



PRODUCT CATALOGUE

Your safety. Our commitment.

Certificates



Certificate of Registration

This is to certify that the Quality Management System of

BIOLINE DIAGNOSTICS LLP

Plot No. H-1478, DSIDC, Narela Industrial Estate, Delhi-110040, India

Has been independently assessed and is compliant with the requirements of:

ISO 13485:2016

For the following scope of activities:

Design, Development, Manufacturing, Marketing of Rapid Test, Bio Chemistry Liquid and Powder Reagent, Urine Strips, Serology Kits, Blood Grouping Serum, Bovine Serum Kits, Coagulation and ELISA Kits.

Trading and Marketing of Haematology Analyzer, Bio Chemistry Analyzer, Urine Analyzer, ELISA Reader and Washer, Point of Care Equipment and Kits, Surgical and Diagnostic.

Certificate Number: M22012

Date of initial registration	01 st October 2022
Date of this certificate	01 st October 2022
Certificate Validity (subject to the company maintaining its system to the required standard Recertification is due on 30 th September 2023)	30 th September 2023

Signature
Authorized Signatory

This certificate is the property of ACM EMB PVT. LTD. and shall be returned immediately on request.
ACM EMB PVT. LTD., 296/48, Vinodanagar Complex, New Market, Muzaffargarh-211001, U.P., India
+91 9629527001 info@acmcert.in



Certificate of Registration

BIOLINE DIAGNOSTICS LLP

Plot No. H-1478, DSIDC, First Floor, Narela Industrial Estate, Delhi-110040, India

has been assessed and Certified by Otabu Certification Pvt. Ltd. as meeting the requirements of:

ISO 9001:2015

Quality Management System

For the following scope of activities:

Manufacturing, Trading, Marketing, Rapids IVD Test Kits and ELISA Test Kits, POCT Fluorescence Analyser and its Cartridges, Liquid Biochemistry Reagents, Serology Latex Kits And Coagulation Kits, Blood Grouping Serums From Columns, Urine Chemistry Strips and its Analyzer, POCT Instruments and Kits, Bovine Test Kits and Medical, Surgical Instruments and Equipments

Issue No: 01	Revision No: 1 NA
Date of Certification: 28 June 2022	2 nd Surveillance Due: 27 June 2024
1 st Surveillance Due: 27 June 2023	Certificate Expiry: 27 June 2023

(subject to the company maintaining its system to the required standard)

Certificate Number: 00282138622

Validity of this certificate can be verified at www.otabucert.com



Dr. Anita Gupta
Managing Director

*Validity of this certificate is subject to successful completion of surveillance audit or to failure due to non compliance audit is not allowed to be conducted. This certificate shall be suspended/revoked. This Certificate of Registration remains the Property of Otabu Certification Pvt. Ltd. and shall be returned immediately upon request.
Otabu Certification Pvt. Ltd., 82 B Ground Floor, Preet Nagar, Uttar Nagar, New Delhi-110009 India
Email: info@otabucert.com website: www.otabucert.com



Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of the directive Medical Council Directive 90269/EEC of June 1993

Supplier Name: **BIOLINE DIAGNOSTICS LLP**

Address: **H-1478, DSIDC, Narela Industrial Area, Delhi-110040, India**

Product: **Rapids IVD Test Kits and other test kits, POCT Fluorescence Analyser and its Cartridges, Liquid Biochemistry Reagents, Serology Latex Kits and Coagulation Kits, Blood Grouping Serums From Columns, Urine Chemistry Strips and its Analyzer, POCT Instruments and Kits, Bovine Test Kits and Medical, Surgical Instruments and Equipments.**

The Certificate holder has provided an audit of all above product quality system covering the holding, manufacture and test operation of the certified product. The audit system has been assessed, approved and is eligible to continue manufacture as eligible in the previous the Medical Council Directive 90269/EEC of June 1993

This certificate is issued under the following conditions:

- It is valid only to the quality system responsible in the manufacture of above referenced models and it does not include the design or development operations of the models.
- The certificate remains valid only for the manufacturing conditions of the quality system as changed.
- The certificate holder is responsible for providing surveillance audits.
- After labelling the relevant CE Approvals, the manufacturer shall affix CE mark devices, or the above referenced models.
- The CE mark is a common symbol that can be used, under the responsibility of the manufacturer, after consultation of the CE regulations of conformity and compliance with all relevant CE Directives. The assessment is based on a single evaluation of the sample of above mentioned product. It does not include an assessment of the manufacturing.

Date of Registration	: 02 June 2020
1st Surveillance Due	: 01 June 2021
2nd Surveillance Due	: 01 June 2022

Certificate Expiry (subject to the company maintaining its system to the required standard): **01 June 2023**

Certificate No.- 200602603

To Verify this certificate please visit at www.otabucert.com.uk





Otabu Certification Limited (UK)

Validity of this Certificate is subject to Annual Surveillance audits done successfully
This Certificate is the property of Otabu Certification Limited (UK) and shall be returned immediately upon request.
Otabu Certification Limited (UK), 82 B Ground Floor, Preet Nagar, Uttar Nagar, New Delhi-110009 India
Email: info@otabucert.com website: www.otabucert.com

Suite 48, 88-90 Hatton Garden, London, EC1N 8PN, UK



Certificate of Compliance

This is to certify that

BIOLINE DIAGNOSTICS LLP

at

H-1478, DSIDC, Narela Industrial Area, Delhi-110040, India

Has been assessed and found working satisfactorily as per the terms of

Good Manufacturing Practice (GMP) System

For the following scope of activities:

Manufacturing of All kinds of Rapids IVD Test Kits and ELISA Test Kits, Liquid Biochemistry Reagents, Serology latex kits and Coagulation Kits, Urine Chemistry Strips and its Analyzer

Certificate Number: 301140720

Validity of this certificate can be verified at www.ukcert.co.uk

Date of Registration	14 July 2020
1 st Surveillance Due	13 July 2021
2 nd Surveillance Due	13 July 2022

Certificate Expiry (subject to the company maintaining its system to the required standard): **13 July 2023**





Authorized Signatory

UK Cert Limited (UK)

1 Nether Place, Colton Park, Birmingham, Birmingham B27 8DL, UK
Email: www.ukcert.co.uk
This certificate is the property of UK Cert Limited (UK) and shall be returned immediately upon request.
UK Cert Limited (UK) is a company registered in England and Wales under the number of 06538484.
The validity of this certificate is subject to successful completion of surveillance audit or to failure due to non compliance audit is not allowed to be conducted. This certificate shall be suspended/revoked.



Established in 2017, Bioline Diagnostics LLP has been dedicated to revolutionizing healthcare in India and emerging markets. Our mission is to develop, manufacture, and market high-quality diagnostic products at affordable prices. We firmly believe that perfect diagnosis is the first crucial step towards effective treatment. Here's a bit more about us:

We specialize in a range of diagnostic solutions, including Immunochromatographic Tests, Biochemistry Test Reagents, POCT (Point of Care Testing), and cutting-edge diagnostic instruments such as Hematology Analyzers, Biochemistry Analyzers, nephelometry, etc

Our corporate office is located in Mumbai, the bustling heart of India's business landscape. Our state-of-the-art manufacturing unit, which is certified by ISO 13485, ISO 9001, and GMP, is situated in New Delhi.

Quality is at the core of our operations. We maintain rigorous quality control and assurance processes to ensure that our products meet the highest standards. Our facility boasts advanced features like temperature and humidity control systems, a well-equipped R&D laboratory, stability chambers, and more.

You may have come across our brand '**Firstview**' and '**Triview**'. It embodies our commitment to early and accurate diagnosis. We firmly believe in the power of timely diagnosis in the treatment of various diseases, even critical ones. 'Triview' is synonymous with excellence in biochemical diagnostics, known for its precision and reliability.

Our manufacturing facility spans 10,000 square meters, adhering to the Medical Device Rule 2017 standards. We have a remarkable production capacity of approximately 100,000 tests/day, ensuring a steady supply to meet healthcare demands. At Bioline Diagnostics LLP, we are not just a company; we are a team of dedicated individuals working tirelessly to enhance healthcare outcomes. Your interest in our products reaffirms our commitment to quality and innovation. We look forward to the opportunity to serve you and support your healthcare goals. If you have any questions or require further information, please do not hesitate to reach out to us. Our team is here to assist you in any way possible.



BH360 3-Diff

Automatic Hematology Analyzer



Automatic 3-Diff Hematology Analyzer

- 21 parameters+3 histograms
- 3-part differentiation of WBC
- 2 counting modes: whole blood and prediluted
- 60 samples per hour
- 10.4" TFT colorful LCD with touch screen
- Built-in thermal printer, optional external printer
- Up to 50000 sample results (including histograms) can be stored



21 Parameters



3-Part
Differential WBC



Internal
Thermal Printer



High Accuracy
& Reliability



Large
Display Screen

Product	Pack Size
Diluent	20 L
Lyse	500 ml
Cleaner	50 ml



Automated Erythrocyte Sedimentation Rate Analyzer

- Instant tube detection
- Citrate tube not required
- Test performed on same tubes in which blood samples taken (edta/cbc)
- Test can be done on small volume of blood (1.5mL)
- Compact 10"/7" touch screen, designed for seamless interaction and clear visualization



BD-C220

Coagulation Analyzer



COMPACT DESIGN | ONE-CHANNEL
SCATTERED LIGHT | INTERNAL PRINTER

Coagulation Analyzer

- Easy keypad operation with LCD display Internal thermal-sensitive printer Reagent position with magnetic rotor
- Scattered light principle and percentage analysis ensures good results
- Open reagent with low consumption, close reagent on request
- Large memory to store up to 6000 test results
- QC and calibration program incorporated
- Auto power-on self-check
- Multi-language software available on request
- Electronically-linked pipette optional

U-220

Urine Analyser



Urine Analyser

- User-friendly LCD display and menu-driven interface
- Bright, cold light source for clear results
- Long-lasting performance
- Highly sensitive light sensor with interference resistance-intelligent pH ratio correction
- Fast, quiet thermal printing
- Seamless computer connectivity via RS-232- Storage for 10,000 test results
- Customizable alert thresholds- Adjustable test sensitivity.
- Easily connect external printers for more printing options.
- Strip Available 10,11 Parameter
- Test speed is 120 test 60 test / hour and manually triggered.

BC 230
Semi-Auto Chemistry Analyzer



Semi-Auto Chemistry Analyzer

- Windows embedded compact 7
- 7" inch true color touch screen (800*480 pixels)
- Flow cell & cuvette testing mode
- 4 USB ports & 1 ethernet port
- Universal power supply

INNOVATION DESIGN,
SMART COMBINATION

BYLYTE Pro
Electrolyte Analyzer



Electrolyte Analyzer

- Ion selective electrode (ISE) technology
- Fully self-developed composition formulations for electrodes and reagents
- CNC metal anodized measuring chamber
- Independent amplifier circuit to eliminate interference
- Auto diagnostic to monitor the instrument
- Automatic A, B calibrations combine with manual calibration option
- Transparent electrode housing
- Dual coefficient alignment for more accurate result
- Specialised quality control statistic groups Low reagent consumption

Easy, Efficient & Effective



Ion Selective Electrode (ISE) Technology



Easy Control with 3 Keys



Low reagent consumption



Internal Thermal Printer

Product	Pack Size
REAGENT PACK	1000 ml



Semi-Auto Chemistry Analyzer

- Direct access to more than 200 tests through test keys
- Maintenance free peristaltic pump
- Unique circuitry for long lamp life
- Triple cuvette system
- Real time graph with online reading
- Multi standard calibration & memory
- Automatic calibration against standard
- Displays actual temperature on screen
- Levey jennings and standard deviation graphs
- Sample carry over prevention facility
- Robust system with built in stabilizer
- Patient report with PID & name
- User friendly software
- USB interface

Test Items

Liver	ALT, AST, ALP, GGT, ALB, ALP, TP, TBIL, DBIL
Heart	TG, Chol, HDL-C, LDL-C, LDH, CK, CK-MB
Kidney	Urea, Creat, UA, Ca, Na, K ⁺
Turbi	ASO, CRP, RF, D-Dimer
Other	HbA1C, Glc



Fully Automatic Chemistry Analyzer

- Random access fully automatic biochemistry analyzer
- New concept and more friendly software
- Automatic washing station for both sample and reagent probe
- Liquid level detection and collision protection for both sample and reagent probe
- Reliable cooling system for reagent chamber, condensate cooling design and peltier cooling system
- double ensure the cooling effect.
- Powerful reaction cuvette washing system ISE Unit & barcode scanner (optional)
- Lower waste and pro-environment



Intelligent parameters auto - setting & optimization function (patented), makes operation easier and free parameter setting error.

ELISA-R206 Plus

Microplate Reader



Microplate Reader

- Accommodates different microplate geometries U, V & Flat
- Plate shaking facility with variable speed and duration
- Digital light control with unique circuit for long lamp life
- Bichromatic readings
- Flexible controls and calibrators positioning
- Storage of calibration curves, controls and plate results
- Patient report with PID & name
- Various Graph curve fit mode : Linear, Point to Point, 4 parameter log regression, Cubic
- Spline, Polynomial with scales such as Log Abs / Conc, Logit Abs / Log Conc, Abs / Conc, Log
- Data transfer to computer, results in Excel format

ELISA-W201 Plus

Microplate Washer



Microplate Washer

- Programmable ELISA washer for 96 well ELISA Plate Strips
- Specially designed 8/12 channel Manifold assembly to prevent any scratching on bottom of well - 12 way manifold is optional
- User friendly touch screen display
- User programmable soak time, wash cycles and dispensing volume
- Cross Wash facility for flat Wells
- Bottles with level sensor
- Various types of microplates such as flat, U, V bottom
- Built-in stabilizer built-in vacuum & dispensing pump

ELISA-R206

Microplate Reader



Microplate Reader

- Easy Windows operation software, with touch screen or mouse, Large LCD display
- 8-channel optical fiber system enables 5 secs' reading for the whole plate
- Bichromatic measurement, calculation modes include Absorbance, Cut-off, Curve, Linear regression Index regression, Logarithm regression, Exponent regression, Power Regression, etc
- Large memory storage up to 100 programs, 1000 patients data, 10000 sample records
- Auto self-check when power on
- With lamp sleeping and wake-up function
- Random positive control and negative control setting
- Multi-assay feature enables up to 12 different assays on one plate
- Powerful QC function: Immediate, Elisa including Westguard Rules, Levey Jennings plot (optional)
- Multifunction result output including patient comprehensive report
- Easy software upgrade by SD card, support USB mouse and keyboard
- Ability to communicate with PC for data management (optional)

ELISA-W201

Microplate Washer



Microplate Washer

- Easy Windows operation system, large LCD display
- Washes flat, U and V-bottom strips and plates
- 12-way or 8-way manifold, automatic and manual positioning
- Large memory, up to 50 wash protocols can be programmed
- Automatic monitoring for vacuum and pressure, automatic rinse cycle
- Washing pressure volume and time adjustable
- Liquid level detection and alert function
- No special airtight bottle required for wash bottle
- Easy maintenance

BH560 pro

Automatic Hematology Analyzer



5 Part Hematology Analyzer

Performance

Parameter	Linearity Range	Precision (CV %)
WBC($10^9/L$)	0.0-500	$\leq 3.0\%$ (3.50-7.00) $\leq 2.5\%$ (7.01-15.00)
RBC ($10^{12}/L$)	0.0-8.5	$\leq 1.5\%$
HGB (g/L)	0-250	$\leq 1.5\%$
PLT ($10^9/L$)	0-4000	$\leq 5.0\%$

Principles

Laser flow cytometry analysis for WBC, DIFF and BASO counting
Electrical impedance method for RBC, PLT counting.

Cyanide-free reagent for HGB with colorimetric method.

Throughput

60 samples per hour

SENSITIVE FLAGGING THAT ASSIST YOUR INSIGHTS

NRBC | EOSINOPHILIA | DIFF | ALLY | IG

Unique 2 Reagent Systems

Product	Pack Size
Diluent	20 L
Lyse	500 ml

FirstView®

One Step Rapid Test Device



Product Name	Type	Pack Size
Chikungunya Ab Rapid Test	Device	25T
Dengue IgG/IgM Rapid Test	Device	25T
Dengue NS 1 Antigen Rapid Test	Device	25T
Dengue NS1 & IgG/IgM Combo Rapid Test	Device	10T
Ferritin Rapid Test	Device	25T
Filariasis Ab Rapid Test	Device	25T
Fecal Occult Blood (FOB) Rapid Test	Device	25T
FSH Rapid Test	Device	25T
H. Pylori AG Rapid Test (Stool)	Device	25T
H. Pylori IgG/IgM Rapid Test (S/P/WB)	Device	25T
HBsAg Rapid Test (S/P)	Device	50T
HBsAg Rapid Test(S/P/WB)	Device	50T
HBsAg Rapid Test	Strip	50T
HCG Rapid Test	Device	50T
	Strip	50T
HCV Rapid Test (S/P/WB)	Device	50T





First View[®]

One Step Rapid Test Device

Product Name	Type	Pack Size
HIV 1/2 Rapid Test (S/P/WB)	Device	50T
HIV 4th Gen. Ab/Ag Rapid Test	Device	50T
HIV 1/2 +Syphilis Combo Rapid Test	Device	50T
IgE Rapid Test	Device	25T
Leptospira Ab Rapid Test	Device	10T
LH Rapid Test	Device	25T
Malaria Pf/Pan Rapid Test	Device	50T
Malaria Pf/Pv Rapid Test	Device	50T
NT-proBNP Rapid Test	Device	10T
Scrub Typhus Rapid Test	Device	25T
Syphilis/VDRL Rapid Test (S/P)	Device	50T
Syphilis/VDRL Rapid Test (S/P/WB)	Device	50T
Syphilis/VDRL Rapid Test	Strip	50T
Toxoplasma Rapid Test	Device	25T
Troponin-I Rapid Test (S/P/WB)	Device	10T
Typhoid IgG/IgM Rapid Test	Device	25T
Vitamin D Rapid Test	Device	10T



TriView® BIOCHEMISTRY

Product Name	Type	Pack Size	Method
Urea GLDH	Liquidstable	5 x 20 ml	UV GLDH
Creatinine K	Liquidstable	2 x 50 ml	JAFFE KINETIC
Uric Acid	Liquidstable	5 x 10 ml	URICASE
	Liquidstable	5 x 20 ml	
SGOT	Liquidstable	5 x 10 ml	IFCC
	Liquidstable	5 x 20 ml	
SGPT	Liquidstable	5 x 10 ml	IFCC
	Liquidstable	5 x 20 ml	
Bilirubin T&D	Liquidstable	2 x 50 ml	Modified Jendrassik
Alkaline Phosphatase	Liquidstable	5 x 10 ml	IFCC AMP
	Liquidstable	5 x 20 ml	
Albumin	Liquidstable	2 x 50 ml	BCG
Cholestrol	Liquidstable	5 x 20 ml	CHOD-PAP
Triglyceride	Liquidstable	5 x 10 ml	GPO-PAP
	Liquidstable	5 x 20 ml	
Chloride	Liquidstable	1 x 25 ml	
Zinc	Liquidstable	1 x 25 ml	
Pyruvate	Liquidstable	1 x 10 ml	
	Liquidstable	1 x 20 ml	
Magnesium	Liquidstable	1 x 10 ml	
	Liquidstable	1 x 20 ml	



Tri✓view® BIOCHEMISTRY

Product Name	Type	Pack Size	Method
LDL-C Direct	Liquidstable	1 x 60 ml	Direct Homogeneous
HDL-C Direct	Liquidstable	1 x 60 ml	Direct Homogeneous
Amylase	Liquidstable	1 x 10 ml	CNPG2
CK Nac	Liquidstable	2 x 10 ml	IFCC
CK-MB	Liquidstable	2 x 10 ml	IFCC
LDH	Liquidstable	1 x 10ml	IFCC L—P
Glucose	Liquidstable	5 x 100 ml	GOD-POD
Total Protein	Liquidstable	2 x 50 ml	Biuret
Ammonia	Liquidstable	5 x 5 ml	GLDH
Lipase	Liquidstable	1 x 12 ml	Enzymatic Colorimetric
Hemoglobin	Liquidstable	500 ml	Cyanide Free
Sodium	Liquidstable	25 x 1 ml	Colorimetric
Potassium	Liquidstable	5 x 1 ml	Tetraphenyl Boron
Phosphorus	Liquidstable	25 x 1ml	Ammonium Molybdate
Calcium	Liquidstable	25 x 1ml	Arsenazo
Calcium	Liquidstable	2 x 50 ml	OCP
GGT 2	Liquidstable	1 x 20 ml R1 2 x 8 ml R2 1 x 4 ml	IFCC
Chloride	Liquidstable	1 x 25 ml	
Zinc	Liquidstable	1 x 25 ml	
Pyruvate	Liquidstable	1 x 25 ml	
Homocystein	Liquidstable	1 x 25 ml	
Iron	Liquidstable	25 x 1 ml	
Copper	Liquidstable	1 x 25 ml	



TriView[®] SEROLOGY

Product Name	Type	Pack Size
CRP	Latex	25 T
		100T
Rheumatoid Factor	Latex	25 T
		100 T
ASO	Latex	25 T
		100 T
RPR	Latex	50 T
Widal	Latex	4 x 5 ml

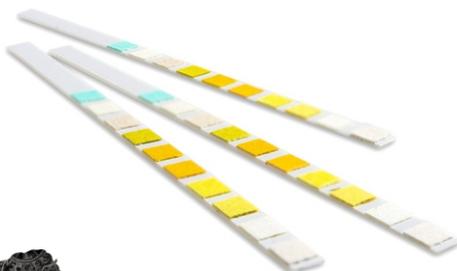
TriView[®] IMMUNOTURBIDIMETRY

Product Name	Type	Pack Size
Rheumatoid Factor (RA)	Turbi	50 ml
ASO	Turbi	50 ml
CRP	Turbi	1 x 50 ml
Fettitin	Turbi	40 ml
D-Dimer	Turbi	40 ml
HbA1C	Turbi	40 ml

FirstView[®]

Urine strips

Product Name	Type	Pack Size
Glucose 1G	Bottles	100 T
Glucose & Protein	Bottles	100 T
Glucose & Ketone	Bottles	100 T
11 Parameter	Bottles	100 T
11 Parameter with Micro	Bottles	100 T
10 Parameter	Bottles	100 T
3P GPPH	Bottles	100 T
4 Parameter	Bottles	100 T



QR 100
Specific Protein Analyzer

Specific Protein Analysis System



Specific Protein Analysis System

- Rapid** New fast immunity measurement system. Test result can be reported within 2 minutes.
- Quantitative** Dual system of nephelometry and turbidimetric tests, high sensitivity, wide testing range.
- Convenient** RF type non-contact magnetic card of reagent information, the human-machine touch screen is easy and visual to operate.
- Reliable** Specimen dilution and calibration of hematokrit (HCT) make the result uniform.

- Reagent Kits**
CRP | hs-CRP | mAlb | Cys-c | RA | ASO | HBA1C | Vitamin D | Anti-CCP | D-dimer | Ferritin

COMING SOON!

FIA

Fluorescence Immunoassay System



- Respiratory Disease** : SARS-CoV-2 Antigen, Influenza A/B, SARS-CoV-2 & Influenza A/B Ag Combo
- SARS-CoV-2 Neutralizing Antibody,
- Cardiac Markers** : cTnI, CK-MB, Myoglobin, NT-proBNP, cTnI/CK-MB/Myo
- Coagulation** : D-Dimer
- Thyroid Function** :TSH, T3, T4
- Diabetes and Renal Function** : HbA1c, Microalbumin,
- Inflammation** : CRP, PCX, IL-6
- Fertility** :(5-HCG
- Others** : Vitamin D

Products under Development

- Gastrointestinal Diseases** : PG-I/PG-II, Gastrin-17, H. pylori Ag, H. pylori IgG
- Allergen** : Animal Protein sIgE, Animal Pelt sIgE, Seafood sIgE, Food Nuts sIgE, Indoor Allergen sIgE FIA Test Tree Pollen sIgE, Fruit sIgE, Weed Pollen sIgE, Total IgE

BD Ultra Hb

Hemoglobin Meter



Direct Measurement of Hemoglobin (Hb) and Hematocrit (Hct)



Direct Sampling



Small Sample Volume



First Results



Clinical Accuracy



Portable



First View®

Blood Glucose Monitoring System

individually packed strip



Easy & Accurate



5 Second Test Time



0.5uL Blood Required



900 Test Memory





BH360 Advance
Automatic Hematology Analyzer



3-Diff Automatic Hematology Analyzer

- Dual Chamber 3-Diff Hematology Analyzer
- 21 parameters and 3 Histograms
- Throughput of 60 samples/ Hour
- Large 10.4" Touch Screen
- 1,00,000 Results in memory with Histogram
- Close System with RFID detection System



Bioline Diagnostics LLP
H-1478, DSIDC, Narela Industrial Area, Delhi - 110 040

Corporate Office : 603, Kamdhenu Commerz, Sector -14, Kharghar, Navi Mumbai - 410 210

☎ +91 9820145370, +91 9870017900