

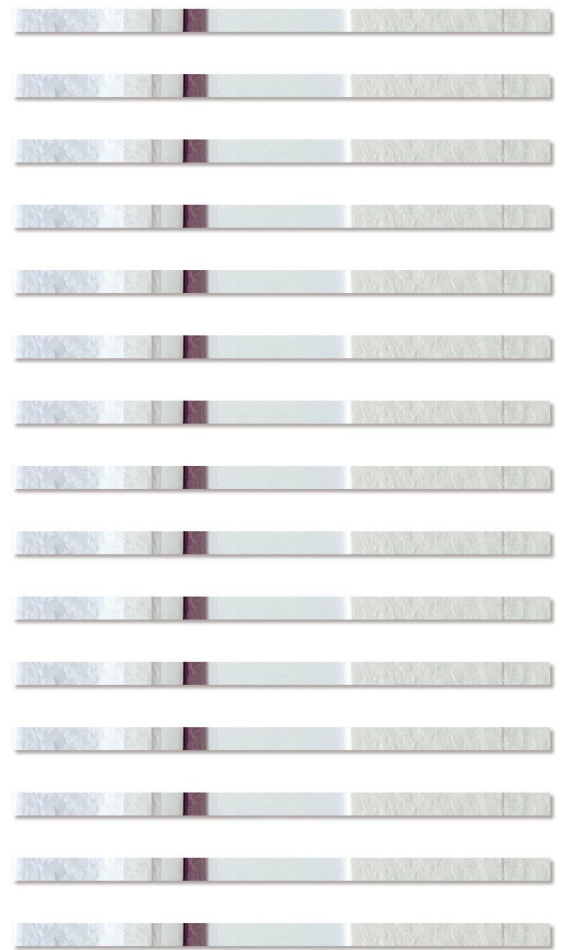
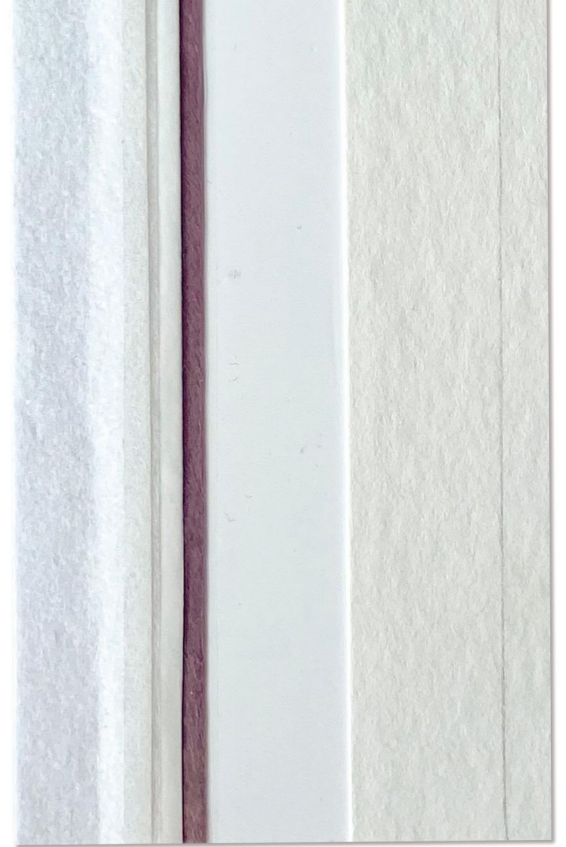


A Professional POCT Source Factory

Committed to Delivering Accurate, Convenient and Stable Products.

Lateral Flow Assay UNCUT SHEET

Product Catalogue
IVD MANUFACTURER SINCE 2003



NewScen Coast Bio-Pharmaceutical Co., Ltd.

Contact NewScen Team :

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Web : www.newscentestkit.com (Uncut Sheet)

Web : www.newscenbiotech.com (Rapid Test)

Email : export@newscen.com



Uncut Sheet



Rapid Test



NewScen Rapid Test Uncut Sheet Product Catalog

Professional manufacturer of lateral flow uncut sheets for rapid test kits globally.

INFECTIOUS DISEASE TEST KIT



HIV1+2(3Lines), HIV 1/2(2Lines), HCV, HBsAg, HBsAb, HEV, TP, TB, HAV, HPAb, HPAg, Adenovirus(Ag), NORO(Ag), ROTA(Ag), Typhoid(Ag), Typhoid(IgG/IgM), HSV(IgG), RSV(Ag), STREP A(Ag), Chlamydia(Ag)

DRUGS OF ABUSE (DOA) TEST KIT

5-IN-1 , MOR, MET, KET, THC, MDMA, AMP, BZD, COC, MTD

TUMOR MARKER TEST KIT

PSA, AFP, CEA, FOB, TF



TROPICAL (MOSQUITO TRANSMITTED) DISEASE TEST KIT

Malaria(Pf/Pan), Dengue(IgG/IgM), Dengue(NS1 Ag), Zika(IgG/IgM), Zika(NS1 Ag), Chikungunya(IgG/IgM)

INFLAMMATORY MARKER TEST KIT

CRP, PCT



RESPIRATORY DISEASE TEST KIT

COVID-19(Ag), COVID-19 Ag & Flu(A+B), Flu(A/B), Flu(A+B), COVID-19(IgG/IgM), COVID-19(NAb)

IRON DEFICIENCY TEST KIT

SF



HORMONE TEST KIT

HCG, LH, FSH, TSH

CARDIAC MARKER TEST KIT

D-Dimer, cTnl

RENAL INJURY TEST KIT

mAlb



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Company Profile



Manufacturer:

NewScen Coast Bio-Pharmaceutical Co., Ltd.

Management System:

ISO 9001 : 2015 , ISO 13485 : 2016

Detection Type Method:

Colloidal Gold

Categories:

STD, Hormone, Iron Deficiency, Tropical Disease, DOA, Tumor Marker, Respiratory Disease, Metabolism, Cardiac Marker, Inflammatory Marker, Renal Injury

Formats:

Cassette, Strip, Midstream, Uncut Sheet For Rapid Diagnostic Test Kits

Versions:

Professional, Self-Testing, OEM Options

Market:

100+ Countries and Regions Globally



R & D Center



Production



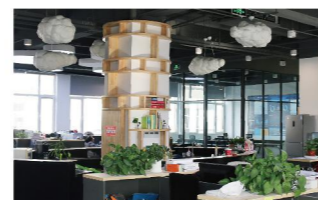
Workshop



QC Center



Remote Center



Office Center

NewScen Certificates

105 Independent Intellectual Property Rights

69 NMPA Medical Device Certificates
 Class III * 11 Class II * 54 Class I * 4

42 CE Certificates
 CLASS D * 1 LIST A * 1 Self-Testing * 5 Others * 35

Certifications by International Authorities



Authorized Invention Patent Certificates

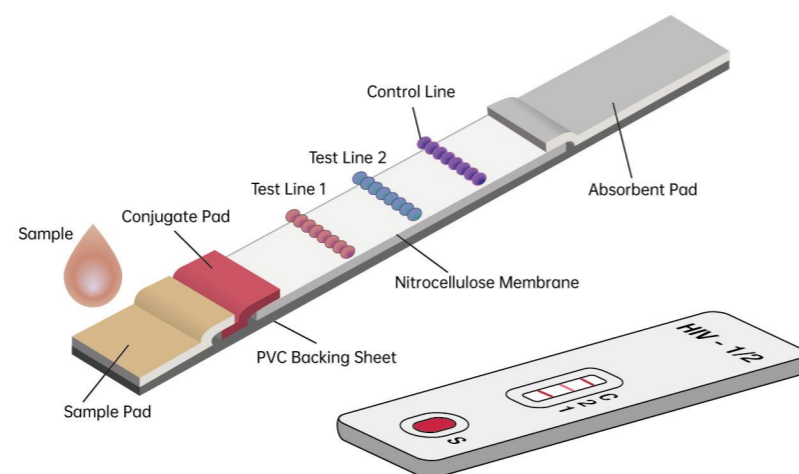


Start from Uncut Sheet

The uncut sheet is consisted of **key components** as below :

- Sample Pad
- Colloidal Gold Conjugate Pad
- NC Membrane
- Absorbent Pad
- PVC Backing Sheet

Upon your receiving of the pre-assembled uncut sheet, it is strongly recommended a 3rd QC inspection procedure be properly arranged **prior to** further operation or processing.



Advantages and Competitiveness



Client-Friendly · User-Friendly

Sensitivity · Specificity · Stability



Customizability · Flexibility

Cost-Effective (OEM · Private Labeling)



Comprehensive · Competitive

Quantitative · Semi-Quantitative · Qualitative



Whole Process Management System

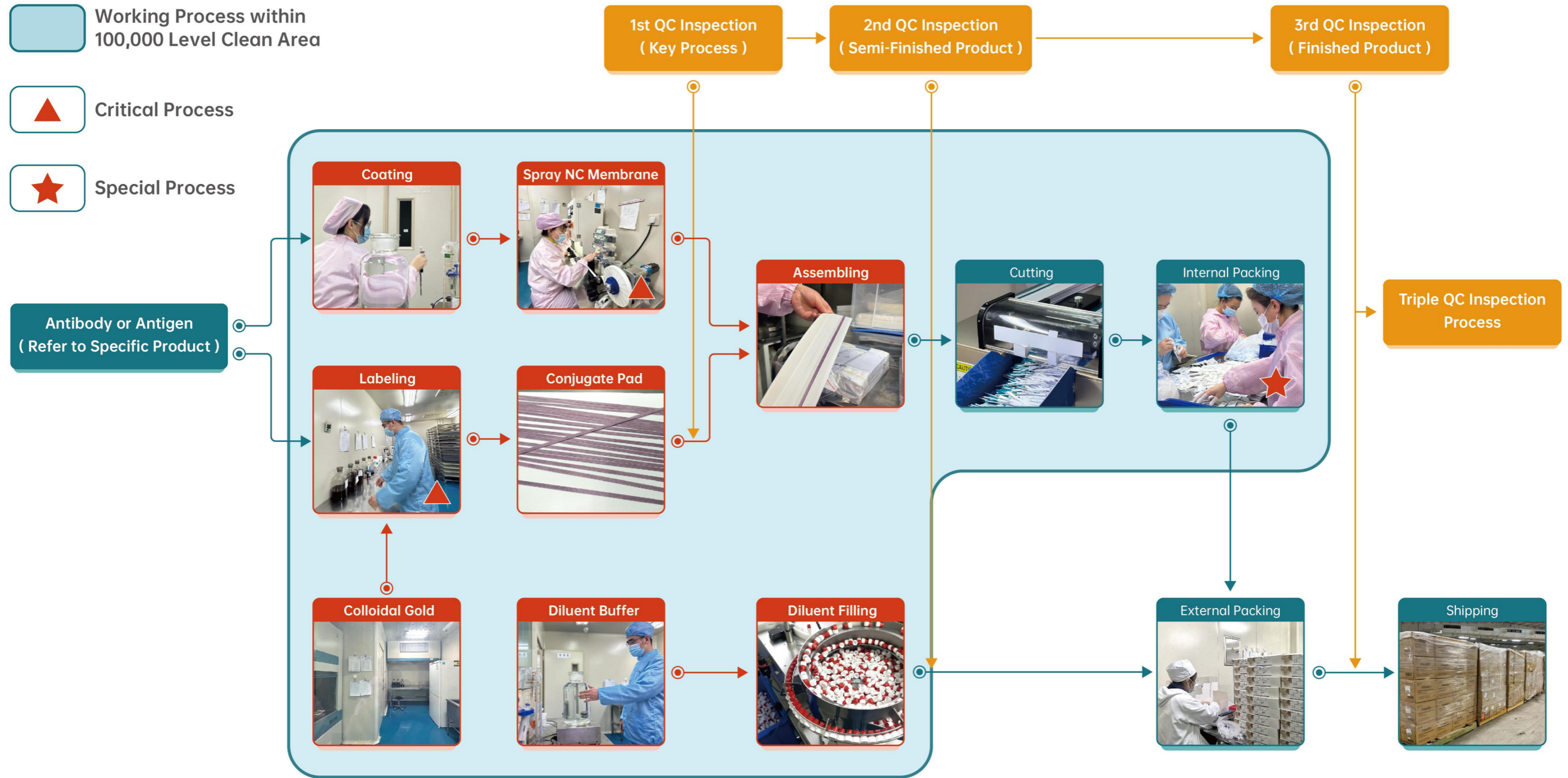
R & D · QC · BD (Global)



Professional Service Team

Manufacture · Delivery

Production Process Flowchart of POCT Finished Products



Remark : Uncut sheet (Semi - Finished Product) is available for shipping from NewScen after 2nd QC Inspection for further operation and processing from client.

Category of Uncut Sheet

INFECTIOUS DISEASE TEST KIT

UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION	
★ HIV 1+2	3 Lines : HIV (1+2) Antibody Rapid Test Kit	WHOLE BLOOD / SERUM / PLASMA	Cassette : 300 * 70 / 60 / 65 mm Strip / Dipstick : 300 * 80 / 70 mm	
HIV 1/2	2 Lines : HIV (1/2) Antibody Rapid Test Kit			
★ HCV	HCV Antibody Rapid Test Kit			
★ HBsAg	Hepatitis B Surface Antigen (HBsAg) Diagnostic Test Kit			
HBsAb	Hepatitis B Surface Antibody (HBsAb) Diagnostic Test Kit			
HEV	Hepatitis E Antibody (HEV IgM) Diagnostic Test Kit			
★ T P	Treponema Pallidum (TP) Antibody Rapid Test Kit			
T B	M. Tuberculosis (TB IgG) Antibody Rapid Test Kit			SERUM / PLASMA (WHOLE BLOOD NOT APPLIED)
HAV	Hepatitis A Antibody (HAV IgM) Diagnostic Test Kit			
HPAb	H. Pylori (HP) Antibody Rapid Test Kit			WHOLE BLOOD / SERUM / PLASMA
★ HPAG	H. Pylori (HP) Antigen Rapid Test Kit	STOOL	Cassette : 300 * 70 / 60 / 65 mm	
ADENOVIRUS (Ag)	Adenovirus Antigen Rapid Test Kit			
NORO (Ag)	Norovirus (NORO) Antigen Rapid Test Kit			
ROTA (Ag)	Rotavirus (ROTA) Antigen Rapid Test Kit			
TYPHOID (Ag)	Typhoid Antigen Rapid Test Kit			
TYPHOID (IgG/IgM)	Typhoid IgG/IgM Antibody Rapid Test Kit			WHOLE BLOOD / SERUM
HSV (IgG)	Herpes Simplex Virus (HSV Type II) IgG Rapid Test Kit	SERUM / PLASMA (WHOLE BLOOD NOT APPLIED)		
RSV (Ag)	Respiratory Syncytial Virus (RSV) Antigen Rapid Test Kit	NASOPHARYNGEAL SWAB		
STREP A (Ag)	Group A Streptococcal Antigen (STREP A) Antigen Rapid Test Kit	SECRETION		
CHLAMYDIA (Ag)	Chlamydia Antigen Rapid Test Kit			

★ Star Products (Hot Sale)



HIV 1+2(3 Lines)

Performance Advantage

IVDR Clinical Evaluation Result

Sen : **100%** ✓
Spe : **99.82%** ✓

WHO Performance Evaluation Result

Sen : **100%** ✓
Spe : **100%** ✓

Certification Threshold

TÜV SÜD high-end certification, the highest quality endorsement

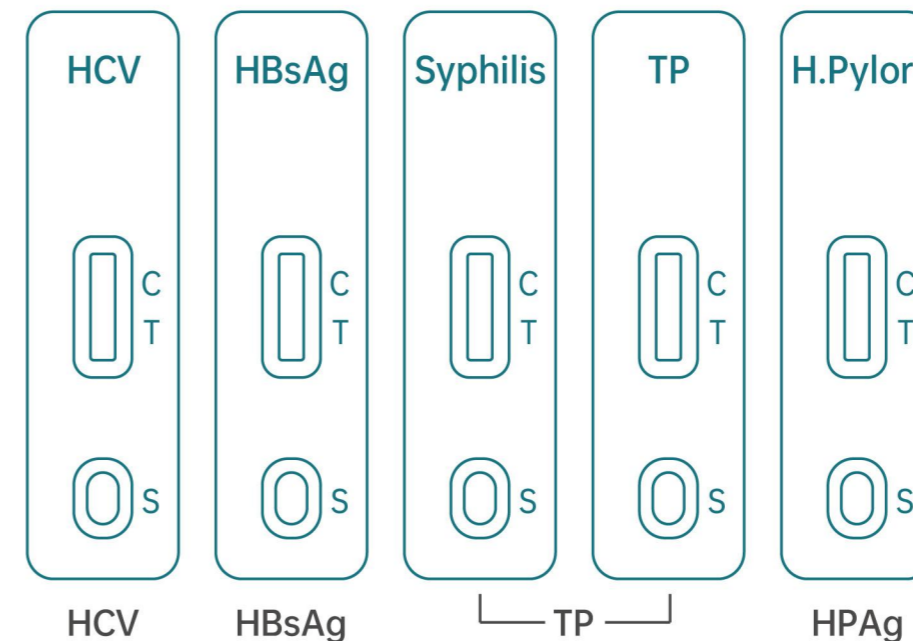


Technical Superiority

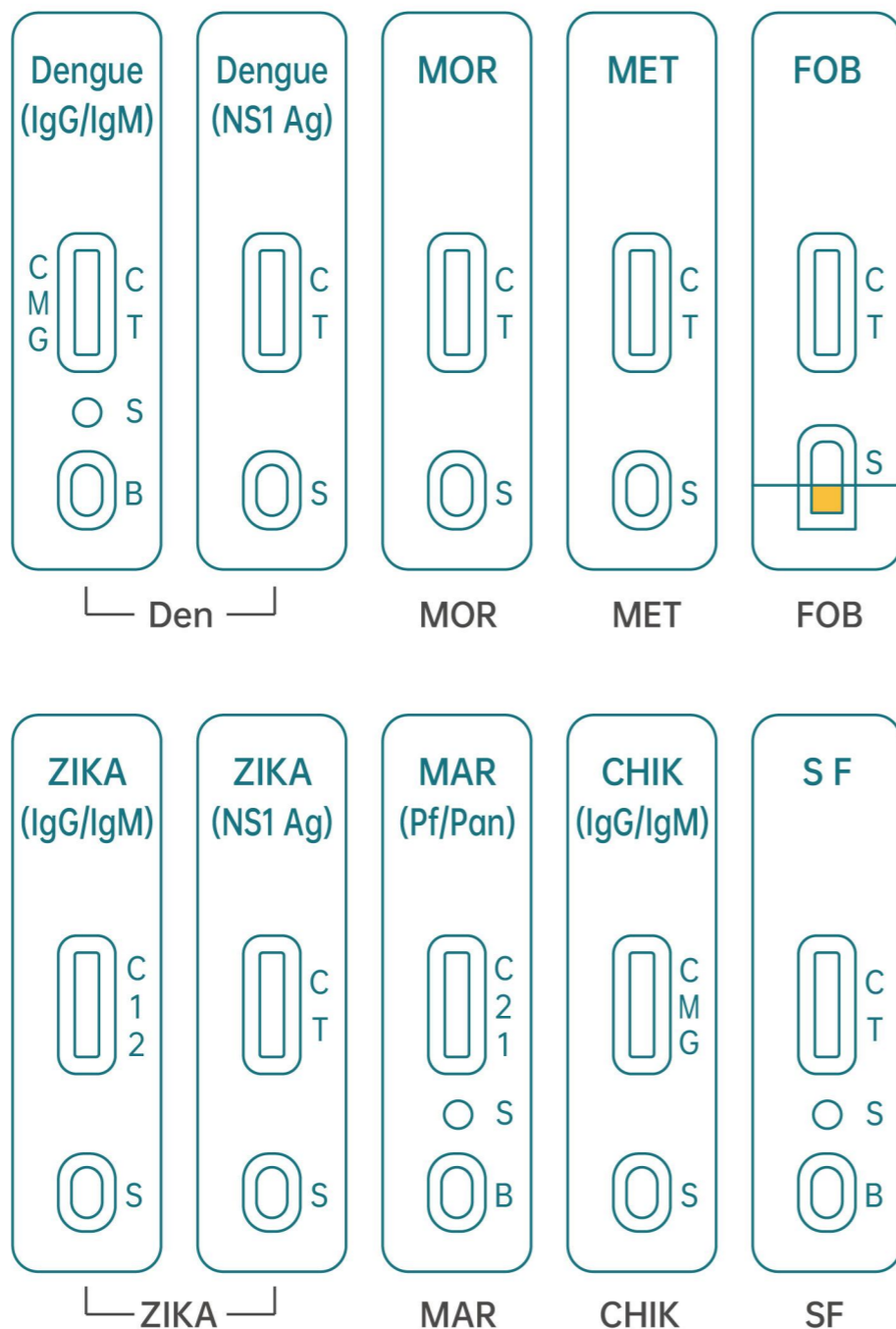
tri-lines, distinguish infection types

Window Period

7 days, no competitor early than 7 days



★ Star Products (Hot Sale)



TROPICAL (MOSQUITO TRANSMITTED) DISEASE TEST KIT

UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION
MAR (Pf/Pan)	Malaria Pf/Pan Antigen Rapid Test Kit	WHOLE BLOOD (SERUM / PLASMA NOT APPLIED)	Cassette : 300 * 70 / 60 / 65 mm
★ DENGUE (IgG/IgM)	Dengue IgG/IgM Rapid Test Kit	WHOLE BLOOD / SERUM / PLASMA	
★ DENGUE (NS1 Ag)	Dengue NS1 Antigen Rapid Test Kit		
ZIKA (IgG/IgM)	Zika Virus IgG/IgM Rapid Test Kit		
ZIKA (NS1 Ag)	Zika NS1 Antigen Rapid Test Kit		
CHIK (IgG/IgM)	Chikungunya IgG/IgM Rapid Test Kit		

DRUGS OF ABUSE (DOA) TEST KIT

UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION
5-IN-1	One Step (MOR / MET / KET / THC / MDMA) Multiple Drug Test Kit	URINE / SALIVA	URINE Cassette: 300 * 70 / 60 / 65 mm Strip / Dipstick: 300 * 80 / 70 mm SALIVA Cassette: 300 * 60 mm
★ MOR	Morphine (MOR) Gold Rapid Screen Test Kit		
★ MET	Methamphetamine (MET) Gold Rapid Screen Test Kit		
KET	Ketamine (KET) Rapid Test Kit		
THC	Tetrahydrocannabinol (THC) Rapid Test Kit		
MDMA	Methylenedioxyamphetamin-Phetamine (MDMA) Rapid Test Kit		
AMP	Amphetamine (AMP) Rapid Test Kit		
BZD	Benzodiazepine (BZD) Rapid Test Kit		
COC	Cocaine (COC) Rapid Test Kit		
MTD	Methadone (MTD) Rapid Test Kit		
BAR	Secobarbital (BAR) Rapid Test Kit	SALIVA	SALIVA Cassette: 300 * 60 mm
BUP	Buprenorphine (BUP) Rapid Test Kit		
BZO	Oxazepam (BZO) Rapid Test Kit		
FTY	Fentanyl (FTY) Rapid Test Kit		
OXY	Oxycodone (OXY) Rapid Test Kit		
PCP	Phencyclidine (PCP) Rapid Test Kit		
TML/TRA	Tramadol (TML/TRA) Rapid Test Kit		

TUMOR MARKER TEST KIT

UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION
PSA	Prostate Specific Antigen (PSA) Diagnostic Test Kit	WHOLE BLOOD / SERUM / PLASMA	Cassette : 300 * 70 / 60 / 65 mm
AFP	Alpha Fetoprotein (AFP) Quantitative Rapid Test Kit		
CEA	Carcino-Embryonic Antigen Quantitative Rapid Test Kit		
★ FOB	One-Step Fecal Occult Blood (FOB) Diagnostic Test Kit	STOOL	(FOB Strip : 300 * 80 / 70 mm)
TF	Transferrin (TF) Rapid Test Kit		

RESPIRATORY DISEASE (COVID-19 / INFLUENZA) TEST KIT

UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION
COVID-19 (Ag)	COVID-19 Antigen Rapid Test Cassette	THROAT / NASAL SWAB	Cassette : 300 * 70 / 60 / 65 mm
COVID-19 Ag & Flu (A+B)	COVID-19 Ag. & Influenza Combo Rapid Test Kit		
Flu (A/B)	Influenza (A/B) Rapid Test Kit		
Flu (A+B)	Influenza (A+B) Combo Rapid Test Kit		
COVID-19 (IgG/IgM)	3 Lines : COVID-19 IgG/IgM Rapid Test Cassette	WHOLE BLOOD / SERUM / PLASMA	
COVID-19 (NAb)	COVID-19 Neutralizing Antibody Rapid Test Cassette		

HORMONE TEST KIT

UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION
HCG	Human Chorionic Gonadotropin (hCG) Tests (Pregnancy tests)	URINE	Midstream : 300 * 70 / 60 / 65 mm
LH	Luteinizing Hormone (LH) Tests (Ovulation tests)		
FSH	Follicle Stimulating Hormone (FSH) Tests (Menopause Tests)		
TSH	Human Thyroid Stimulating Hormone (TSH) Quantitative Rapid Test Kit	WHOLE BLOOD / SERUM / PLASMA	Cassette : 300 * 70 / 60 / 65 mm

IRON DEFICIENCY TEST KIT

UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION
★ SF	Serum Ferritin (SF) Rapid Test Kit	WHOLE BLOOD / SERUM / PLASMA	Cassette : 300 * 70 / 60 / 65 mm

CARDIAC MARKER TEST KIT

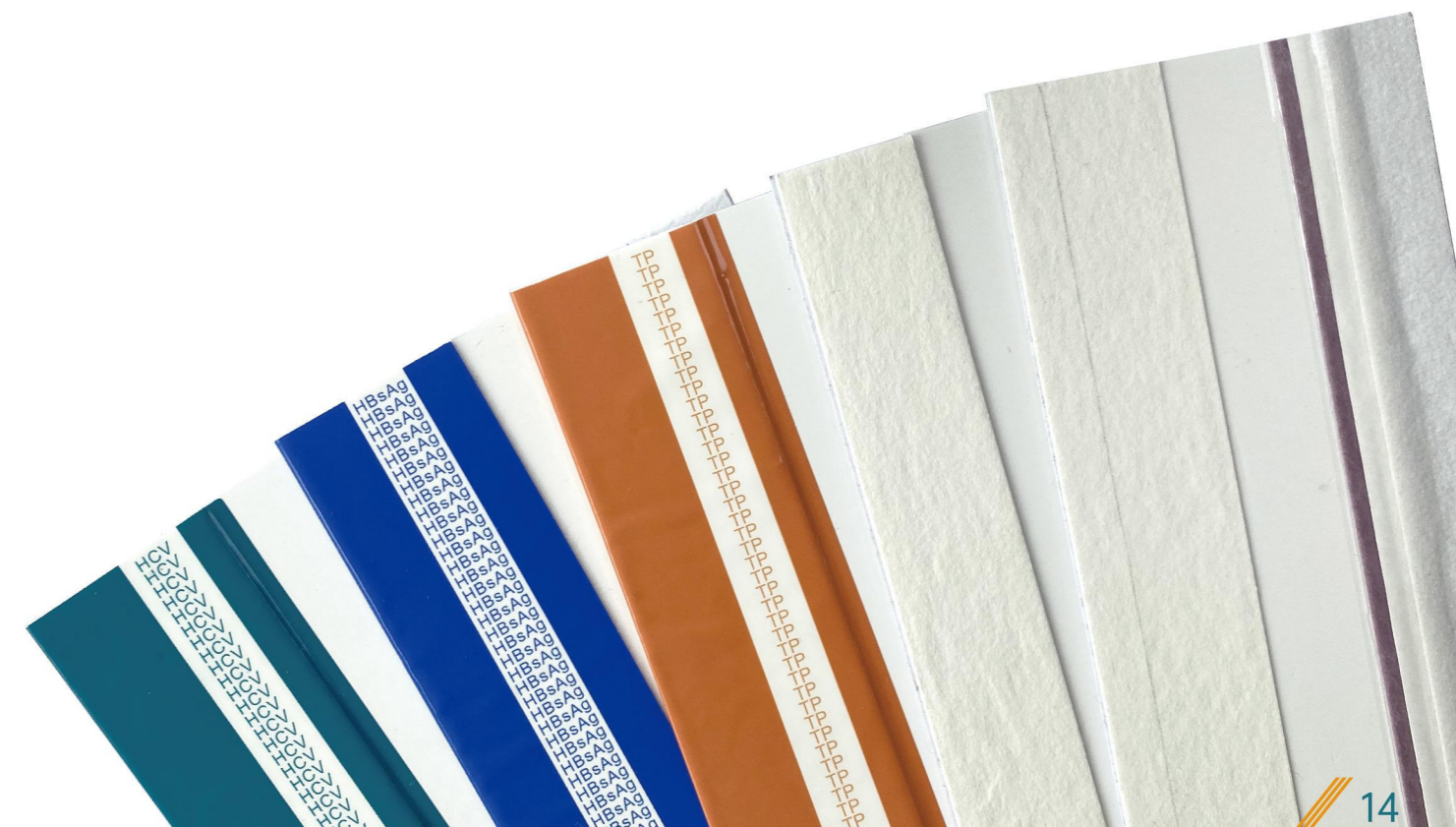
UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION
D-Dimer	D-Dimer Quantitative Rapid Test Kit	WHOLE BLOOD / PLASMA	Cassette : 300 * 70 / 60 / 65 mm
cTnl	Cardiac Troponin-I (cTnl) Quantitative Rapid Test Kit	WHOLE BLOOD / SERUM / PLASMA	

INFLAMMATORY MARKER TEST KIT

UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION
CRP	C-Reactive Protein (CRP) Quantitative Rapid Test Kit	WHOLE BLOOD / SERUM / PLASMA	Cassette : 300 * 70 / 60 / 65 mm
PCT	Human Procalcitonin (PCT) Quantitative Rapid Test Kit		

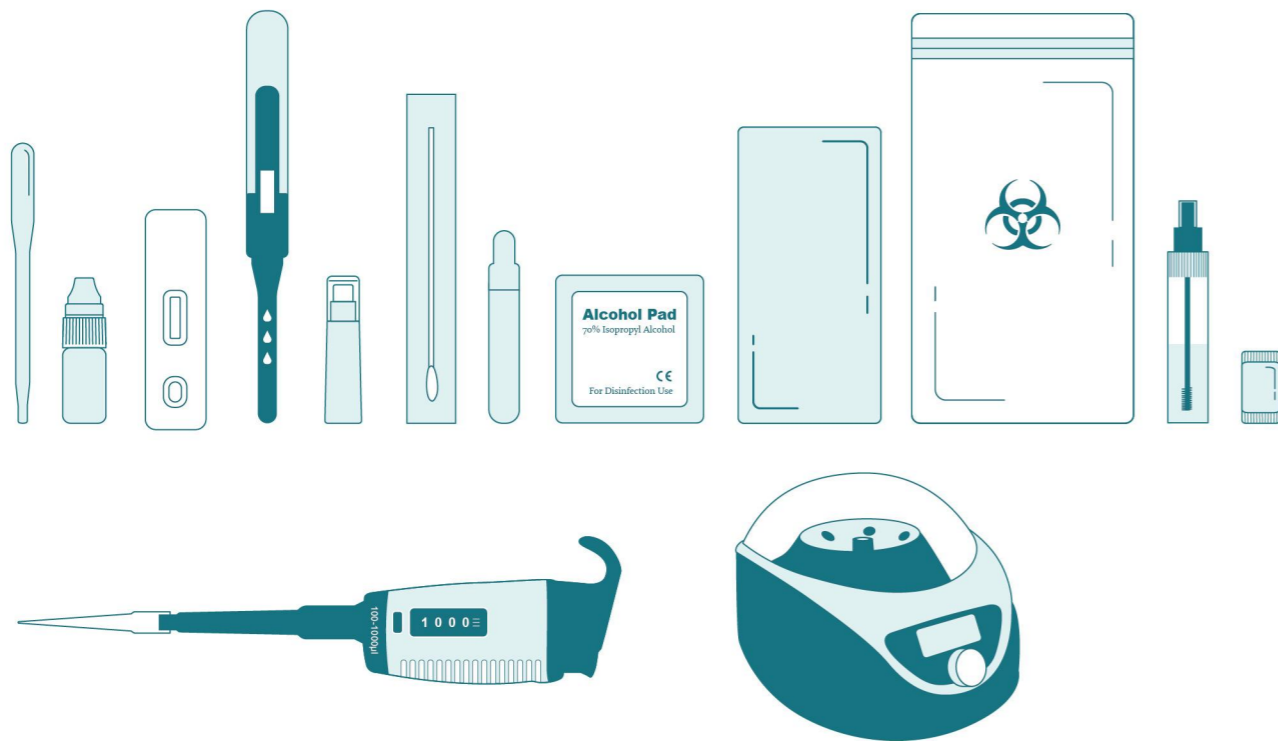
RENAL INJURY TEST KIT

UNCUT SHEET	PRODUCT DESCRIPTION	SPECIMEN	SPECIFICATION
mAlb	Urine Microalbumin (mAlb) Quantitative Rapid Test Kit	URINE	Cassette : 300 * 70 / 60 / 65 mm



Accessory

- Disposable Plastic Dropper (In Bag)
- Sample Diluent Buffer (In Bottle)
- Cassette / Midstream (Empty Housing)
- Sterile Safety Lancet (CE Mark)
- Throat / Nasal Swab (CE Mark)
- Sample Collection Tube (Secretion)
- Alcohol Pad (CE Mark)
- Aluminum Foil Pouch (Customized)
- Biohazardous Waste Bag (Customized)
- Sample Collection Tube (Stool)
- Desiccant (CE Mark)
- Pipette
- Centrifuge



★ Remark : Accessories are optional and flexible for OEM requirements.
Equipments are optional for clients and / or end-users.

FAQs

Basic Info (NewScen · Manufacturer)

About us :

- MOQ : 200 Uncut Sheets
- Method : Lateral Flow Assay (Immunochromatography Assay)
- Capacity : $\geq 10,000$ Uncut Sheets (Regular Daily Output / Production Line)
- Category : 10 Categories (64 Kinds of Uncut Sheets in 10 Categories)

Trial Order (OEM · Private Labeling)

About you :

- Standard : QC Inspection Standard (Preferably in a Check Form, or the descriptions in details including requirements for the Performance / Appearance, etc.)
- Design : Design and Dimensions Drawing with precise sheet component position in details
- Format : Cassette / Midstream / Strip (Preferably in Picture with Dimension)

Sample (Regular Format · Evaluation)

For uncut sheet sample from NewScen, please contact us by website / e-mail / social media :

- Website : www.newscentestkit.com
- E-mail : export@newscen.com
- Social Media : Facebook / Youtube / LinkedIn / Instagram / Twitter





 **EU-IVDR**



Custom Samples Tailored Solutions

Beyond Typical OEM Cooperation

Name Card

