

Wondfo®

# Wondfo POCT Qualitative Rapid Diagnostic Reagent

NEW POCT SOLUTION



WONDFO BIOTECH  
WeAreWorkingForYourHealth

Wondfo®

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FSC CE FDA ifcc

Guangzhou Wondfo Biotech Co., Ltd.

# ENTERPRISE INTRODUCTION



**Guangzhou Wondfo Biotech Co., Ltd (Wondfo)** is a leading manufacturer of Medical Diagnostic Tests in China. The company was established in 1992, With highly experienced staff, ISO13485 compliance, Wondfo offers premium quality products or OEM, directly from the production facility. The company is efficiently structured to provide lasting healthcare solutions to domestic and international market.

Currently Wondfo employs over 1000 employees housed in state of art facility encompassing over 40,000 square meters of space in Guangzhou Scientific City Based on the technical resources from South China University of Technology, over 30% of the employed R&D staff has completed master and doctorate degree from prestigious worldwide institution. By consistently investing resources in staff training and technological development Wondfo is constantly building a professional team in quality control, production, management, and marketing operations.

Wondfo has pioneered and advanced engineering techniques in immunological tests manufacturing by combining artistry of the development team with technological application of automated manufacturing equipment. In order to assure the best product quality and stability, Wondfo established the aseptic workshops (over 3,000 square meters), equipped temperature and humidity controlled environment. Wondfo also housed a technical team developing immune-fluorescence technology, monoclonal antibody research, gene engineering, microfluidic and medical information solution.

Wondfo pays strict attention to quality control processes while utilizing cost cutting application of automated equipment, resulting in super quality products with very affordable prices. Wondfo also focuses on excellent client-centered support with experienced sales and marketing team that is fluent in both Chinese and English, in addition to strong international import- export experience. The future plans include product diversification with strong marketing expansion into the world market.

FDA

CE

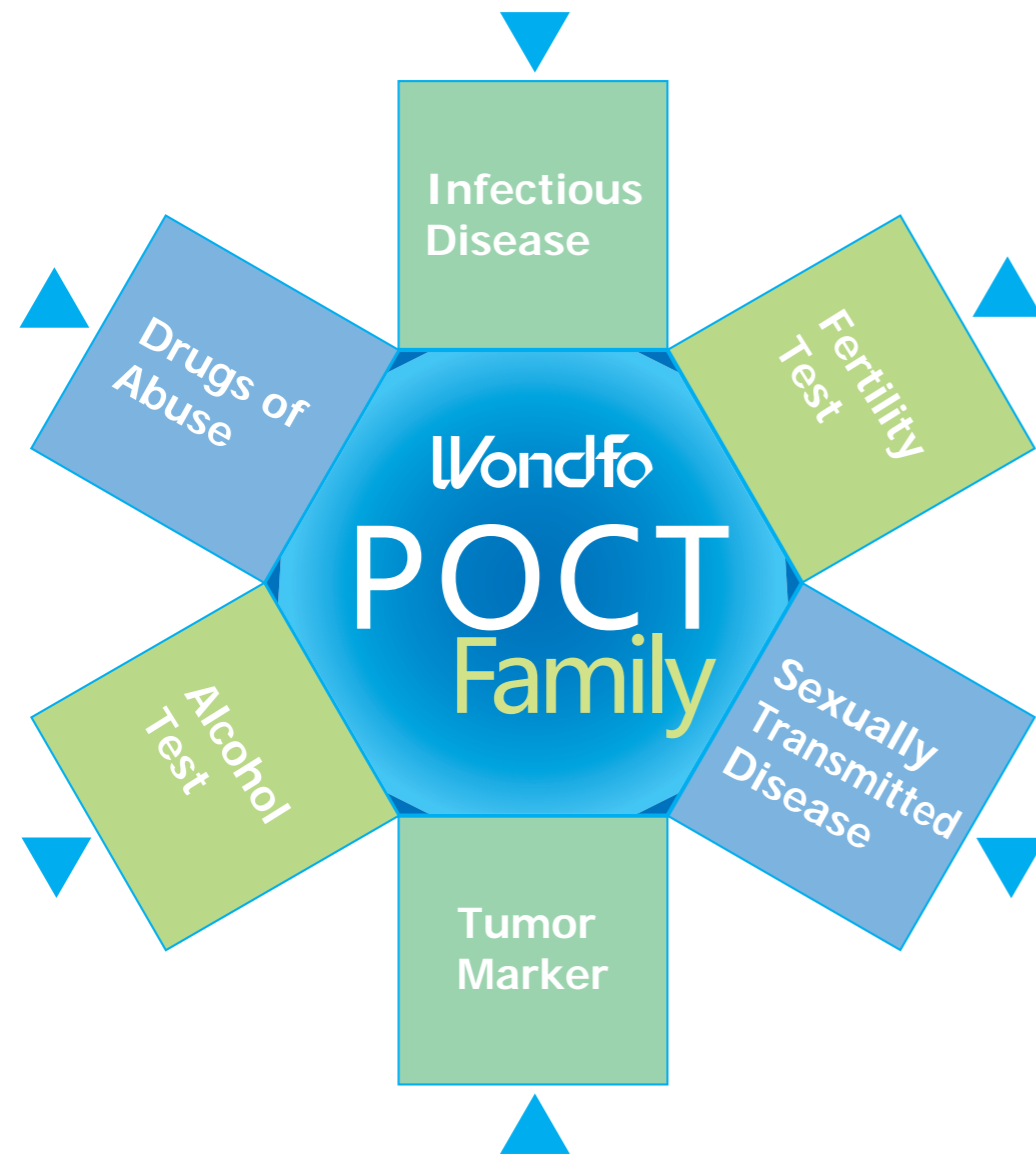


FSC



Wondfo Biotech Co., Ltd

# PRODUCTS



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## Infectious Disease series

### Rapid Test kit

**Principle:** Colloidal gold immunochromatographic method

**Application:** Single test and suitable for professional use

**Advantage:** Easy to use, easy to read result, easy to carry;  
High sensitivity and specificity, safe and reliable



Class	Product Name	Specimen	Format	Sensitivity	Packing Specifications	Qualification
	HBsAg Hepatitis B Surface Antigen Test	Serum/Plasma/WB	Strip/Cassette	2 ng/mL	25T/Box	CFDA
	HBsAb Hepatitis B Surface Antibody Test	Serum/Plasma/WB	Strip/Cassette	10 ng/mL-30ng/mL	25T/Box	CFDA
<b>Hepatitis</b>	HBcAb Hepatitis B Core Antibody Test	Serum/Plasma/WB	Strip/Cassette	Custom	25T/Box	CFDA
	Hepatitis B Virus Combo Test(5 items)	Serum/Plasma/WB	Panel	Custom	25T/Box	CFDA
	HCV Hepatitis C Virus Test	Serum/Plasma/WB	Strip/Cassette	2 ng/mL	25T/Box	CFDA
	HIV1/2 Test (2 Lines)	Serum/Plasma/WB	Cassette	2 NCU/mL	25T/Box	CFDA
<b>HIV</b>	HIV1/2 Test (3 Lines)	Serum/Plasma/WB	Cassette	2 NCU/mL	25T/Box	CFDA
	HIV1/2 oral fluid Test	Oral Fluid	Cassette	Custom	1T/Box	CFDA
	HIV-Syphilis Test (3 lines)	Whole Blood	Cassette	Custom	25T/Box	
	Malaria P.f Test	Whole Blood	Cassette	Custom	25T/Box	CFDA ☺☺
<b>Malaria</b>	Malaria P.f/Pan Test	Whole Blood	Cassette	Custom	25T/Box	CFDA ☺☺
	Malaria P.f/P.v Test	Whole Blood	Cassette	Custom	25T/Box	☺☺
<b>H.Pylori</b>	H.Pylori Antibody Test	Serum/Plasma	Strip/Cassette	Custom	25T/Box	☺☺
	H.Pylori Antigen Test	Feces	Strip/Cassette	Custom	25T/Box	CFDA ☺☺
	Flu A Test	Nasal Swab	Cassette	5.1×10 TCID /ml	25T/Box	CFDA ☺☺
<b>Flu</b>	Flu B Test	Nasal Swab	Cassette	1.5×10 TCID /ml	25T/Box	CFDA ☺☺
	Flu A &B	Nasal Swab	Cassette	Flu A: 5.1×10 TCID /ml	25T/Box	CFDA ☺☺
		Nasal Swab	Cassette	Flu B :1.5×10 TCID /ml	25T/Box	CFDA ☺☺
<b>Dengue</b>	Dengue NS1 Antigen Test	Whole Blood	Cassette	Custom	25T/Box	☺☺
	Dengue IgG/IgM Antibody Test	Whole Blood	Cassette	Custom	25T/Box	☺☺
<b>Others</b>	H7 Subtype Influenza Test	Sputum, Swab	Cassette	Custom	25T/Box	CFDA
	MP (Mycoplasma pneumonia) Test	Serum/Plasma	Cassette	Custom	25T/Box	
	Rotavirus Test	Feces	Cassette	Custom	25T/Box	
	Adenovirus Test	Feces	Cassette	Custom	25T/Box	

**Parameters**

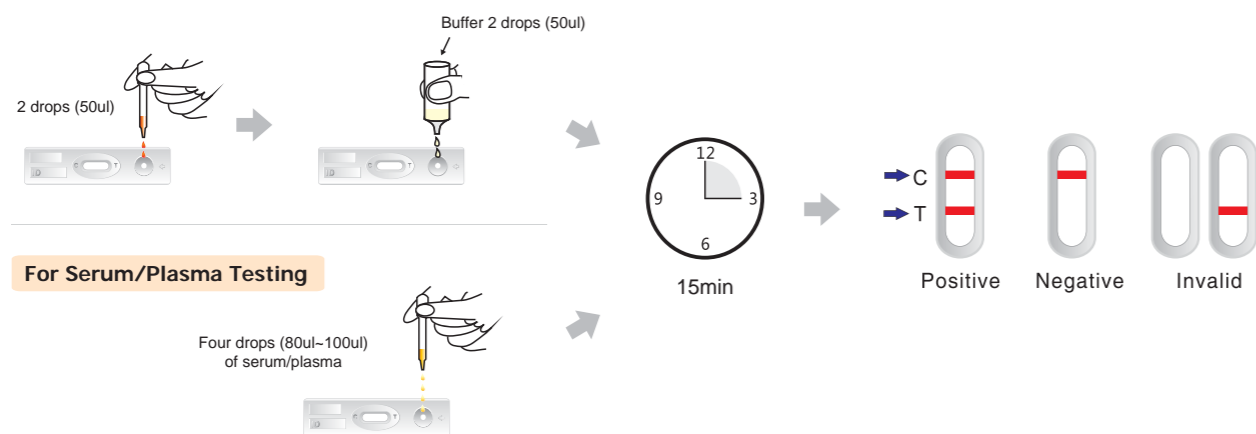
Test time	15 min
Storage temperature	4-30 °C
Shelf life	24 months

**Test Procedure & Interpretation**

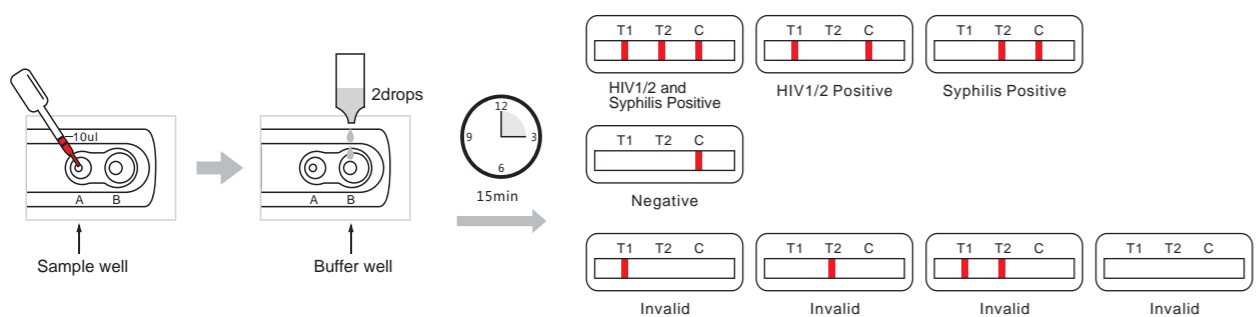
**Flu**



**Hepatitis (WB)**



**HIV-Syphilis**



**Fertility Tests**

**Principle:** Colloidal gold immunochromatographic method.

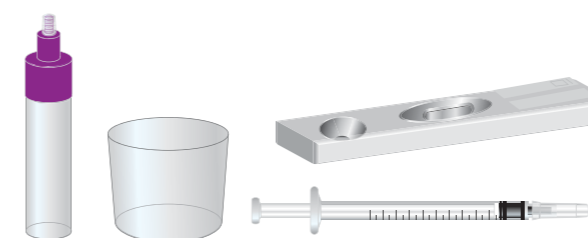
**Format:** Strip/Cassette/Midstream/Digital Test.

**Feature:** Easy to use, easy to read result, easy to carry.

**Advantage:** High sensitivity and specificity (>99%).



Class	Product	Format	Width	Specimen	Sensitivity	Qualification
Pregnancy Test	HCG Test	Strip	2.5mm	Urine/Serum	10mIU/mL 20mIU/mL 25mIU/mL	CFDA CE FDA
		Cassette	3.5mm			
		Midstream	4.0mm			
			5.0mm 6.0mm			
Ovulation Test	LH Test	Strip	2.5mm	Urine/Serum	25mIU/mL	CFDA CE FDA
		Cassette	3.5mm			
		Midstream	4.0mm 5.0mm 6.0mm			
Ovulation Test	FSH Test	Strip	2.5mm	Urine/Serum	25mIU/mL	CFDA CE
		Cassette	3.5mm			
		Midstream	4.0mm 5.0mm 6.0mm			
Male Fertility Tests	Sperm concentration test	Cassette	Custom	Sperm	15×10 <sup>6</sup> /ml	CFDA CE
Digital Pregnancy Test	Digital Pregnancy Test (DM-102)	Digital pen	Custom	Urine	25 mIU/mL	CFDA CE
	Digital Pregnancy Test (DM-111)	Digital pen	Custom	Urine	25 mIU/mL	



Sperm concentration test kit



DM-102 (single-use)



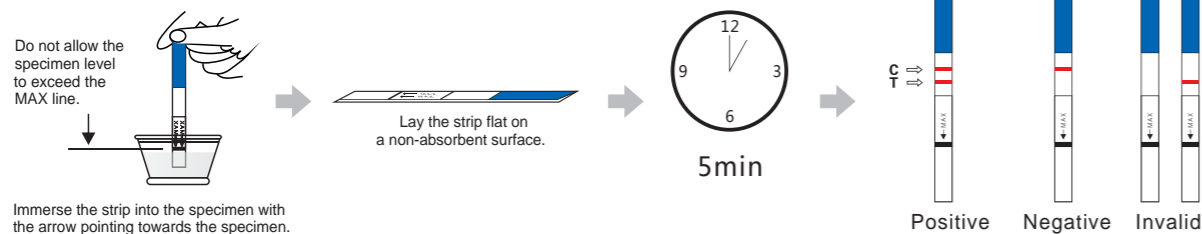
DM-111 (repeatedly-use)

### Parameters

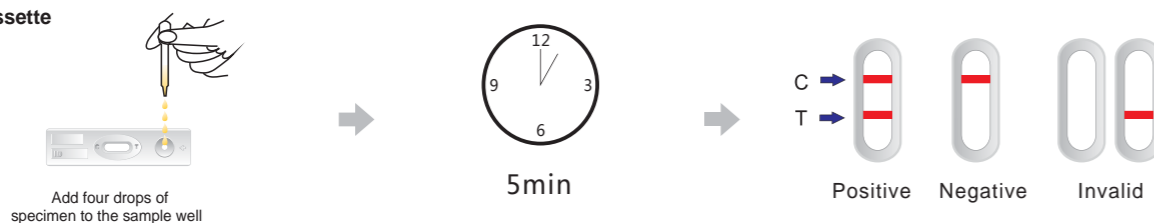
<b>Name</b>	One Step hCG Pregnancy test / One Step LH Ovulation test
<b>Format</b>	Strip/Cassette/Midstream/Digital Test
<b>Specimen</b>	Urine
<b>Sensitivity</b>	hCG: 25mIU/ml, 20mIU/ml, 10mIU/ml LH : 25mIU
<b>Test time</b>	5 min
<b>Storage temperature</b>	4-30 °C
<b>Shelf life</b>	24 months

### Test Procedure & Interpretation

#### Strip



#### Cassette



#### Midstream



#### Digital Pregnancy pen



## Drugs of Abuse Tests

More than 20 Test items: AMP BAR BZO OXY MTD KET MOP COC

THC MET MDMA OPI PCP TCA TRA BUP

PPX EDDP K2 (New) etc.

Various formats: Strip, Cassette, Multi - Test Panel, Multi - Test Cup

Reliable: Adulteration test optional



### One Step DOA Test

Product	Test items	Format	Specimen	Sensitivity	Qualification
MOP(Morphine) Test	Morphine	Strip/Cassette/Panel	urine	300ng/ml; 100ng/ml	CE FDA
AMP(Amphetamine) Test	Amphetamine	Strip/Cassette/Panel	urine	1000ng/ml; 300ng/ml	CE FDA
BAR(Barbiturates) Test	Barbiturates	Strip/Cassette/Panel	urine	300ng/ml	CE FDA
BZO (Benzodiazepines) Test	Benzodiazepines	Strip/Cassette/Panel	urine	300ng/ml	CE FDA
COC(Cocaine) Test	Cocaine	Strip/Cassette/Panel	urine	300ng/ml	CE FDA
mAMP/MET(Methamphetamine) Test	Methamphetamine	Strip/Cassette/Panel	urine	1000ng/ml; 500ng/ml	CE FDA
MDMA(Ecstasy) Test	Ecstasy	Strip/Cassette/Panel	urine	500ng/ml	CE FDA
BUP(Buprenorphine) Test	Buprenorphine	Strip/Cassette/Panel	urine	10ng/ml	CE FDA
MTD( Methadone) Test	Methadone	Strip/Cassette/Panel	urine	300ng/ml; 200ng/ml	CE FDA
OPI (Opiate) Test	Opiate	Strip/Cassette/Panel	urine	2000ng/ml	CE FDA
PCP(Phencyclidine) Test	Phencyclidine	Strip/Cassette/Panel	urine	25ng/ml	CE FDA
TCA(Tricyclic Antidepressants) Test	Tricyclic Antidepressants	Strip/Cassette/Panel	urine	1000ng/ml	CE FDA
THC(Marijuana/Cannabinoids) Test	Marijuana/Cannabinoids	Strip/Cassette/Panel	urine	50ng/ml	CE FDA
OXY(Oxycodone) Test	Oxycodone	Strip/Cassette/Panel	urine	100ng/ml	CE FDA
KET(Ketamine) Test	Ketamine	Strip/Cassette/Panel	urine	1000ng/ml	CE FDA
PPX(Propoxyphene) Test	Propoxyphene	Strip/Cassette/Panel	urine	300ng/ml	CE FDA
KET(Ketamine) Test	Ketamine	Strip/Cassette/Panel	urine	1000ng/ml	CE FDA
EDDP	EDDP	Strip/Cassette/Panel	urine	300ng/ml	CE FDA
TRA(Tramadol) Test	Tramadol	Strip/Cassette/Panel	urine	1000ng/ml	CE FDA
K2 (Synthesis Cannabis )Test *	Synthesis Cannabis	Strip/Cassette/Panel	urine	50ng/ml	CE FDA
FTY (Fentanyl) Test *	Fentanyl	Strip/Cassette/Panel	urine	20ng/ml	CE FDA
AMP (Amphetamine) Oral Fluid Test	Amphetamine	Cassette	Oral Fluid	50ng/ml	CE FDA
BZO(Benzodiazepines) Test	Benzodiazepines	Cassette	Oral Fluid	30ng/ml	CE FDA
COC (Cocaine) Oral Fluid Test	Cocaine	Cassette	Oral Fluid	20ng/ml	CE FDA
THC(Marijuana) Oral Fluid Test	Marijuana	Cassette	Oral Fluid	50ng/ml	CE FDA
MET (Methamphetamine) Oral Fluid Test	Methamphetamine	Cassette	Oral Fluid	50ng/ml	CE FDA
MOP (Morphine) Oral Fluid Test	Morphine	Cassette	Oral Fluid	40ng/ml	CE FDA



Panel

### One Step DOA Multi- Test

Product	Test items	Format	Specimen	Sensitivity	Qualification
DOA Multi-Test Panel	2-12 test item; More than 20 for optional	Panel	urine	Variable	CE FDA
DOA Multi-Test Cup	5-18 test item; More than 20 for optional	Key-Cup	urine	Variable	CE FDA
DOA Multi-Test Cup	5-18 test item; More than 20 for optional	T-Cup	urine	Variable	CE FDA
DOA Multi-Test Cup	5-18 test item; More than 20 for optional	Q-Cup	urine	Variable	CE FDA



Q-Cup

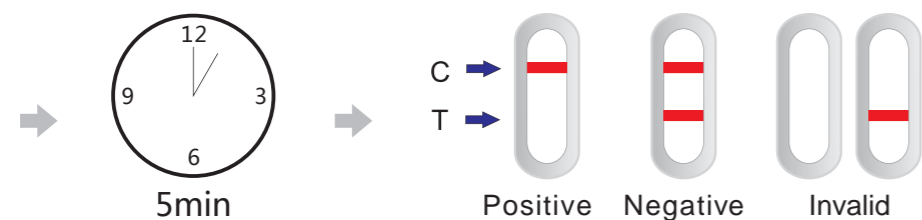
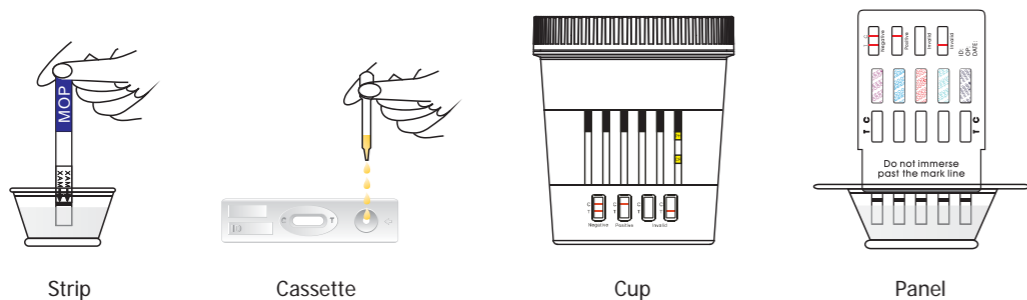
T-Cup

Key-Cup

Multi-Drug Oral Fluid Test Cassette

### Test Procedure & Interpretation

One step



## Tumor Marker Tests

**Principle:** Colloidal gold immunochromatographic method

**Feature:** Easy to use, easy to read result, easy to carry

**Advantage:** Easy to use, easy to read result, easy to carry; High sensitivity and specificity, safe and reliable

**Application:** Single test and suitable for professional use

Product	Format	Specimen	Sensitivity	Qualification
FOB (Fecal Occult Blood) Test	Strip/Cassette	Feces	200ng/ml; 50ng/ml	CFDA CE
PSA (Prostate Specific Antigen) Test	Strip/Cassette	Serum/Plasma	4ng/ml	CE
AFP (Alpha-Fetoprotein) Test	Strip/Cassette	Serum/Plasma	25ng/ml	
CEA (Carcinoma Embryonic Antigen) Test	Strip/Cassette	Serum/Plasma	5ng/ml	

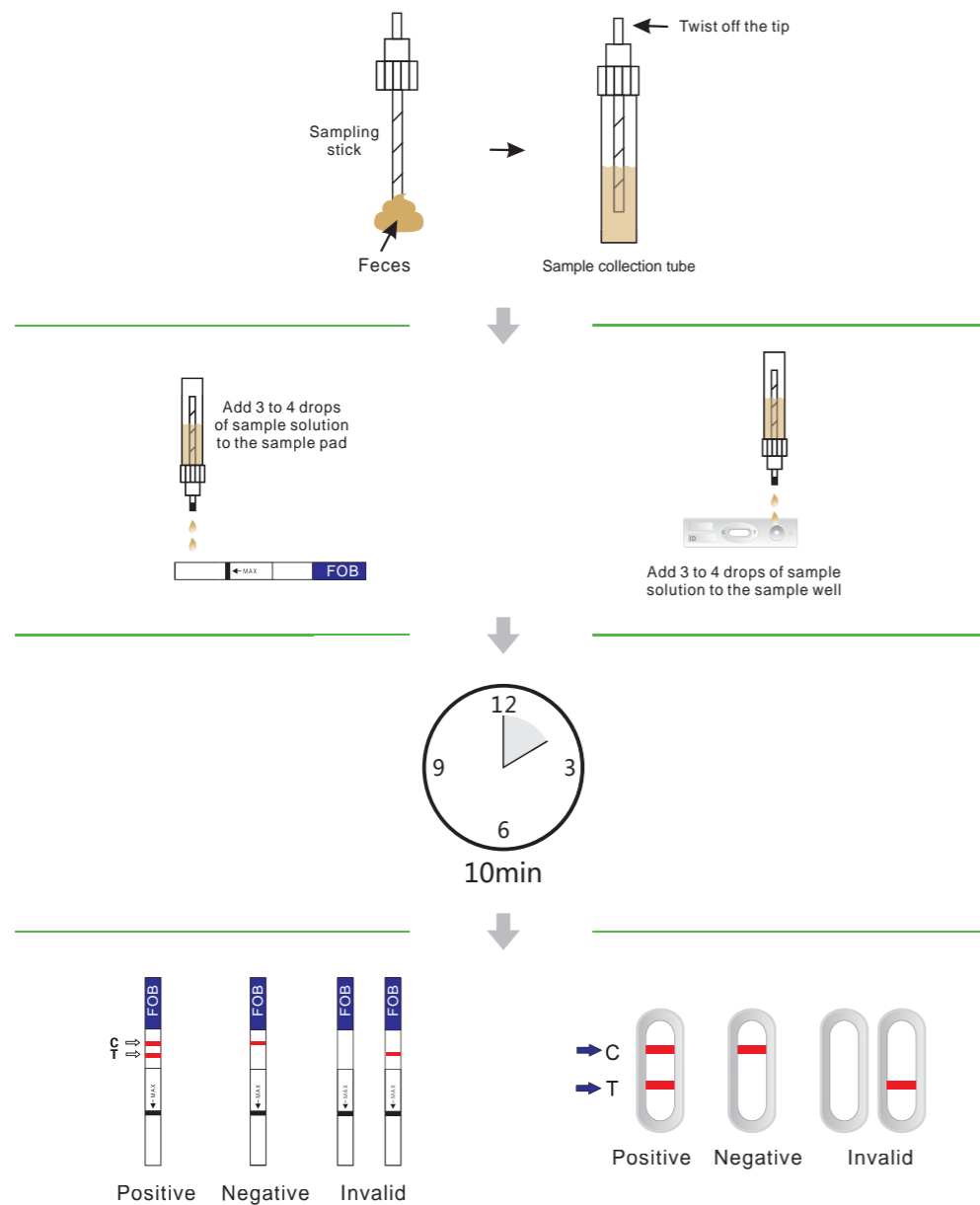
**FOB (Fecal Occult Blood)** is the trace amount of blood in fecal which can not be seen with eyes. It could be the early clinical symptom of the common malignant tumor, the gastric cancer or colonic cancer, or the indicator or enter on ulcer. An early detection of FOB is vital in life saving for it can be check up out in the early stage of the diseases



Parameters

Name	One Step Fecal Occult Blood (FOB) Test
Format	Strip/Cassette
Specimen	Feces
Sensitivity	50ng/ml; 200ng/ml
Test time	10-15 min
Storage temperature	4-30 °C
Shelf life	24 months
Packing specification	40 T/ Box; 100T/Box

Test Procedure & Interpretation



STD (Sexually Transmitted Disease) Tests

**Principle:** Colloidal gold immunochromatographic method

**Feature:** Easy to use, easy to read result, easy to carry

**Advantage:** Easy to use, easy to read result, easy to carry; High sensitivity and specificity, safe and reliable

**Application:** Single test and suitable for professional use

**Storage temperature:** 4 °C-30 °C

**Shelf life:** 24 months

Product	Format	Specimen	Sensitivity	Qualification
Syphilis (TP) Test	Strip/Cassette	Serum/Plasma/Whole Blood	2NCU/ml	CFDA CE
Syphilis - HIV Test	Cassette	Whole Blood	TP:2NCU/ml	
Syphilis – HbsAg Test	Cassette	Serum/Plasma/Whole Blood	TP:2NCU/ml HBsAg:2ng/ml	CFDA
Chlamydia Test	Cassette	Swab/Urine	5X10 <sup>4</sup> IFU/ml	CFDA CE
Gonorrhea Test	Strip/Cassette	Swab/Urine	1X10 <sup>6</sup> CFU/ml	CFDA CE

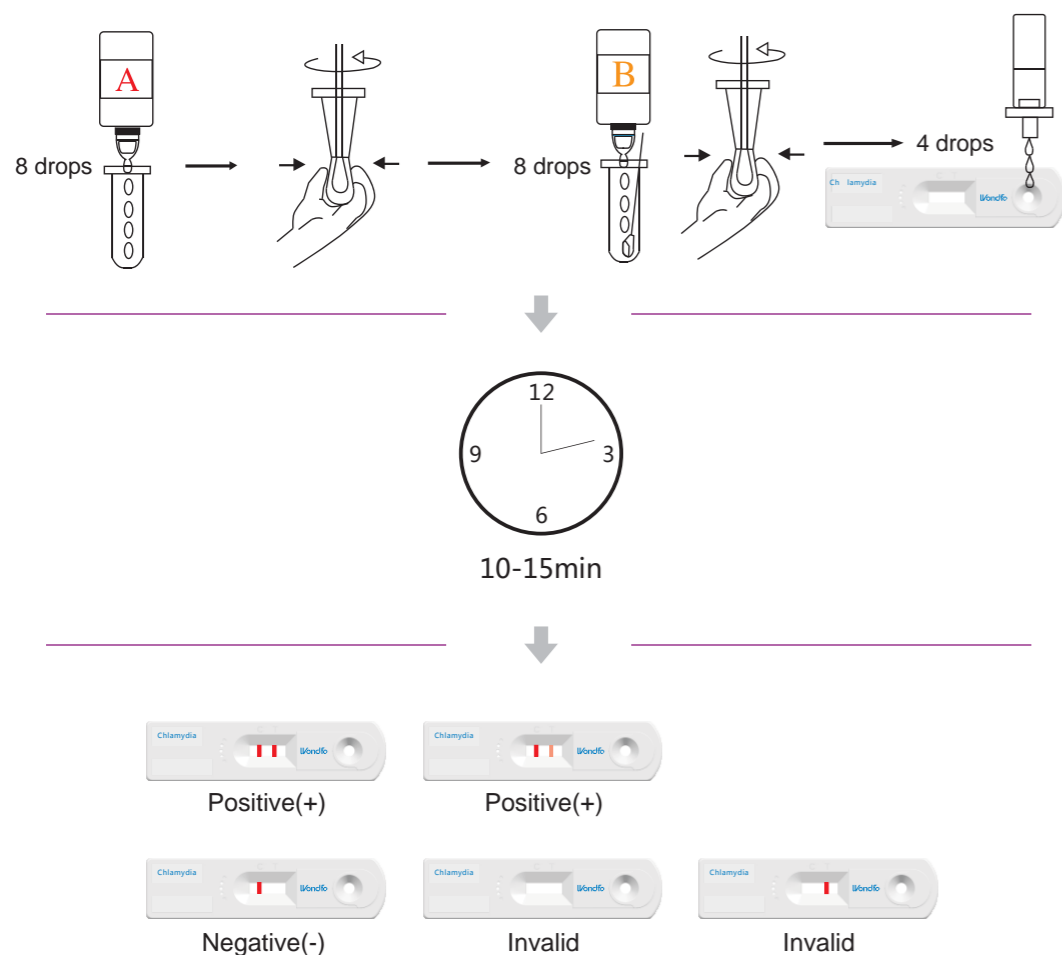




### Parameters

<b>Name</b>	Chlamydia rapid test
<b>Format</b>	Strip / Cassette
<b>Specimen</b>	Swab / Urine
<b>Detection limit</b>	5 × 10 <sup>4</sup> IFU/ml
<b>Test time</b>	10-15 min
<b>Storage temperature</b>	4-30 °C
<b>Shelf life</b>	24 months
<b>Packing specification</b>	40 T/ Box; 100T/Box

### Test Procedure & Interpretation



## Other New Rapid Tests (Alcohol, Cardiac)

**Principle:** Colloidal gold immunochromatographic method

**Feature:** Easy to use, easy to read result, easy to carry

**Advantage:** Easy to use, easy to read result, easy to carry;  
High sensitivity and specificity, safe and reliable

**Application:** Single test and suitable for professional use



### Alcohol Test

Product	Format	Specimen	Sensitivity	Packing Specifications	Qualification
Alcohol Saliva Test	Strip	Saliva	10mg/dl	50T/Box	CE
Alcohol Urine Test	Strip/Cassette	Urine	10mg/dl	50T/Box	CE

### Cardiac Test

Product	Format	Specimen	Sensitivity	Packing Specifications	Qualification
Troponin I Test	Cassette	Serum / Plasma / Whole Blood	1ng/ml	25T/Box	CFDA CE
H-FABP Test	Cassette	Serum / Plasma / Whole Blood	7ng/ml	25T/Box	CFDA

### Other Test NEW

Product	Format	Specimen	Sensitivity	Packing Specifications	Qualification
Strep A Test	Cassette	Serum / Plasma / Whole Blood	Custom	25T/Box	CFDA CE FDA
Urinalysis Reagents Strip (1-10 Parameter)	Strip	Urine	Custom	50T/Box	CE
Typhoid (IgG/IgM)	Cassette	Serum/ Plasma	Custom	25T/Box	

## Parameters

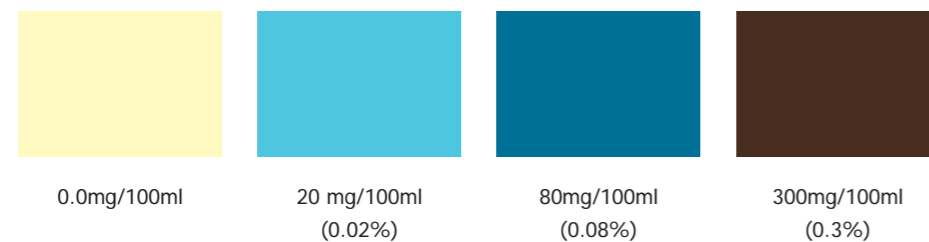
<b>Name</b>	One Step Alcohol Saliva / Urine Test
<b>Format</b>	Strip/Cassette
<b>Specimen</b>	Saliva / Urine
<b>Test time</b>	2-5 min
<b>storage temperature</b>	4-30 °C
<b>Shelf life</b>	24 months

## Test Procedure & Interpretation

### Alcohol Saliva Test Strip

1. Remove a strip from the foil pouch by tearing at the notch and place it on a level surface.
2. Saturate the reactive pad by dipping the reaction pad into the saliva specimen collected in a sputum cup, or by applying saliva directly to the reaction pad. After 10 seconds, shake off the excess saliva.
3. Immediately start timer and at 2 minutes, compare the reactive pad with the provided colored chart below.

### Blood Alcohol Concentration



**NOTE:** Results after 2 minutes may be not accurate.

# Wondfo

## OUR VISION

Provide professional product and service of rapid diagnosis and chronic disease management; pursue better and convenient user experience; promote high-standard life and health quality; fulfill shared dream of our staff, customers and partners.



**1** Overseas Lab

**2** Branches

**8** Overseas Offices

Cover more than **120** Countries and Areas

Supply **136,800** Health Institutions

Benefit **2,895,780,000** People