cat.No.	Description	Type	Pack size	Specimen	Shelf Life
Hepatitis	10112	<b>HBsAg</b>	Card	30T/Kit	Serum/Plasma	18M
	10125	<b>HBsAg</b>	Strip	25T x 4/Kit	Serum/Plasma	12M
	10135	<b>HBsAg</b>	Multi	10T x 10/Kit	Serum/Plasma	18M
	10212	<b>Anti-HBs</b>	Card	30T/Kit	Serum/Plasma	18M
	10225	<b>Anti-HBs</b>	Strip	25T x 4/Kit	Serum/Plasma	12M
	10235	<b>Anti-HBs</b>	Multi	10T x 10/Kit	Serum/Plasma	18M
	11012	<b>HCV</b>	Card	30T/Kit	Serum/Plasma/Whole blood	18M
	11035	<b>HCV</b>	Multi	10T x 10/Kit	Serum/Plasma/Whole blood	18M
Infectious Disease	11112	<b>HIV 1/2</b>	Card	30T/Kit	Serum/Plasma/Whole blood	18M
	11135	<b>HIV 1/2</b>	Multi	10T x 10/Kit	Serum/Plasma/Whole blood	18M
	11219	<b>HSV-2</b>	Card	10T/Kit	Serum/Plasma/Whole blood	18M
	11321	<b>Influenza A&amp;B Test</b>	Strip	20T/Kit	Nasal swab/Throat swab/ Nasopharyngeal swab	24M
	10412	<b>H.pylori</b>	Card	30T/Kit	Serum/Plasma/Whole blood	18M
	10511	<b>H.pylori Ag</b>	Card	20T/Kit	Stool	24M
	17112	<b>Dengue IgG/IgM</b>	Card	30T/Kit	Serum/Plasma/Whole blood	24M
	17212	<b>Dengue NS1 Ag</b>	Card	30T/Kit	Serum/Plasma/Whole blood	24M
	17311	<b>Dengue Combo</b>	Card	10T/Kit	Serum/Plasma/Whole blood	24M
	17012	<b>Malaria P.f/PAN</b>	Card	30T/Kit	Whole blood	24M
	17412	<b>Malaria P.f/P.v</b>	Card	30T/Kit	Whole blood	24M
	17512	<b>Malaria Ab P.f/P.v</b>	Card	30T/Kit	Serum/Plasma/Whole blood	24M
	17712	<b>TB</b>	Card	30T/Kit	Serum/Plasma	24M
	17812	<b>Syphilis</b>	Card	30T/Kit	Serum/Plasma/Whole blood	24M
	Gastrointestinal Infection	11411	<b>Norovirus</b>	Card	20T/Kit	Stool
11511		<b>Rotavirus</b>	Card	20T/Kit	Stool	24M
11611		<b>Adenovirus</b>	Card	20T/Kit	Stool	24M
11711		<b>Rota/Adeno</b>	Card	20T/Kit	Stool	24M
11811		<b>Noro/Rota/Adeno</b>	Card	20T/Kit	Stool	24M
11454		<b>Norovirus</b>	Microplate	96T/Kit	Stool	12M
11554		<b>Rotavirus</b>	Microplate	96T/Kit	Stool	12M
11654		<b>Adenovirus</b>	Microplate	96T/Kit	Stool	12M
Asthma / Allergy	11954	<b>K<sup>o</sup>EDN</b>	Microplate	96T/Kit	Serum/Urine	12M
Tumor Marker	13012	<b>AFP</b>	Card	30T/Kit	Serum/Plasma	18M
	13035	<b>AFP</b>	Multi	10T x 10/Kit	Serum/Plasma	18M
	13112	<b>PSA</b>	Card	30T/Kit	Serum/Plasma	18M
	13212	<b>CEA</b>	Card	30T/Kit	Serum/Plasma	24M
	13333	<b>FOB</b>	Multi	50T/Kit	Stool	24M
Fertility Hormone	14011	<b>hCG</b>	Card	25T/Kit	Urine	24M
	14025	<b>hCG</b>	Strip	25T x 4/Kit	Urine	18M
	14010	<b>hCG(GoodSense)</b>	Card	1T/Kit	Urine	24M
	14040	<b>hCG(GoodSense)</b>	Mid-Stream	1T/Kit	Urine	24M
	14111	<b>LH</b>	Card	25T/Kit	Urine	18M
Acute Myocardial Infarction	12019	<b>Troponin I</b>	Card	10T/Kit	Serum/Plasma/Whole blood	18M
	12519	<b>Cardiac 3 in 1 (cTni/CK-MB/Myo)</b>	Card	10T/Kit	Serum/Plasma/Whole blood	24M



## Hepatitis B Virus One-Step Rapid Kit

# HBsAg/Anti-HBs Rapid Card



BioTracer™ HBsAg/Anti-HBs Rapid Card is an immunochromatography based one-step in vitro diagnostic test for the qualitative determination of HBsAg and Anti-HBs in human serum or plasma.



### General Information

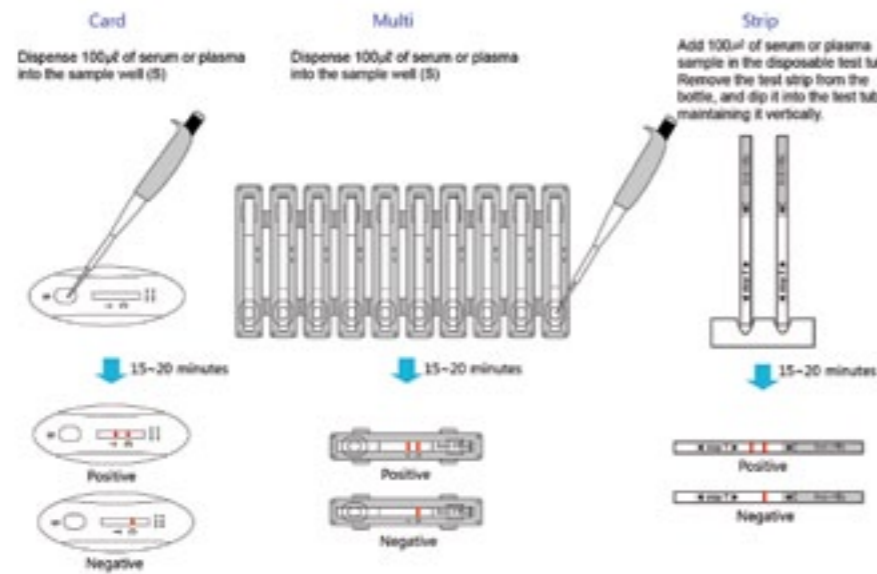
- HBsAg : Hepatitis B virus Surface Antigen Test
- Anti-HBs : Hepatitis B virus Surface Antibody Test
- Immunochromatography based one-step in vitro diagnostic test
- Analytical sensitivity : 1ng/ml of HBsAg, 30mIU/ml of Anti-HBs
- HBsAg - Sensitivity : 99.4%, Specificity : 99.9%
- Anti-HBs - Sensitivity : 99.2%, Specificity : 99.9%
- Specimen : Serum or Plasma
- Reading Time : 15~20 min
- Storage : 2~30°C

		BioTracer™ HBsAg Rapid Card		Total
		Positive	Negative	
ELISA	Positive	163	1	164
	Negative	0	92	92
Total		163	93	256

		BioTracer™ Anti-HBs Rapid Card		Total
		Positive	Negative	
ELISA	Positive	244	2	246
	Negative	0	98	98
Total		244	100	344

### Test Procedure

A positive result will not change once it has been established at 20 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 20 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
10112	HBsAg	Card	30T/Kit	Serum/Plasma	18M
10125	HBsAg	Strip	25Tx4/Kit	Serum/Plasma	12M
10135	HBsAg	Multi	10Tx10/Kit	Serum/Plasma	18M
10212	Anti-HBs	Card	30T/Kit	Serum/Plasma	18M
10225	Anti-HBs	Strip	25Tx4/Kit	Serum/Plasma	12M
10235	Anti-HBs	Multi	10Tx10/Kit	Serum/Plasma	18M

## Hepatitis C Virus One-Step Rapid Kit

# HCV Rapid Card



BioTracer™ HCV Rapid Card is a sensitive immunoassay for the qualitative detection of antibodies to HCV in human serum, plasma or whole blood.



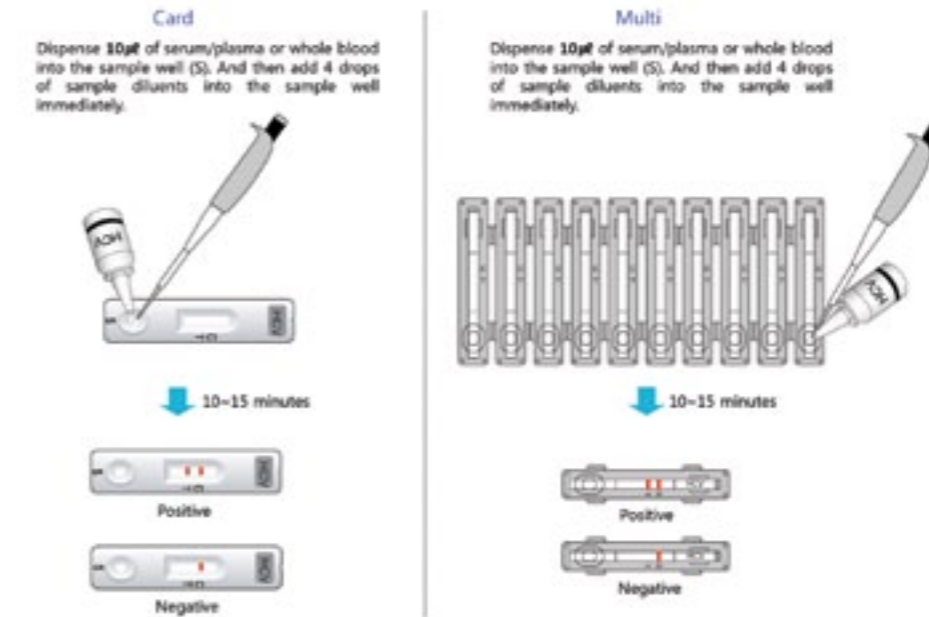
### General Information

- Hepatitis C virus Antibody Test
- Immunochromatography based one-step in vitro diagnostic test
- Applied highly purified recombinant proteins : Core, NS3, NS4, NS5
- Sensitivity : 98.7%, Specificity : 99%
- Specimen : Serum, Plasma or Whole Blood
- Reading Time : 10~15 min
- Storage : 1~30°C

		BioTracer™ HCV Rapid Card		Total
		Positive	Negative	
ELISA	Positive	152	2	154
	Negative	2	198	200
Total		154	200	354

### Test Procedure

A positive result will not change once it has been established at 15 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 15 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11012	HCV	Card	30T/Kit	Serum/Plasma/Whole blood	18M
11035	HCV	Multi	10Tx10/Kit	Serum/Plasma/Whole blood	18M

## Infectious Disease One-Step Rapid Kit HIV1/2 Rapid Card



BioTracer™ HIV1/2 Rapid Card is an immunochromatography based one-step in vitro diagnostic test for the qualitative determination of antibodies against HIV1/2 in human serum, plasma or whole blood.



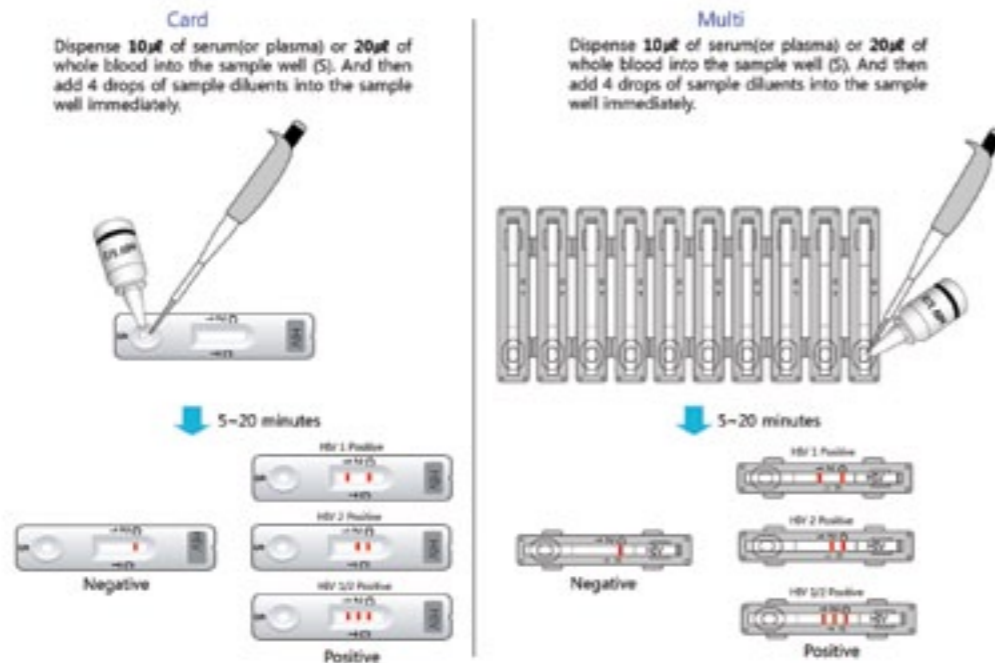
### General Information

- Immunochromatography based one-step in vitro diagnostic test
- No instruments needed
- Applied highly purified HIV recombinant proteins : p24, gp41 and gp36
- Detect HIV type 1 and type 2 with separate test lines at one time
- Sensitivity : 99.9%, Specificity : 99.7%
- Specimen : Serum, Plasma or Whole Blood
- Reading Time : 5~20 min
- Storage : 1~30°C

Feature Comparison	Auto Immuno-analyzer	ELISA	BioTracer™ HIV1/2 Rapid Card
Cost	High	High	Moderate
>99% Sensitivity and Specificity	Yes	Yes	Yes
Easy Test Procedure	No	No	Yes
Fast Results	No	No	Yes

	BioTracer™ HIV1/2 Rapid Card		Total
	Positive	Negative	
ELISA	Positive	425	425
	Negative	1	329
Total	426	329	755

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11112	HIV 1/2	Card	30T/Kit	Serum/Plasma/Whole blood	18M
11135	HIV 1/2	Multi	10Tx10/Kit	Serum/Plasma/Whole blood	18M

## Infectious Disease One-Step Rapid Kit HSV-2 Rapid Card



BioTracer™ HSV-2 Rapid Card is Point-of-Care-Testing for the detection of Herpes Simplex Virus type 2 (HSV-2) antibodies.



### General Information

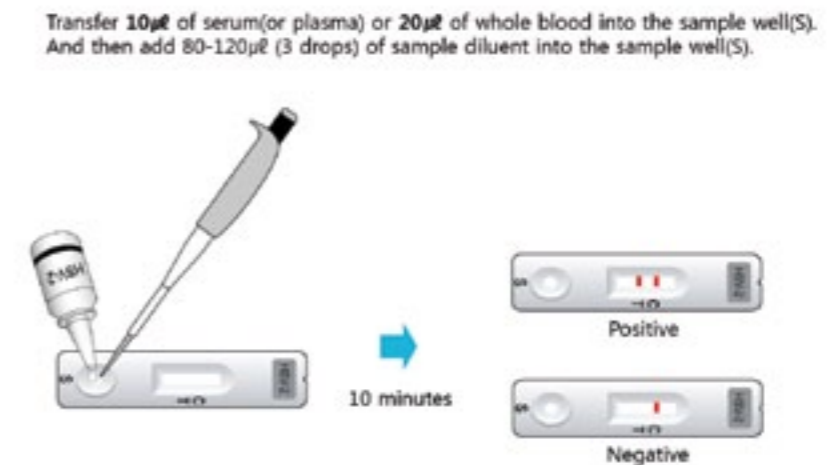
- Herpes Simplex Virus type 2 Antibody Test
- Immunochromatography based one-step in vitro diagnostic test
- No instruments needed
- Sensitivity : 97.2%, Specificity : 97.6%
- Specimen : Serum, Plasma or Whole Blood
- Reading Time : 10~20 min
- Simple and easy to use Lateral-flow type test compared to Flow-through type test
- Storage : 4~30°C

A study was performed using 421 positive and negative serum specimens. Each specimen was assayed with the BioTracer™ HSV-2 Rapid Card and a FDA approved ELISA kit.

		BioTracer™ HSV-2 Rapid Card		Total
		Positive	Negative	
HerpeSelect® 2 ELISA IgG	Positive	207	6	213
	Negative	5	203	208
Total		212	209	421

### Test Procedure

A positive result will not change once it has been established at 10~20 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 20 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11219	HSV-2	Card	10T/Kit	Serum/Plasma/Whole blood	18M



Infectious Disease One-Step Rapid Kit

# Influenza A&B Test



BioTracer™ Influenza A&B Test is Point-of-Care-Testing which can easily detect infection of Influenza type A and B in respiratory organs.



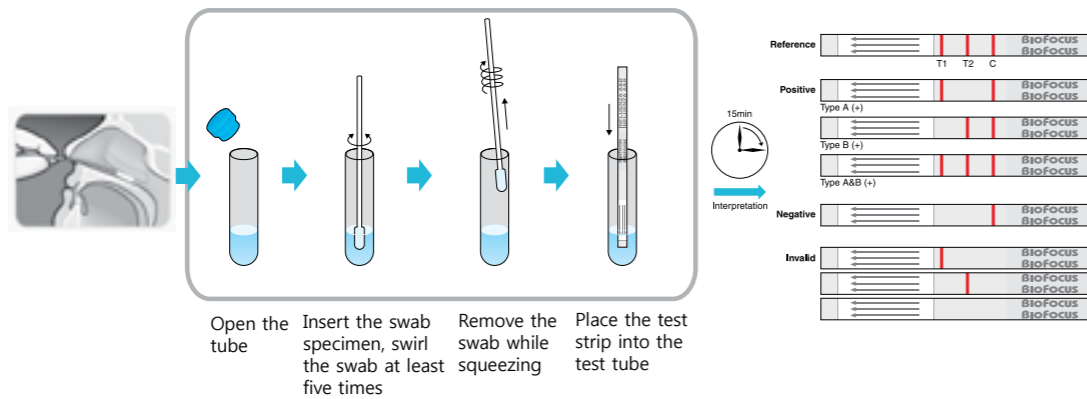
### General Information

- Influenza type A and B with separate test line at one time
- Immunochromatography based one-step in vitro diagnostic test
- Sensitivity : 94.9%, Specificity : 99.9%
- Specimen : Nasal swab or Throat swab or Nasopharyngeal swab
- Reading Time : 10~15 min
- Storage : 2~30°C

	Culture	Immunofluorescence	PCR	BioTracer™ Influenza A&B Test
Accuracy	Limited to laboratories	Limited to laboratories	Limited to laboratories	High specificity & sensitivity
Instrumentation	No instruments needed (Need to confirm test)	Need of expensive instrument	Need of expensive instrument	No instruments needed
Simplicity	Long incubation time needed	Technical experience required	Technical experience required	All materials provided, Ready to use reagent
Assay time	12~48 hr.	24~48 hr.	2~3 hr.	10~15 min.
Cost	High	High	High	Moderate

### Test Procedure

A positive result will not change once it has been established at 15 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 15 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11321	Influenza A&B Test	Strip	20T/Kit	Nasal swab/Throat swab/ Nasopharyngeal swab	24M

Infectious Disease One-Step Rapid Kit

# H.pylori Rapid Card



BioTracer™ H.pylori Rapid Card is immunochromatography based one-step in vitro diagnostic test for the qualitative determination of antibodies against H.pylori in human serum, plasma or whole blood.

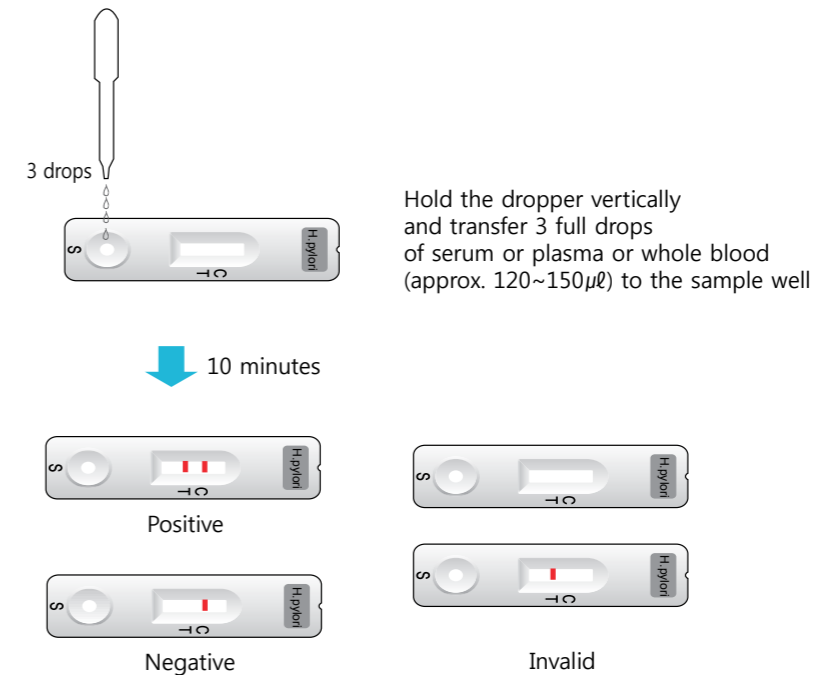


### General Information

- Serology Test
- Immunochromatography based one-step in vitro diagnostic test
- No instruments needed
- Sensitivity : 100 %, Specificity : 97%
- Specimen : Serum, Plasma or Whole blood
- Reading Time : 10 min
- Storage: 2~30°C

ELISA	BioTracer™ H.pylori Rapid Card		Total
	Positive	Negative	
	30	0	30
	2	65	67
Total	32	65	97

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
10412	H.pylori	Card	30T/Kit	Serum/Plasma/Whole blood	18M

Infectious Disease One-Step Rapid Kit

# H.pylori Ag Rapid Card



BioTracer™ H.pylori Ag Rapid Card is chromatographic immunoassay for the qualitative determination of the Helicobacter pylori antigen in human stool sample.



### General Information

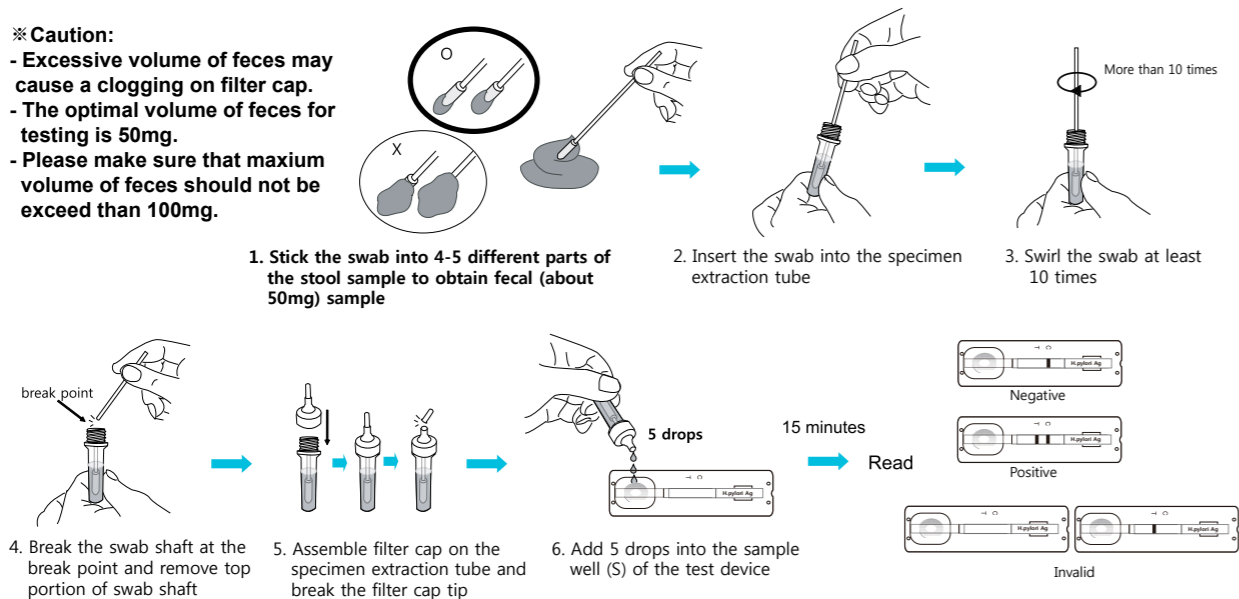
- Immunochromatography based one-step in vitro diagnostic test
- Detect Helicobacter pylori antigen in human stool
- Specimen : Human stool
- Sensitivity : 99.1% (106/107)
- Specificity :98.3% (59/60)
- No instruments needed
- Reading time : 15 min
- Storage : 1~30°C

		BioTracer™ H.pylori Ag Rapid Card		Total
		Positive	Negative	
Ref.	Positive	106	1	107
	Negative	1	59	60
Total		107	60	167

### Test Procedure

※ Caution:

- Excessive volume of feces may cause a clogging on filter cap.
- The optimal volume of feces for testing is 50mg.
- Please make sure that maximum volume of feces should not be exceed than 100mg.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
10511	H.pylori Ag	Card	20T/Kit	Stool	24M

Infectious Disease One-Step Rapid Kit

# Dengue IgG/IgM Rapid Card



BioTracer™ Dengue IgG/IgM Rapid Card is intended for the detection and differentiation of IgG and IgM to dengue virus (DEN1, DEN2, DEN3 and DEN4) in human serum, plasma or whole blood.

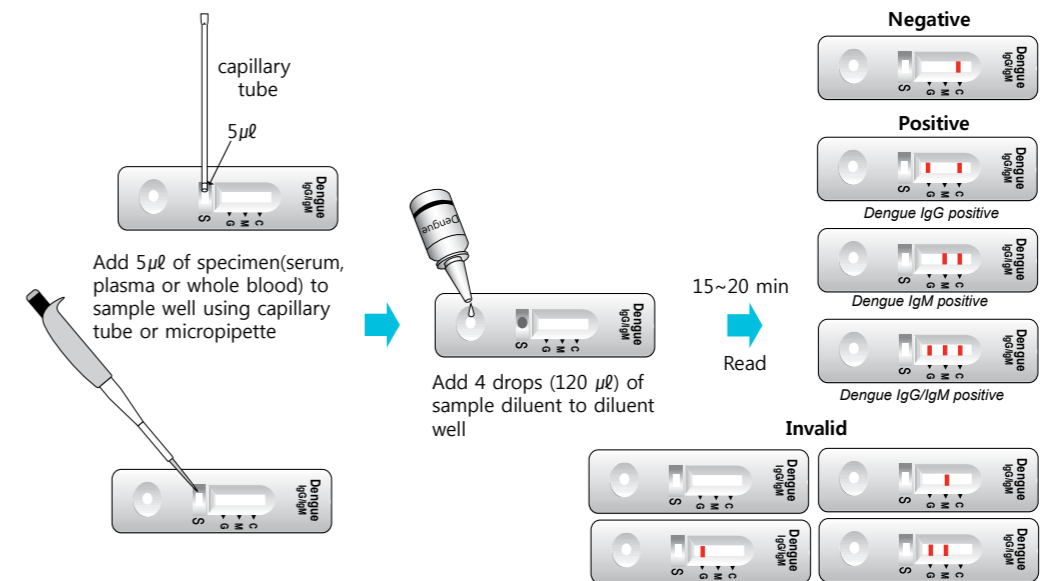


### General Information

- Immunochromatography based one-step in vitro diagnostic test
- No instruments needed
- Sensitivity : 91.3% (84/92), Specificity : 92% (230/250)
- Specimen : Serum, Plasma or Whole blood
- Reading Time : 15~20 min
- Storage : 1~30°C

Reference method (HI test)	BioTracer™ Dengue IgG/IgM Rapid Card			Total
	IgM Positive	IgG Positive	Negative	
Dengue IgM Positive	25	0	5	30
Dengue IgG Positive	0	59	3	62
Negative	12	8	230	250
Total	37	67	238	342

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
17112	Dengue IgG/IgM	Card	30T/Kit	Serum/Plasma/Whole blood	24M



Infectious Disease One-Step Rapid Kit

# Dengue NS1 Ag Rapid Card



BioTracer™ Dengue NS1 Ag Rapid Card is intended for the detection of dengue virus NS1 antigen in human serum, plasma or whole blood specimens for the diagnosis of early acute dengue infection.

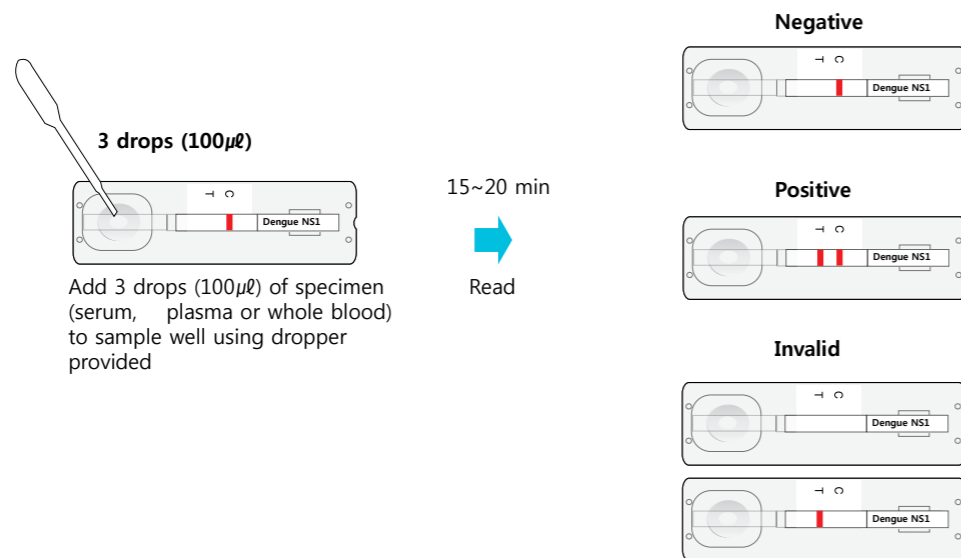


### General Information

- Immunochromatography based one-step in vitro diagnostic test
- No instruments needed
- Sensitivity : 93.3% (98/105), Specificity : 98.5% (194/197)
- Specimen : Serum, plasma or Whole blood
- Reading time : 15~20 min
- Storage : 1~30°C

Feature Comparison		BioTracer™ Dengue NS1 Ag Rapid Card		Total
		Positive	Negative	
RT PCR or Viral culture	Positive	98	7	105
	Negative	3	194	197
Total		101	201	302

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
17212	Dengue NS1 Ag	Card	30T/Kit	Serum/Plasma/Whole blood	24M

Infectious Disease One-Step Rapid Kit

# Dengue Combo Rapid Card



BioTracer™ Dengue Combo Rapid Card is intended for detection of NS1 antigen and IgG/IgM antibodies to dengue virus (DEN 1, DEN2, DEN3, and DEN4) in human serum, plasma or human blood specimens.

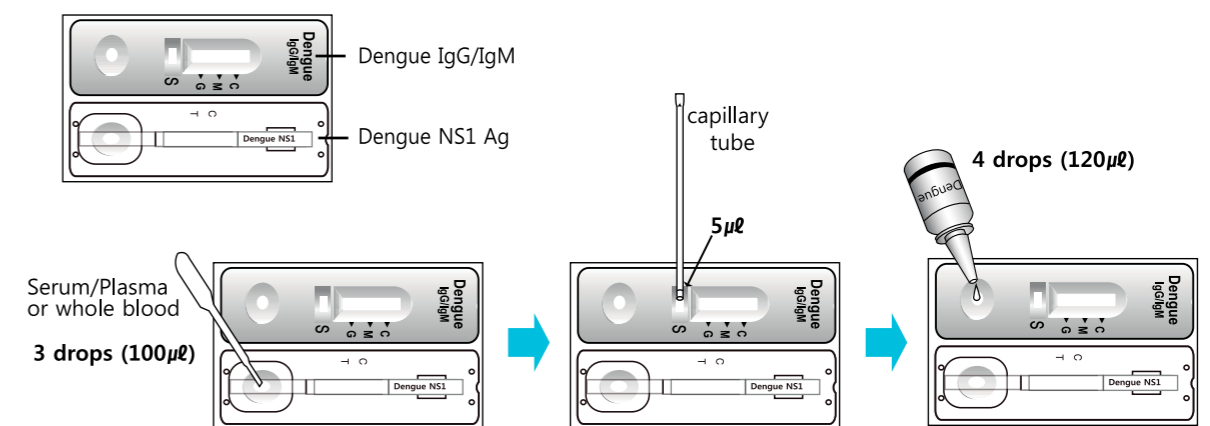


### General Information

- Immunochromatography based one-step in vitro diagnostic test
- Detect NS1 antigen and IgG/IgM antibodies at one time
- Specimen : Serum, Plasma or Whole blood
- Reading time : 15~20 min
- Storage : 1~30°C

	Sensitivity	Specificity
NS1 Ag	93.3% (98/105)	98.5% (194/197)
IgG/IgM	91.3% (84/92)	92.0% (230/250)

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
17311	Dengue Combo	Card	10T/Kit	Serum/Plasma/Whole blood	24M

Infectious Disease One-Step Rapid Kit

# Malaria P.f/PAN Rapid Card



BioTracer™ Malaria P.f/PAN Rapid Card is an immunochromatography based one-step in vitro diagnostic test for the qualitative determination of *P.falciparum* specific HRP-II (Histidin Rich protein II) and Plasmodium specific pLDH (Plasmodium lactate dehydrogenase) in human whole blood.



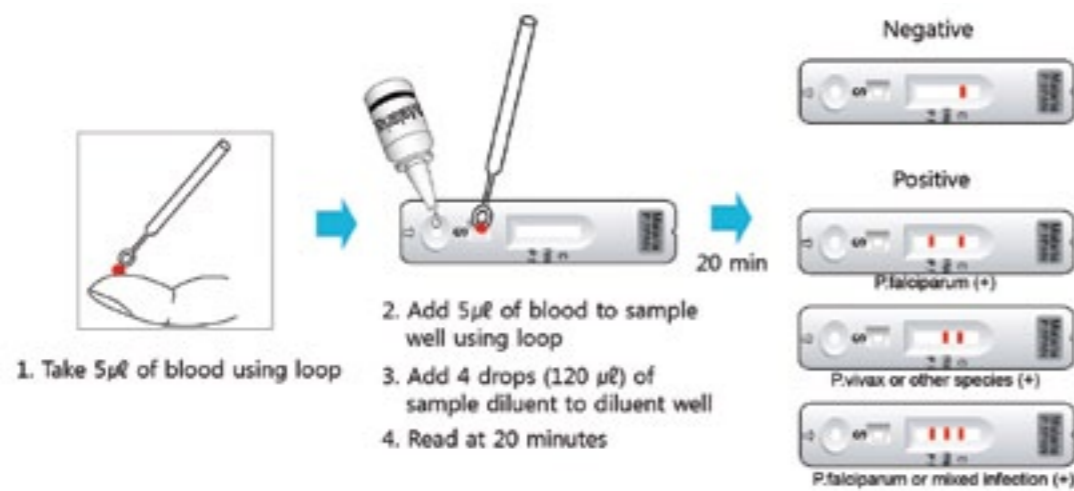
### General Information

- Malaria *P.falciparum* and the other plasmodium with separate test line at one time
- Differential detection of *P.falciparum* and the other plasmodium
- Sensitivity : 99.6% for P.f, 95.9% for Non-P.f
- Specificity : 99.3%
- No instruments needed
- Specimen : whole blood
- Reading Time : 20 min
- Storage : 1~30°C

Reference method (Microscopic examination)	BioTracer™ Malaria P.f / PAN Rapid Card		Total
	Positive	Negative	
P.f Positive	271	1	272
Non-P.f Positive	94	4	98
Negative	2	298	300

### Test Procedure

A positive result will not change once it has been established at 20 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 20 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
17012	Malaria P.f/PAN	Card	30T/Kit	Whole blood	24M

Infectious Disease One-Step Rapid Kit

# Malaria P.f/P.v Rapid Card



BioTracer™ Malaria P.f/P.v is intended for the detection and differentiation of *Plasmodium falciparum* (P.f) antigen and *Plasmodium vivax* (P.v) antigen in human blood specimen.



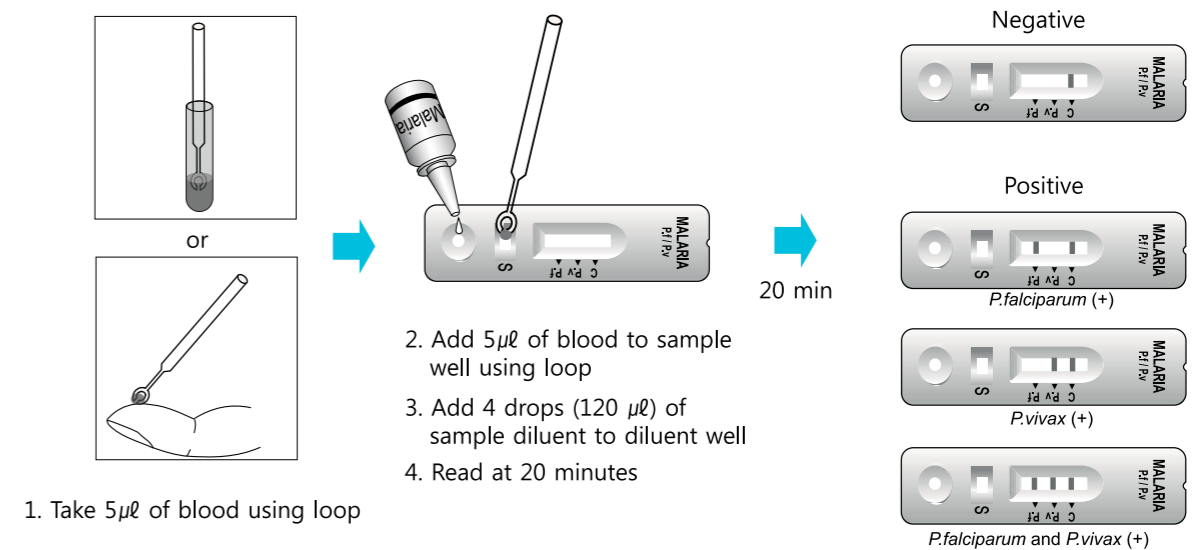
### General Information

- Immunochromatography based one-step in vitro diagnostic test
- Detect Malaria P.f/P.v antigen
- Specimen : Whole blood
- Sensitivity : P.f-99.6% (271/272), P.v-98.0% (98/100)
- Specificity : 99.3% (298/300)
- No instruments needed
- Reading time : 20 min
- Storage : 1~30°C

Reference method (Microscopic examination)	BioTracer™ Malaria P.f / P.v Rapid Card		Total
	Positive	Negative	
P.f Positive	271	1	272
P.v Positive	98	2	100
Negative	2	298	300

### Test Procedure

A positive result will not change once it has been established at 20 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 20 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
17412	Malaria P.f/P.v	Card	30T/Kit	Whole blood	24M



Infectious Disease One-Step Rapid Kit

# Malaria Ab P.f/P.v



BioTracer™ Malaria Ab P.f/P.v is chromatographic immunoassay for the qualitative detection of antibodies of all isotype (IgG, IgM, IgA) specific to Plasmodium falciparum and Plasmodium vivax at the same time in human serum, plasma or whole blood.

BioTracer™ Malaria Ab P.f/P.v is intended for professional use only for an initial screening test and Malaria antibody positive sample should be confirmed by a supplemental assay.



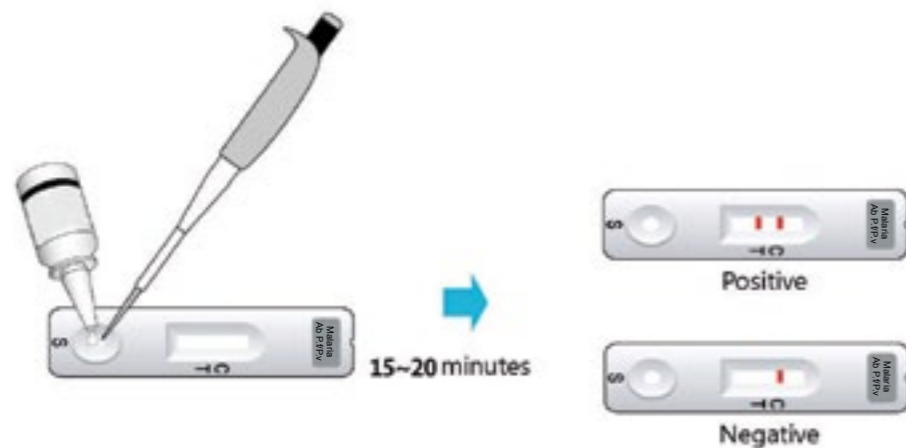
### General Information

- Immunochromatography based one-step in vitro diagnostic test
- Detect Malaria Ab P.f/P.v
- Specimen : Serum, plasma, whole blood
- Relative serological Sensitivity : 90% (99/110)
- Relative serological Specificity : 99.1% (218/220)
- No instruments needed
- Reading time : 15~20 min
- Storage : 1~30°C

		BioTracer™ Malaria Ab P.f/P.v		Total
		Positive	Negative	
Microscopic Examination (Giemsa Stain)	Positive	99	11	110
	Negative	2	218	220
Total		101	229	330

### Test Procedure

Transfer 10µl of serum(or plasma) or 20µl of whole blood into the sample well(S).  
And then add 4 drops of sample diluent into the sample well(S).



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
17512	Malaria Ab P.f/P.v	Card	30T/Kit	Serum/Plasma/Whole blood	24M

Infectious Disease One-Step Rapid Kit

# TB Rapid Card



BioTracer™ TB Rapid Card is intended for the detection of antibodies to Mycobacterium tuberculosis in human serum or plasma.

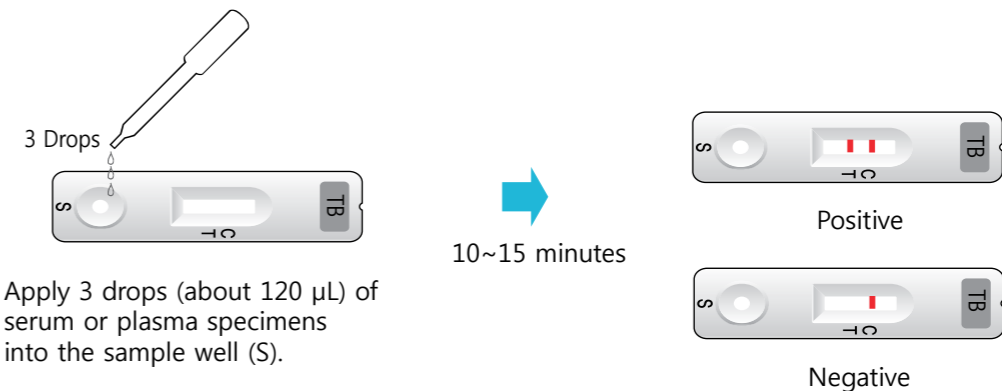


### General Information

- Immunochromatography based one-step in vitro diagnostic test
- No instruments needed
- Sensitivity : >82.5% (66/80)
- Specificity : 92.7% (306/330)
- Specimen : Serum, Plasma
- Reading Time : 10~15 min
- Storage : 2~30°C

		BioTracer™ TB Rapid Card		Total
		Positive	Negative	
TB Patients	Positive	66	14	80
	Negative	24	306	330
Total		90	320	410

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
17712	TB	Card	30T/Kit	Serum/Plasma	24M

Malaria Ab P.f/P.v

TB Rapid Card

Infectious Disease One-Step Rapid Kit

# Syphilis Rapid Card



BioTracer™ Syphilis Rapid Card is qualitative screening test kit for the detection of antibodies to *Treponema pallidum* in human blood.

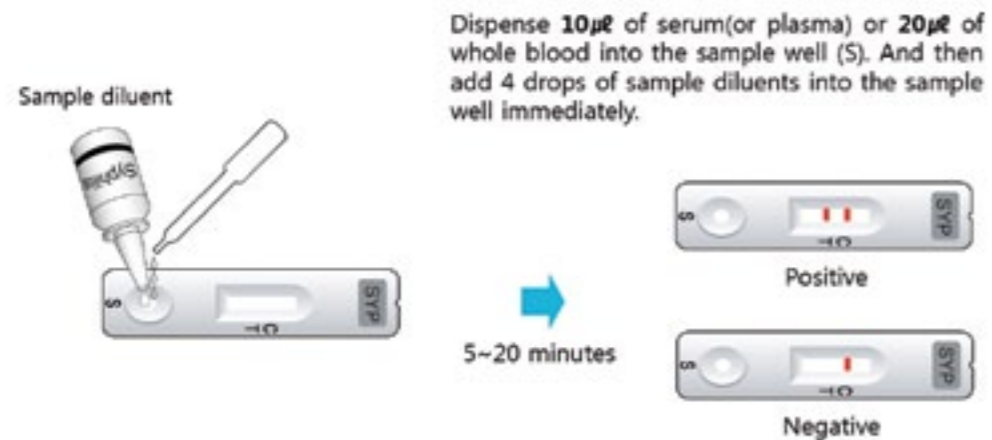


### General Information

- *Treponema pallidum* Antibody Test
- Immunochromatography based one-step in vitro diagnostic test
- No instruments needed
- Sensitivity : 99.4% (169/170)
- Specificity : 99.5% (199/200)
- Specimen : Serum, Plasma or Whole blood
- Reading Time : 5~20 min
- Storage : 1~30°C

		BioTracer™ Syphilis Rapid Card		Total
		Positive	Negative	
Syphilis ELISA	Positive	169	1	170
	Negative	1	199	200
Total		170	200	370

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
17812	Syphilis	Card	30T/Kit	Serum/Plasma/Whole blood	24M

Gastrointestinal Infection One-Step Rapid Kit

# Norovirus Rapid Test



BioTracer™ Norovirus Rapid Test is an immunochromatography based one-step in vitro diagnostic test for the qualitative determination of Norovirus in human stool specimens.

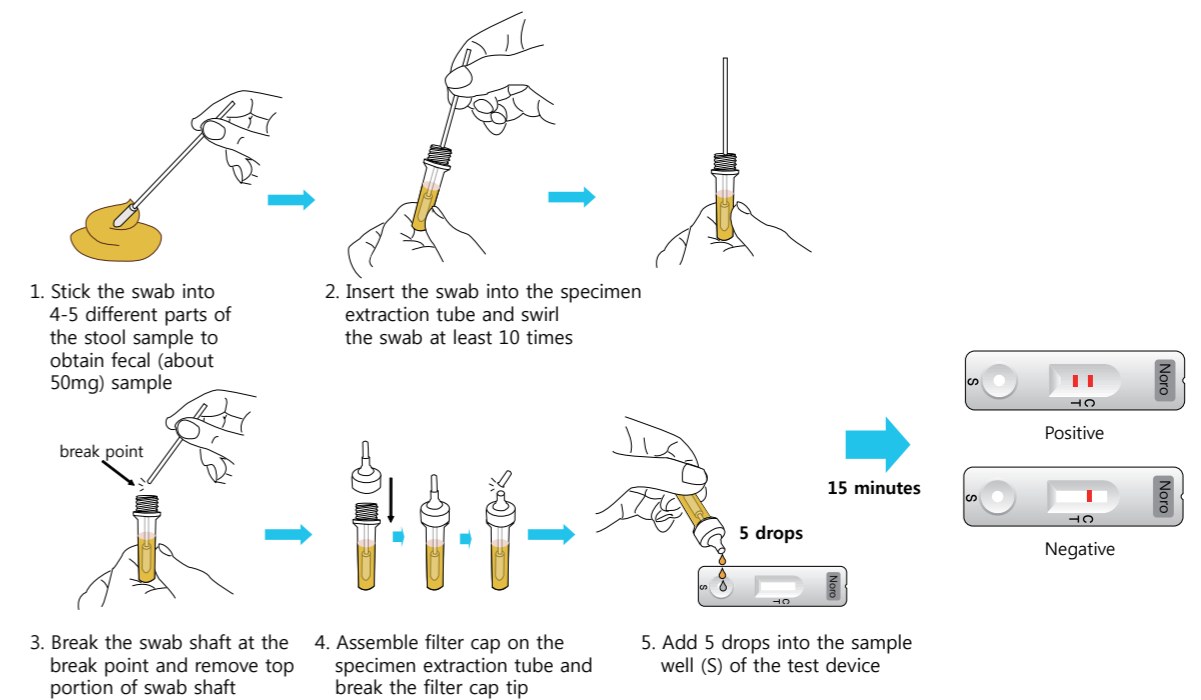


### General Information

- Immunochromatography based one-step in vitro diagnostic test
- Detect Norovirus in human stool
- Specimen : Human stool
- Sensitivity : 85.1% (148/174)
- Specificity : 99.3% (149/150)
- Reading Time : 15 min
- Storage : 1~30°C

		BioTracer™ Norovirus Rapid Test		Total
		Positive	Negative	
PCR	Positive	148	26	174
	Negative	1	149	150
Total		149	175	324

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11411	Norovirus	Card	20T/Kit	Stool	24M



## Gastrointestinal Infection One-step Rapid Kit

# Rotavirus Rapid Card



BioTracer™ Rotavirus Rapid Card is an immunochromatography based one-step in vitro diagnostic test for the qualitative determination of Rotavirus in human stool specimens.

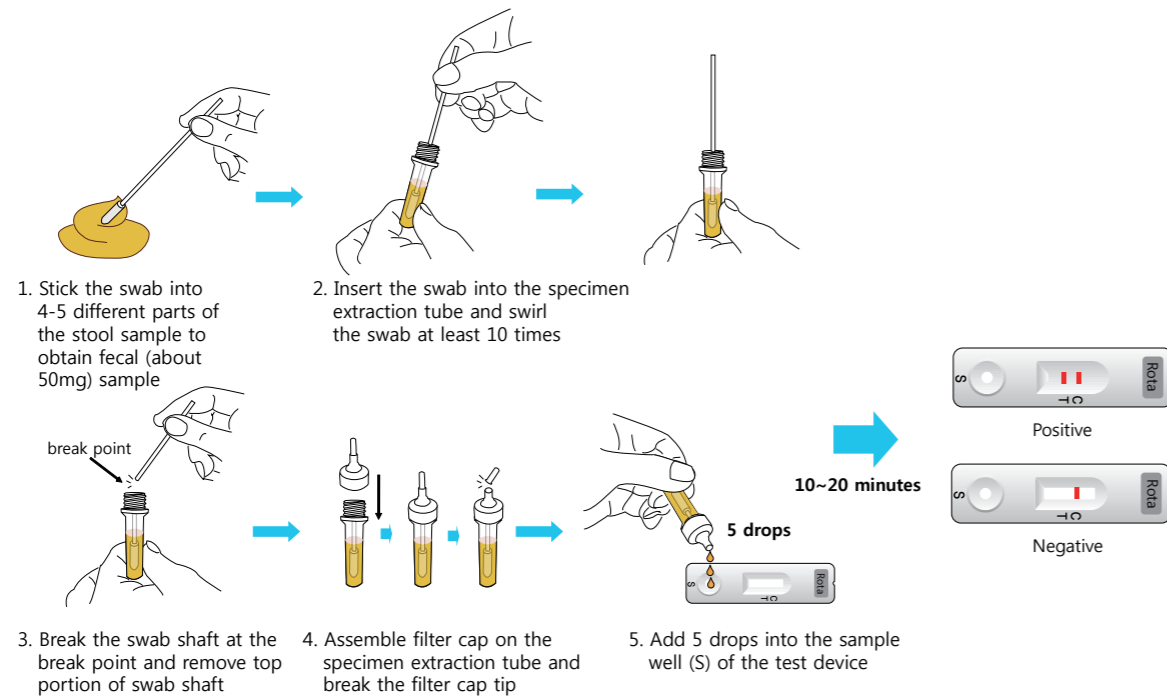
### General Information

- Immunochromatography based one-step in vitro diagnostic test
- Detect Group A Rotavirus
- Specimen : Human stool
- Sensitivity : 99%, Specificity : >99.9%
- Reading Time : 10~20 min
- Storage : 1~30°C



Feature Comparison		BioTracer™ Rotavirus Rapid Card		Total
		Positive	Negative	
ELISA	Positive	99	1	100
	Negative	0	100	100
Total		99	101	200

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11511	Rotavirus	Card	20T/Kit	Stool	24M

## Gastrointestinal Infection One-step Rapid Kit

# Adenovirus Rapid Card



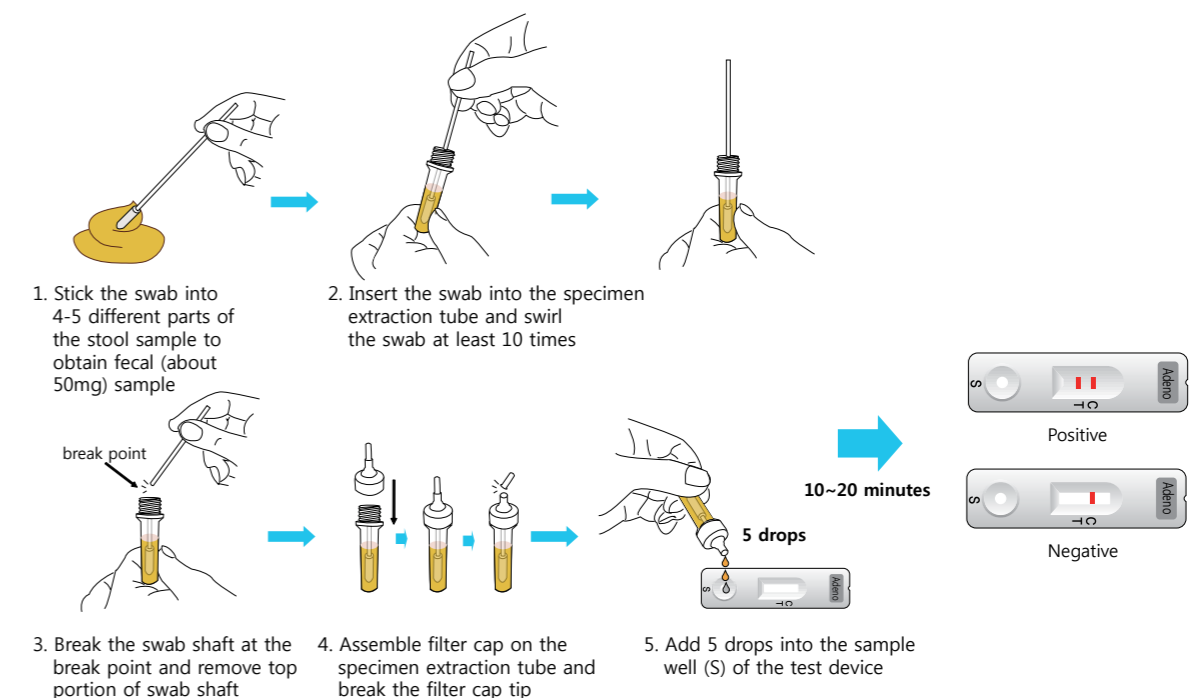
BioTracer™ Adenovirus Rapid Card is an immunochromatography based one-step in vitro diagnostic test for the qualitative determination of Adenovirus in human stool specimens.

### General Information

- Immunochromatography based one-step in vitro diagnostic test
- Detect Adenovirus in human stool
- Specimen : Human stool
- Sensitivity : 97%, Specificity : >99%
- Reading Time : 10~20 min
- Storage : 1~30°C

Feature Comparison		BioTracer™ Adenovirus Rapid Card		Total
		Positive	Negative	
ELISA	Positive	96	3	99
	Negative	0	100	100
Total		96	103	199

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11611	Adenovirus	Card	20T/Kit	Stool	24M

## Gastrointestinal Infection One-step Rapid Kit

# Rota/Adeno Rapid Card



BioTracer™ Rota/Adeno Rapid Card is an immunochromatography based one-step in vitro diagnostic test for the qualitative determination of Rota and Adeno in human stool specimens.



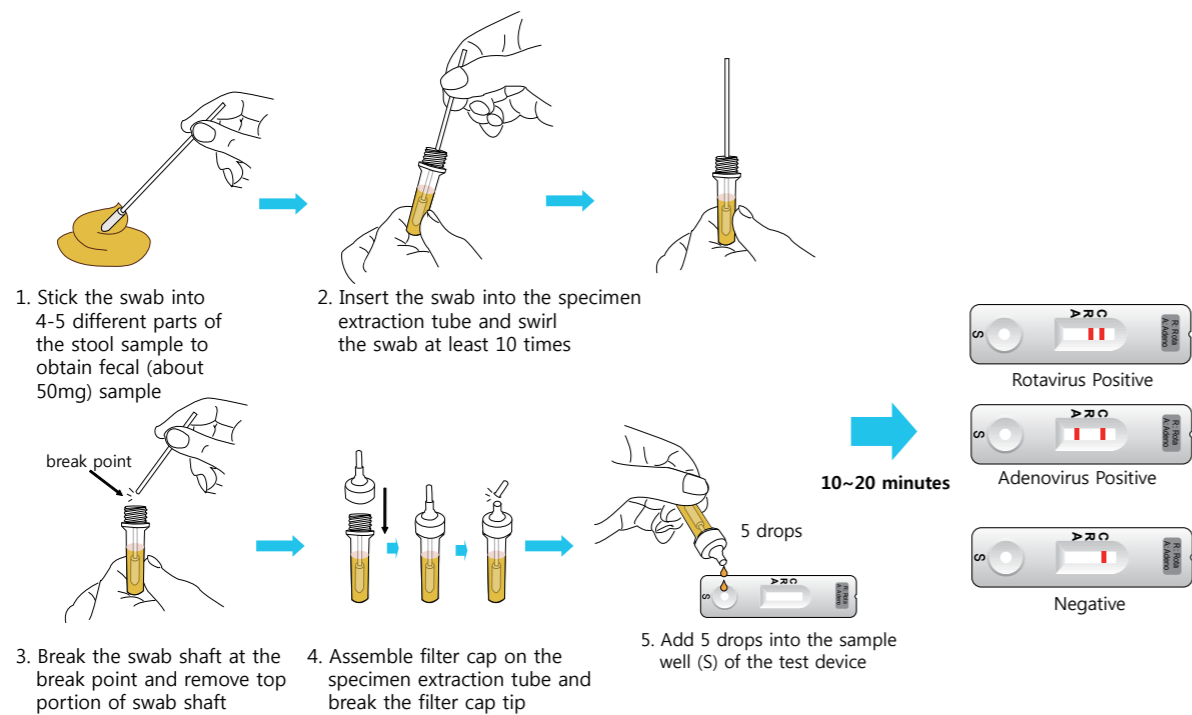
### General Information

- Immunochromatography based one-step in vitro diagnostic test
- Detect Group A Rotavirus & Adenovirus
- Specimen : Human stool
- Rotavirus - Sensitivity : 99%, Specificity : >99.9%
- Adenovirus – Sensitivity : 97%, Specificity : >99.9%
- Reading Time : 10~20 min
- Storage : 1~30°C

Feature Comparison	BioTracer™ Rota Rapid Card		Total	
	Positive	Negative		
ELISA	Positive	99	1	100
	Negative	0	100	100
Total		99	101	200

Feature Comparison	BioTracer™ Adeno Rapid Card		Total	
	Positive	Negative		
ELISA	Positive	96	3	99
	Negative	0	100	100
Total		96	103	199

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11711	Rota/Adeno	Card	20T/Kit	Stool	24M

## Gastrointestinal Infection One-step Rapid Kit

# Noro/Rota/Adeno Rapid Card



BioTracer™ Noro/Rota/Adeno Rapid Card is an immunochromatography based one-step in vitro diagnostic test for the qualitative determination of Noro/Rota/Adeno in human stool specimens.

### General Information

- Immunochromatography based one-step in vitro diagnostic test
- Detect Noro/Rota/Adenovirus in human stool
- Specimen : Human stool
- Reading Time : 10~20 min
- Storage : 1~30°C

#### < Sensitivity and Specificity for Norovirus >

Feature Comparison	BioTracer™ Noro Rapid Card		Total	
	Positive	Negative		
PCR	Positive	53	13	66
	Negative	1	99	100
Total		54	112	166

The sensitivity is 80%(53/66) and the specificity is 99%(99/100)

#### < Sensitivity and Specificity for Rotavirus >

Feature Comparison	BioTracer™ Rota Rapid Card		Total	
	Positive	Negative		
ELISA	Positive	99	1	100
	Negative	0	100	100
Total		99	101	200

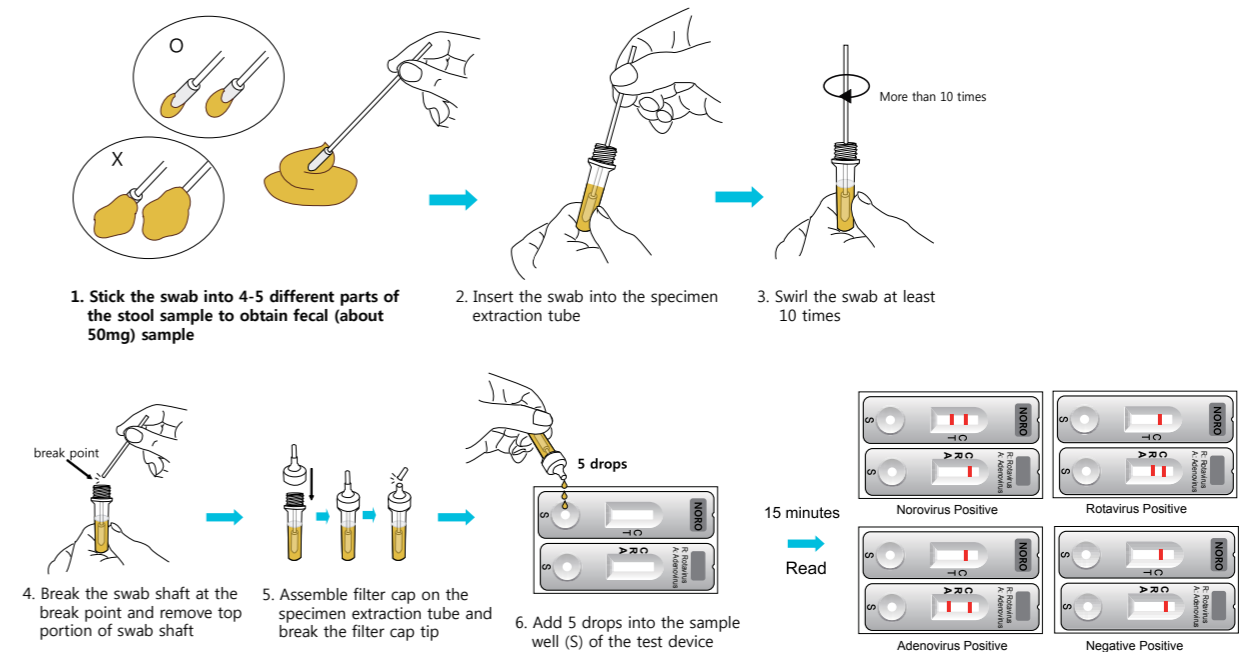
The sensitivity is 99%(90/100) and the specificity is ≥99.9%(100/100)

#### < Sensitivity and Specificity for Adenovirus >

Feature Comparison	BioTracer™ Adeno Rapid Card		Total	
	Positive	Negative		
ELISA	Positive	96	3	99
	Negative	0	100	100
Total		96	103	199

The sensitivity is 97%(96/99) and the specificity is ≥99.9%(100/100)

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11811	Noro/Rota/Adeno	Card	20T/Kit	Stool	24M



## Tumor Marker One-Step Rapid Kit

# AFP/PSA/CEA Rapid Card



BioTracer™ AFP/PSA/CEA Rapid Card is an immunochromatography based one-step in vitro diagnostic test of the qualitative detection of AFP, PSA and CEA in human serum or plasma.



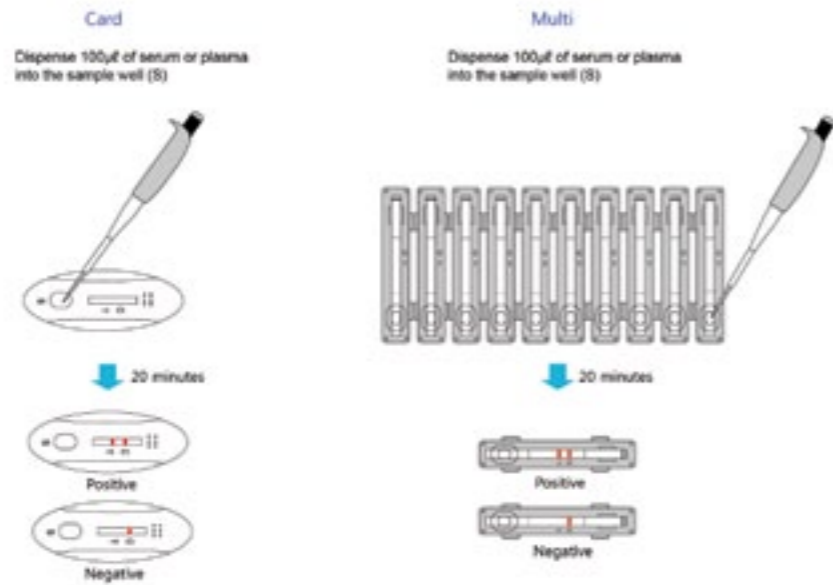
### General Information

- AFP : Alpha-Feto Protein Test to detect Liver Cancer
- PSA : Prostate-specific Antigen Test to detect Prostate Cancer
- CEA : Carcinoembryonic Antigen Test to detect Colorectal Cancer
- Immunochromatography based one step in vitro diagnostic test
- No instruments needed
- Specimen : Serum or plasma
- Reading Time : 20min
- Storage : 2~30°C

	AFP	PSA	CEA
Analytical Sensitivity	20ng/ml	3ng/ml	5ng/ml
Sensitivity	99.9%	99.9%	99.9%
Specificity	98.8%	99.4%	99.8%

### Test Procedure

A positive result will not change once it has been established at 20 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 20 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
13012	AFP	Card	30T/Kit	Serum/Plasma	18M
13035	AFP	Multi	10T x 10/Kit	Serum/Plasma	18M
13112	PSA	Card	30T/Kit	Serum/Plasma	18M
13212	CEA	Card	30T/Kit	Serum/Plasma	24M

## Tumor Marker One-Step Rapid Kit

# FOB Rapid Card



BioTracer™ FOB Rapid Card is a qualitative test for the detection of human blood hemoglobin in human stool specimens and early diagnosis for Colon Cancer.

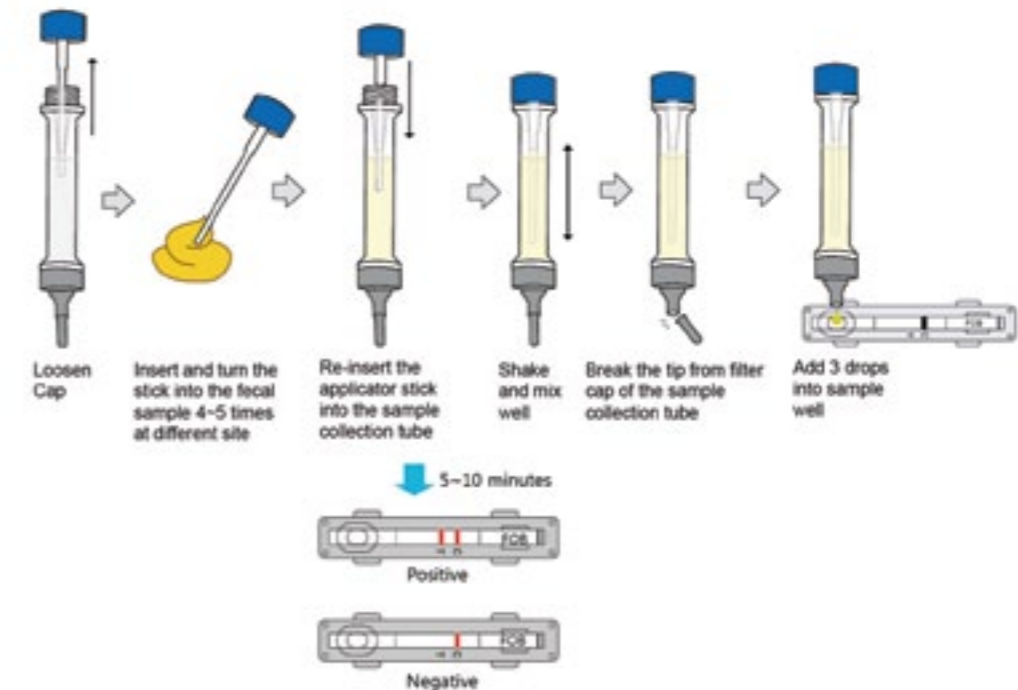


### General Information

- Screening test for Fecal Occult Blood
- Immunochromatography based one-step in vitro diagnostic test
- No instruments needed
- All material provided, ready to use reagent
- No Cross reactivity
  - Bovine Hemoglobin, Swine hemoglobin, Horse hemoglobin, Bilirubin, Bovine serum albumin Vitamin C
- Analytical sensitivity : 50ng/ml of FOB
- Sensitivity : 99%(97/98), Specificity: 99.9%(202/202)
- Specimen : Stool
- Reading Time : 5~10 min
- Storage : 2~30°C

### Test Procedure

A positive result will not change once it has been established at 10 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 10 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
13333	FOB	Multi	50T/Kit	Stool	24M

Fertility Hormone One-step Rapid Kit

# hCG Rapid Card/Good Sence



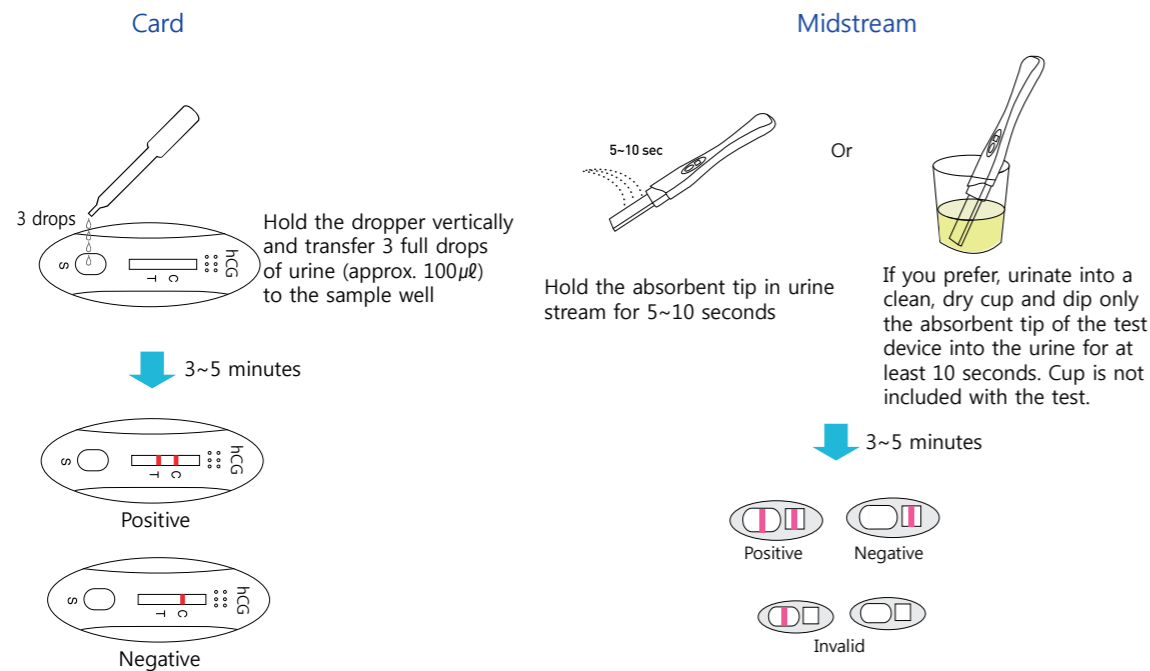
BioTracer™ hCG Rapid Card is an immunochromatography based one-step in vitro diagnostic test of the qualitative detection of hCG in human urine.



### General Information

- Easy to use
- Analytical sensitivity : 25mIU/ml of hCG
- Sensitivity : 99.9%, Specificity : 99.9%
- Specimen : Urine
- Reading Time : 3~5 min
- Immunochromatography based one-step in vitro diagnostic test
- No cross reactivity : hLH(500mIU/mL), hFSH(1,000mIU/mL), and hTSH(1,000µIU/mL)
- U.S FDA cleared
- Storage : 1~30°C

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
14011	hCG	Card	25T/Kit	Urine	24M
14025	hCG	Strip	25T X 4/Kit	Urine	18M
14010	hCG(Goodsense)	Card	1T/Kit	Urine	24M
14040	hCG(Goodsense)	Midstream	1T/Kit	Urine	24M

Fertility Hormone One-step Rapid Kit

# LH Rapid Card



BioTracer™ LH Rapid Card is a rapid one-step test to help predict the time of ovulation and peak fertility. This product detects the LH surge in urine, signaling that ovulation is likely to occur in the next 24~36 hours.

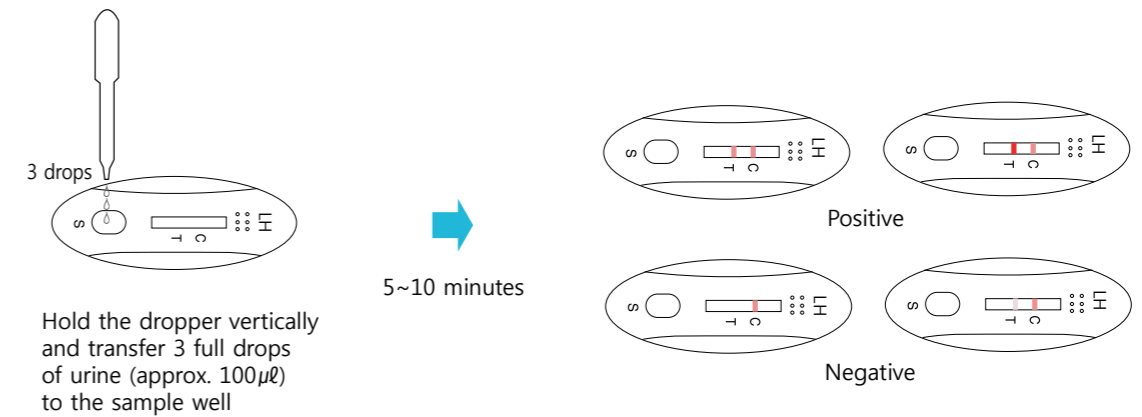


### General Information

- Ovulation Test to detect Luteinizing Hormone in Urine
- Immunochromatography based one-step in vitro diagnostic test
- Analytical sensitivity : 40mIU/ml of LH
- Sensitivity : 99.9%, Specificity : 99.9%
- Specimen : Urine
- Reading Time : 5~10 min
- No cross reactivity : hCG(1,000mIU/mL), hFSH(1,000mIU/mL), and hTSH(1,000µIU/mL)
- Storage : 2~30°C

### Test Procedure

A positive result will not change once it has been established at 10 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 10 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
14111	LH	Card	25T/Kit	Urine	18M



## Acute Myocardial Infarction One-Step Rapid Kit

# Troponin I Rapid Card/Cardiac 3 in 1



BioTracer™ Troponin I Rapid Card/Cardiac 3 in 1 is intended for the qualitative determination of Cardiac Troponin I, CK-MB and Myoglobin in human serum, plasma or whole blood.



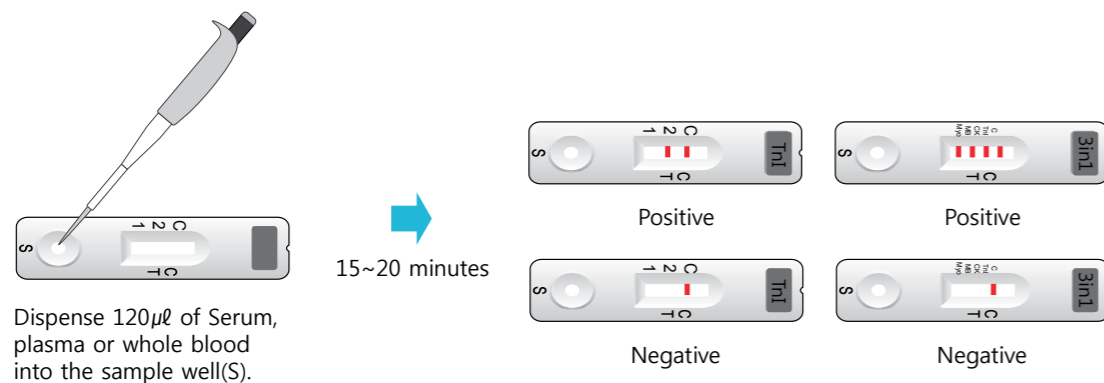
### General Information

- Immunochromatography based one-step in vitro diagnostic test
- Point of care test at Emergency Room
- No instruments needed
- No cross reactivity
- Specimen : Serum, Plasma or Whole Blood
- Reading Time : 15~20 min
- Storage : 2~30°C

	Troponin I	CK-MB	Myoglobin
Analytical Sensitivity	1ng/ml	5ng/ml	70ng/ml
Sensitivity	98.0%	99.0%	99.9%
Specificity	96.1%	94.6%	93.6%

### Test Procedure

The myoglobin test results may be showed false negative in over 12 hours after onset of chest pain. A positive result will not change once it has been established at 20 minutes, however in order to prevent any incorrect results, the test results should not be interpreted after 20 minutes.



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
12019	Troponin I	Card	10T/Kit	Serum/Plasma/Whole blood	18M
12519	Cardiac 3 in 1 (cTnI/CK-MB/Myo)	Card	10T/Kit	Serum/Plasma/Whole blood	24M

## Gastrointestinal Infection ELISA Kit

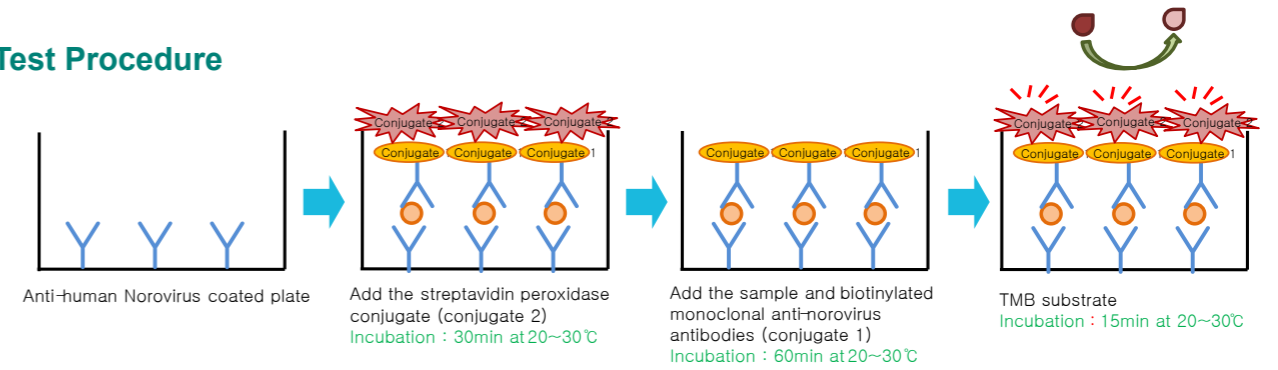
# Norovirus ELISA



### General Information

- Enzyme immunoassay for the qualitative detection of Norovirus in human fecal specimen.
- Specimen : Human stool
- Sensitivity : 80%
- Specificity : 99%
- Storage : 2~8°C

### Test Procedure



## Gastrointestinal Infection ELISA Kit

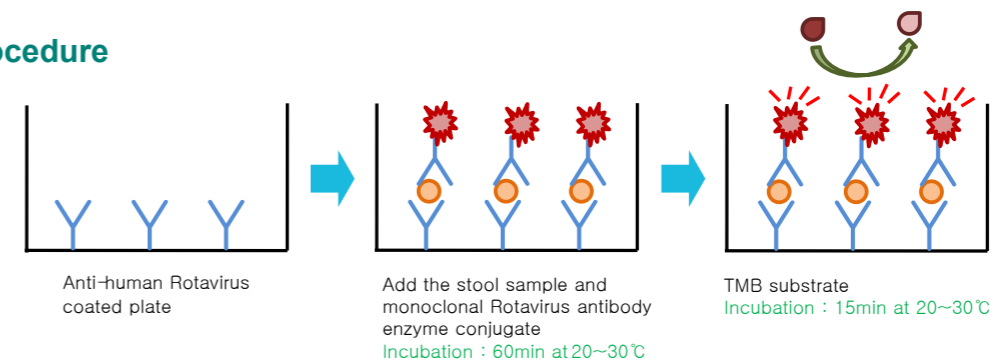
# Rotavirus ELISA



### General Information

- Enzyme immunoassay for the qualitative detection of Rotavirus in human fecal specimen
- Detect group A Rotavirus
- Specimen : Human stool
- Sensitivity : 99.4%
- Specificity : 99.9%
- Storage : 2~8°C

### Test Procedure



### Ordering Information

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11454	Norovirus	Microplate	96T/Kit	Stool	12M
11554	Rotavirus	Microplate	96T/Kit	Stool	12M

Troponin I Rapid Card/Cardiac 3 in 1

ELISA

Gastrointestinal Infection ELISA Kit

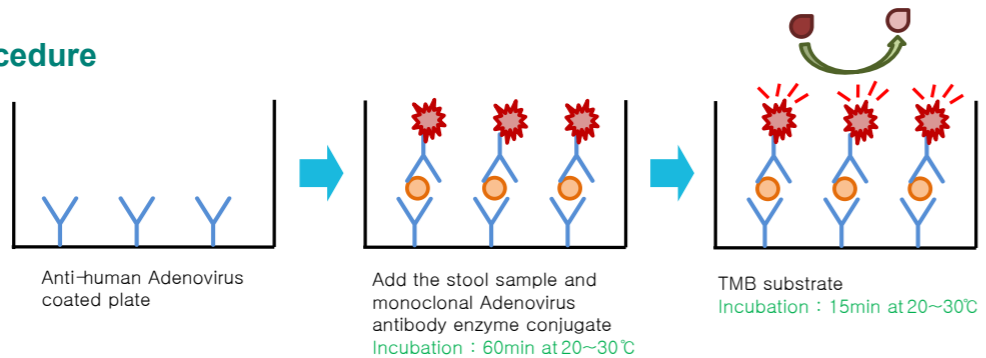
# Adenovirus ELISA



**General Information**

- Enzyme immunoassay for the qualitative detection of Adenovirus in human fecal specimen
- Specimen : Human stool
- Sensitivity : 99%
- Specificity : 99.9%
- Storage : 2~8°C

**Test Procedure**



Asthma/Allergy ELISA Kit

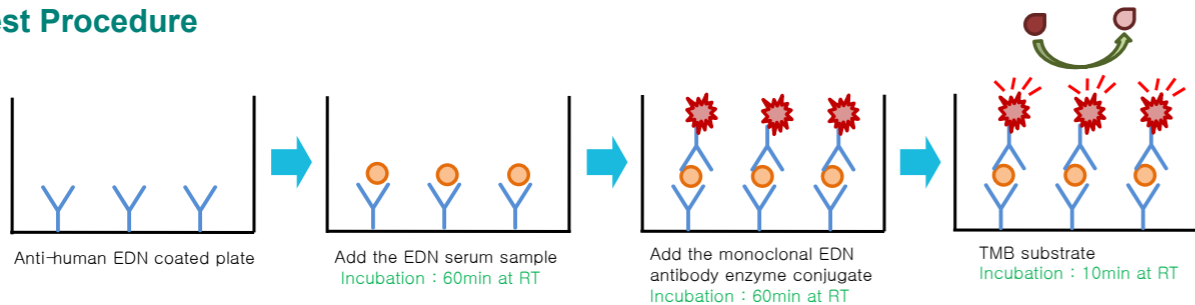
# K<sup>®</sup>EDN ELISA



**General Information**

- Enzyme immunoassay for the quantitative detection of EDN in human serum
- Specimen : Human serum, Urine
- Sensitivity : 98%
- Cut off : 0.6ng/ml
- Storage : 2~8°C

**Test Procedure**



**Ordering Information**

Cat. No	Product	Type	Pack Size	Specimen	Shelf Life
11654	Adenovirus	Microplate	96T/Kit	Stool	12M
11954	K <sup>®</sup> EDN	Microplate	96T/Kit	Serum / Urine	12M

## Ordering Information

**+ Orders**

Orders can be placed by fax or e-mail which shall include the following information: Catalogue Number, Quantity, Description, Company name, PO number, special instructions with billing and shipping address.

**+ Shipping**

All of our products are shipped by FCA, Seoul (Incheon International airport), Republic of Korea. Our shipping agent will figure out the cost (upon buyer's expected shipping term) to the nearest international airport in buyer's region.

**+ Delivery Cost**

Total cost of transit to buyer's region will be informed by email or fax.

**+ Cancellation**

Any cancellation notice must be received in 3 days after issuing purchase order. Special order with particular package cannot be cancelled.

**+ Bulk Orders**

We are able to provide products of bulk format at competitive prices.

**+ Pricing**

Prices are quoted in US dollars or Euro and are subject to change without notice.

**+ Terms**

FCA Seoul (Incheon international airport) Republic of Korea. Prepayment by Telegraphic Transfer.

**+ Return Policy**

No returns will be accepted without mutual consent. All claims for return shall be informed within 10 days after receipt of goods. Credit will not be issued for products that have expired or are not in their original containers.

**+ Damage/Shortage Claims**

Shipment must be inspected immediately upon receipt and discrepancies reported in writing within 7 working days. The carrier is responsible for any damage or shortage. These must be reported immediately for an inspection by the carrier before a claim can be issued.

**+ Confidentiality**

Proprietary arrangements with our customers are entirely confidential.



## Bank Information

Bank Name	Woori Bank
Branch	Sanbyeok Branch
Bank Address	516, Beonyeong-ro, Gunpo-si, Gyeonggi-do, Korea
Tel No.	82-31-395-2001
Fax No.	82-31-392-7767
Account No.	784-277581-41-002
Swift Code	HVBKRRSE
Account Name	Bio Focus Co., Ltd.

