



Lab Diagnostic Systems (SMC) Pvt Ltd

# CATALOGUE

## 2022 / 23

A PRODUCT TO OWN





## LDS PRODUCT PORTFOLIO

LDS, through its products, has revolutionized the local markets and the clinical diagnostics industry. The organization looks forward to future products aligned with its vision of innovation, dynamic diagnostic solutions, accessibility, convenience, and affordability.



### Rapid Test Line

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- Infectious Disease
- Blood Borne Disease
- Vector Borne Disease
- Hepatitis
- Hormone
- Gastrointestinal Disease



### Blood Glucose Monitoring System

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### Molecular Diagnostic Product Line

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- viGen Viral Nucleic Acid Auto Extraction Kit
- viGen-Q Typhoid PCR Kit
- viGen-Q Fever Panel Multiplex PCR Kit
- Viral Transport Medium



### POCT Coagulation Analyzer

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### POCT Chemistry Analyser

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# LDS

## INTRODUCTION

Lab Diagnostic Systems was conceived as the first-of-its-kind In Vitro Diagnostics (IVD) manufacturer in Pakistan. Before LDS, no local organizations manufactured products offering affordable and easily accessible diagnostic solutions. During the global crisis brought about by the COVID-19 pandemic, the lack of a local market for diagnostic solutions became immensely pronounced. It became clear that Pakistan needed its own products offering affordable and accessible solutions. LDS became the first to produce Pakistan's first locally manufactured, DRAP (Drug Regulatory Authority of Pakistan) approved VTM (Viral Transport Medium).

Being the pioneer, LDS set market precedents and helped regulate the local market. It facilitated local businesses and strengthened communities nationwide. Today, LDS proudly stakes claims to the first ever DRAP (Drug Regulatory Authority of Pakistan) approved warehouse facility in Pakistan and the first ever locally produced, DRAP approved IVD (In Vitro Diagnosis) solutions. The story of LDS is a story of turning

challenges into opportunities and focusing on improving access to healthcare-related services in Pakistan.

1700 cubic meters of the 18,000 square foot facility stores various products at optimal temperature. Temperature-sensitive goods can be stored in the cutting-edge warehouse. Strict internal standards do not take chances with subpar quality, from the raw materials to the finished product. The protocols abide with ISO 13485 standards in addition to the CDC (Centers for Disease Control and Prevention) and WHO (World Health Organization) recommendations.

LDS recognizes its corporate social responsibility. We advocate for effective solutions to local and global social issues.



# RAPID TEST LINE

The R-test product line offers extensive range of rapid tests for clinical diagnosis. The test are manufactured in Pakistan’s first ever DRAP approved facility. The products have been produced in accordance with the ISO 3845, GMP standards. The clinical performance of all R-test featured products are evaluated against gold standards. International quality standards make in-house quality checks rigorous and meticulous. Local production of the R-test product line ensures its easy availability, affordability, and accessibility. The R-test line is a way forward to sustainability of the IVD solutions market in Pakistan.

## Ordering Information

Product	Pack Size	CAT No.
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### INFECTIOUS DISEASE

R-test SARS-CoV2 Ag	50 Test	R-10050
R-test SARS-CoV-2 Ag & Flu A/B Combo Rapid Test	50 Test	R-26050
R-Test Cholera Antigen Rapid Test	50 Test	R-25050
R-Test Typhoid Ag Rapid Test	50 Test	R-17050

### BLOOD BORNE DISEASES

R-Test HIV 1/2 Ab Rapid Test	50 Test	R-14050
R-test Syphilis Ab Rapid Test	50 Test	R-19050

### VECTOR BORNE DISEASES

R-Test Malaria Pf/Pv Ag Rapid Test	50 Test	R-20050
R-Test Dengue NS1Ag Rapid Test	50 Test	R-22050
R-Test Dengue NS1 Ag Self-Test	1 Test	R-23001
R-Test Dengue NS1 Ag & Malaria Pf/Pv Ag Combo Rapid Test	50 Test	R-24050

### HEPATITIS

R-Test HCV Ab Rapid Test	50 Test	R-13050
R-Test HBsAg Rapid Test	50 Test	R-12050

### HORMONE

R-Test hCG Pregnancy Rapid Test	50 Test	R-11050S
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### GASTROINTESTINAL DISEASE

R-Test H. Pylori Ag Rapid Test	50 Test	R-16050
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# RAPID TEST LINE

## INFECTIOUS DISEASE

### SARS-CoV-2 Rapid Antigen

It is a lateral flow assay intended for the qualitative detection of nucleocapsid protein antigen from SARSCoV-2 in direct anterior nasal swab specimens.

#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Nasal Swab
Testing Time	15mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	99.1%
Relative Sensitivity	95.7%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test Covid-19 Rapid Antigen Self-Test	1 Test	R-10001
R-test SARS-CoV2 Ag	50 Test	R-10050



### SARS-CoV-2 Ag & Flu A/B Combo

The R-test SARS-CoV-2 Ag & Flu A/B Combo Rapid Test is a rapid immunoassay to be used as an aid for the differential diagnosis of 2019-nCoV and influenza type A and type B.

#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Nasal Swab
Testing Time	15mins
Storage Condition	2-30 °C

#### Test Performance

Product	Relative Specificity	Relative Sensitivity
Ag	100%	87.27%
Influenza Type A	97.6%	100%
Influenza Type B	97.3%	100%

#### Ordering Information

Product	Pack Size	CAT No.
R-test SARS-CoV-2 Ag & Flu A/B Combo Rapid Test	50 Test	R-26050



# RAPID TEST LINE

## INFECTIOUS DISEASE

### Cholera Antigen Rapid Test

The R-test Cholera Ag Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection and differentiation of *Vibrio Cholerae* (*V. Cholerae*) O139 antigen and O1 antigen.

#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Human Faeces
Testing Time	10mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	98.8%
Relative Sensitivity	96.7%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test Cholera Antigen Rapid Test	50 Test	R-25050



### Typhoid Antigen Rapid Test

The R-test Typhoid Ag Rapid Test is a lateral flow chromatographic immunoassay by providing a quick direct visual test for the *Salmonella typhi*.

#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Human Urine or Serum
Testing Time	05 mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	98.8%
Relative Sensitivity	96.7%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test Typhoid Ag Rapid Test	50 Test	R-17050



# RAPID TEST LINE

## BLOOD BORNE DISEASES

### HIV-1 & HIV-2 Rapid Antigen

The R-test HIV 1/2 Ab Rapid Test is a lateral flow immunoassay for the simultaneous detection and differentiation of HIV-1 and HIV-2 antibodies (IgG, IgM, IgA).



#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Serum, plasma or whole blood
Testing Time	15mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	100%
Relative Sensitivity	100%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test HIV 1/2 Ab Rapid Test	50 Test	R-14050

### Syphilis Antibody

The R-test Syphilis Ab Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of antibodies including IgG, IgM, and IgA to Syphilis. It is intended to be used as a screening test and as an aid in the diagnosis of infection with Syphilis.



#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Serum, plasma or whole blood
Testing Time	15mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	98.8%
Relative Sensitivity	100%

#### Ordering Information

Product	Pack Size	CAT No.
R-test Syphilis Ab Rapid Test	50 Test	R-19050

# RAPID TEST LINE

## VECTOR BORNE DISEASES

### Malaria Pf/Pv Antigen Rapid Test

The R-test Malaria Pf/Pv Ag Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of Plasmodium falciparum (Pf) and vivax (Pv) antigen.



#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Serum, plasma or whole blood
Testing Time	30mins
Storage Condition	2-30 °C

#### Test Performance

Product	Relative Specificity	Relative Sensitivity
Malaria Pf	100%	94.4%
Malaria Pv	100%	98%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test Malaria Pf/Pv Ag Rapid Test	50 Test	R-20050

### Dengue NS1 Antigen Test

The R-test Dengue NS1 Ag Rapid Test is a lateral flow immunoassay for the detection of dengue NS1 antigen (DEN1, 2, 3, 4).



#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Serum, plasma or whole blood
Testing Time	25mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	99%
Relative Sensitivity	100%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test Dengue NS1 Ag Rapid Test	50 Test	R-22050
R-Test Dengue NS1 Ag Self-Test	1 Test	R-23001



# RAPID TEST LINE

## VECTOR BORNE DISEASES

### Dengue NS1 Ag & Malaria Pf/Pv Ag Combo Rapid Test

The R-test Dengue NS1 Ag & Malaria Pv/Pf Ag Combo Rapid Test is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of dengue NS1 antigen (DEN1, 2, 3, 4), Plasmodium falciparum (Pf) and vivax (Pv) antigen.



Dengue & Malaria Combo

#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Serum, plasma or whole blood
Testing Time	25mins
Storage Condition	2-30 °C

#### Test Performance

Product	Relative Specificity	Relative Sensitivity
Dengue NS1	99%	100%
Malaria Pf	100%	94.4%
Malaria Pv	100%	98%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test Dengue NS1 Ag & Malaria Pf/Pv Ag Combo Rapid Test	50 Test	R-24050

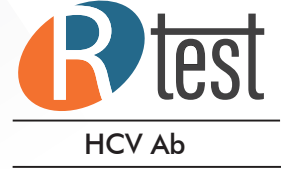


# RAPID TEST LINE

## HEPATITIS

### HCV Ab Rapid Test

The R-test HCV Ab Rapid Test is a double antigen lateral flow chromatographic immunoassay for the qualitative detection of anti-hepatitis C virus antibodies (IgG, IgM, IgA).



#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Serum, plasma
Testing Time	15mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	99.6%
Relative Sensitivity	98.7%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test HCV Ab Rapid Test	50 Test	R-13050

### HBsAg Rapid Test

The R-test HbsAg Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of hepatitis B surface antigen (HBsAg).



#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Serum or plasma, whole blood
Testing Time	15mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	100%
Relative Sensitivity	100%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test HBsAg Rapid Test	50 Test	R-12050

# RAPID TEST LINE

## HORMONE

### hCG Pregnancy Rapid Test

The R-test hCG Rapid Test is a lateral flow chromatographic immunoassay for the early detection of pregnancy, by providing a quick direct visual test for the placental hormone, hCG, at the cut-off level of 10 mIU /mL of human urine or serum.



#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Urine, serum
Testing Time	05 mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	100%
Relative Sensitivity	100%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test hCG Pregnancy Rapid Test	50 Test	R-11050S

## GASTROINTESTINAL DISEASE

### H. Pylori Ag Rapid Test

R-test H. pylori Ag Rapid Test is used for the qualitative detection of Helicobacter pylori antigens in human stool samples in vitro, and is suitable for the auxiliary diagnosis of Helicobacter pylori infection.



#### Product Specifications

Test Method	Colloidal Gold Immunochromatography
Test Type	IVD
Specimen Type	Human stool
Testing Time	15mins
Storage Condition	2-30 °C

#### Test Performance

Relative Specificity	100%
Relative Sensitivity	100%

#### Ordering Information

Product	Pack Size	CAT No.
R-Test H. Pylori Ag Rapid Test	50 Test	R-16050

# MOLECULAR DIAGNOSTIC PRODUCT LINE

## viGen

The LDS facility manufactures local products for molecular diagnostics. The range includes Viral Transport Medium, extraction and amplification kits, and extraction panels customized to our local needs. All test are DRAP approved and in compliance with international quality standards. Clinical performance evaluation is done against the industry's gold standards, yielding promising results. Being the future of diagnostics, a local market for molecular diagnostics is a giant leap towards sustainability of health-care services and their accessibility in Pakistan.

### viGen-Q Fever Panel Multiplex PCR Kit

A multiplexed Real-Time PCR kit which is intended for qualitative rapid detection & differentiation of tropical fever causing pathogens from human clinical samples. It includes three tubes assay targeting eight major pathogens including bacteria, viruses & parasites.

#### Product Specifications

Test principle	oligonucleotide hydrolysis principle which allows higher specificity and sensitivity. The different targets are detected with the help of three different dyes (FAM/Green, HEX/VIC/Yellow & Texas Red/ROX/Orange).
Sample Type	Whole blood or Plasma / serum samples of human origin
Target pathogens	Salmonella spp., Plasmodium spp., Dengu virus
Testing time	07 hours
Storage condition	2-30 C
Target Regions	Conserved regions of the genome of each pathogen
Reaction Volume	15µl in each tube
Reaction Time	100-120 Minutes PCR run
LOD Data	103 copies/ml
Compatible Instruments	Applied Biosystems™ 7500 series, Applied Biosystems™ StepOne series, Applied Biosystems™ QuantStudio® series, RotorGene Q, Bio-Rad Roche - LightCycler® 480 – II

#### Test Performance

Relative Specificity	98.77%
Relative Sensitivity	97.89%

#### Ordering Information

Product	Pack Size	CAT No.
viGen-Q Fever Panel Multiplex PCR Kit	48 Reactions	VGQ-11048

## viGEN

#### Ordering Information

Product	Pack Size	CAT No.
viGen-Q Typhoid PCR Kit	48 Reactions	VGQ-10048
COVID-19 sample collection and transport kit	48 Reactions	CTK-3100
viGen Viral Nucleic Acid Auto Extraction Kit	64 Tests	VG-10064

# piXi-300

## POCT COAGULATION ANALYZER

Point-of-care testing is the face of modern diagnostics. Technological advancement in the field of diagnostics is focused on providing results nearer to places offering patient care. In Pakistan, where tertiary care accessibility and point of care services in rural areas remains acutely inadequate, LDS's point-of-care solutions promise improved care through efficient, reliable, affordable, and accessible diagnostic solutions. Point-of-Care testing is sought as a solution to local and global healthcare crisis. LDS is committed to strengthening and empowering the Pakistani healthcare system by revolutionizing and modernizing diagnostics according to the most advanced insights gained from trends in medical/diagnostics research.

### piXi-300

A state-of-the-art coagulation analyzer perfectly designed for point-of-care testing. Pixi-300 is an easy-to-use instrument, that gives fast and accurate results. It is a compact portable instrument, with minimum interference and high visualization of results.

#### Product Specifications

Test Items	PT, APTT, FIB, DD, AT, FDP, ACT, Anti-Xa
Specimen Type	Whole blood or plasma
Testing Time	12 min
Available Panel	Coagulation 4 test panel, coagulation 5 test panel
Reagent Type	Lyophilized reagent
Sample Volume	180 $\mu$ l
Code Identification	QR code and Scanner, automated identification of test
Visualization of results	On screen, and built in printer
Operating System	Android 5 inch touch screen with LIS/HIS support
Size	270 mm $\times$ 180mm $\times$ 155mm
Weight	3kg



# staGna-100

## POCT CHEMISTRY ANALYZER

### staGna-100 key features

A compact, state-of-the-art, dynamic Chemistry Analyzer, the perfect solution for Point of Care testing. Stagna-100 offers a free choice of multiple lyophilized discs that offer a unique and complete approach to personalized medicine. The small footprint of the Stagna-100 and pre-packaged reagent, equip it perfectly for portability and on-site testing.

### Product Specifications

Test principle	Photometric colorimetry
Connection	On-line use of LIS system
Sample volume	140 $\mu$ l
Test time	$\leq$ 15 min
Code Identification	QR code and Scanner, reagent disk
Reaction temperature	37 $\pm$ 0.5 $^{\circ}$ C
Light Source	LED lamp
Printer	Built in thermal printer
Operating system	Android 5-inch touch screen with LIS/HIS support
Size	270 mm $\times$ 180mm $\times$ 155mm
Weight	$\leq$ 3kg

### Test Items

Liver Function	TP ALB GLO* ALB/GLO* ALT AST GGT ALP TBIL DBIL IBIL*
Glucose and Lipid	TG CHOL HDL-C LDL-C* GLU GSP*
Renal Function	ALB CRE UREA UA Ca <sup>2+</sup> PHOS CO <sub>2</sub>
Electrolyte 7	K <sup>+</sup> Ca <sup>2+</sup> Na <sup>+</sup> Cl <sup>-</sup> CO <sub>2</sub> Mg <sup>2+</sup> PHOS
General Chemistry 8	GLU AMY CRE UREA K <sup>+</sup> Na <sup>+</sup> Cl <sup>-</sup> CO <sub>2</sub>
General Chemistry 9	TP ALB TBIL CRE UREA GGT AST ALT GLU
General Chemistry 13 I	TP ALB GLO* ALB/GLO* ALT AST TBIL DBIL IBIL* TG CHOL HDL-C LDL-C* GLU CRE UREA UA
General Chemistry 13 II	TP ALB ALT AST TBIL DBIL UA UREA CRE GLU TG CHOL HDL-C
General Chemistry 15	TP ALB GLO* ALB/GLO* ALT AST GGT ALP TBIL DBIL IBIL* TG CHOL HDL-C LDL-C* GLU CRE UREA UA
Emergency Room 13	AST CK CK-MB LDH $\alpha$ -HBDH GLU AMY CRE UA K <sup>+</sup> Na <sup>+</sup> Cl <sup>-</sup> CO <sub>2</sub>
Liver and Renal Function	TP ALB GLO* ALB/GLO* ALT AST GGT TBIL GLU CRE UREA
Myocardial Enzyme	AST CK CK-MB LDH $\alpha$ -HBDH



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