



### **About us**

World leaders in the lab diagnostics market, we are specialists in the immunodiagnostic and molecular diagnostic segments and active in the Licensed Technologies business

We have been developing, producing and marketing reagent kits for laboratory diagnostics all over the world, for over 50 years. Our broad offering of diagnostic tests and Licensed Technology solutions, made available thanks to ongoing investments in research, positions us as the player with the widest range of specialty solutions in the sector and identifies the Group as the "Diagnostics Specialist".

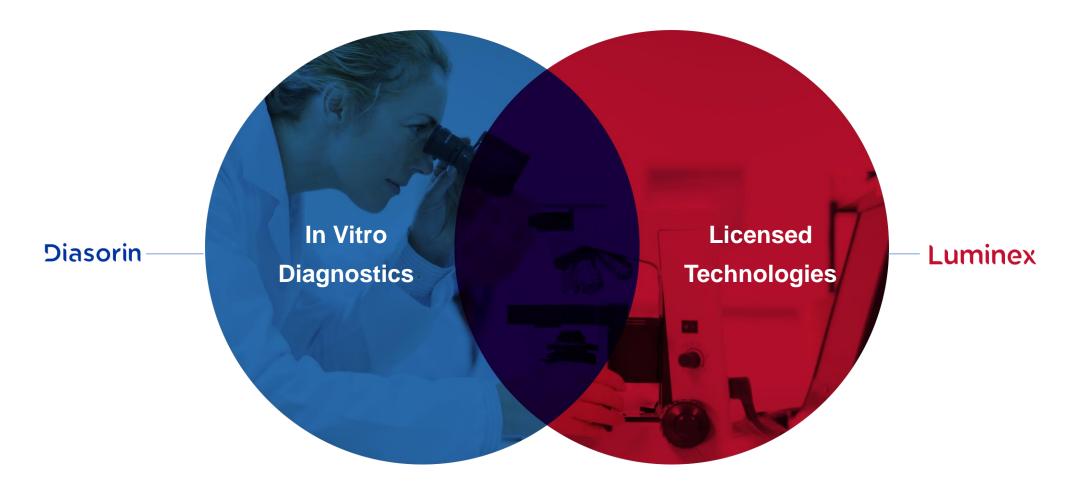
Diagnosis is the first step towards understanding a person's state of health. This is why our tests can make the difference: they are precise and reliable and enable delivery of early diagnosis of various pathologies for millions of people who will then be able to receive the most appropriate therapy.

Listed on the Italian Stock Exchange in the FTSE MIB Index





# Our business





# **Our business**

### **In Vitro Diagnostics**

We market and develop diagnostic tests and solutions in the **immunodiagnostic** and **molecular diagnostic** sectors.

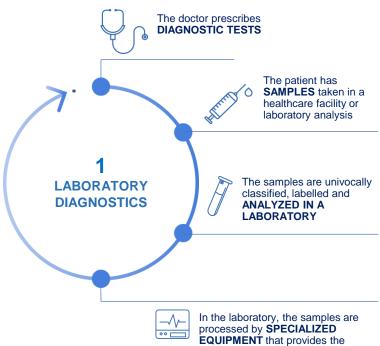
We offer technological and innovative solutions ranging from hospital and commercial analysis laboratories to decentralized contexts.

### **Licensed Technologies**

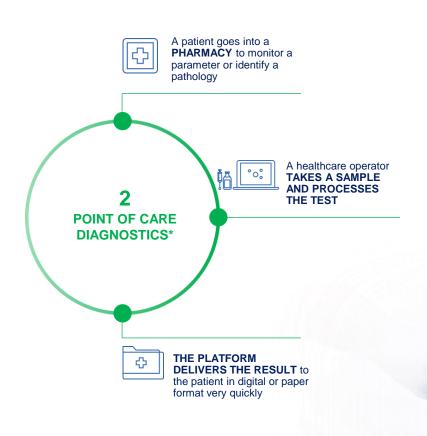
We enable scientists get quick and reliable responses to complex biological issues with innovative and unique solutions supporting different markets including biomedical research, genomic and proteomic research, clinical diagnostics and vaccine and drug development.



### From needs to our solutions



\* The outcome of the tests performed by the patient will allow the doctor to take the most correct therapeutic path In the laboratory, the samples are processed by SPECIALIZED EQUIPMENT that provides the diagnostic responses required on the basis of the reaction between the samples and the DIAGNOSTIC TEST REAGENTS







\*Coming soon

## **Our story**

Foundation of SORIN, a nuclear energy production center in Saluggia (Vercelli, Italy), by a JV between FIAT and Montecatini.

The opening of Europe's first in vitro diagnostics center.



A management buyout brings Diasorin ownership back to Italy.



Diasorin continues to grow organically and inorganically, expanding geographically and investing in technology and product innovation.

It forms numerous partnerships with leading players in the global diagnostics market (Roche, Beckman Coulter, Meridian Bioscience).



Diasorin stock is included in the FTSE MIB.

Diasorin enters a partnership with Qiagen for latent tuberculosis testing. Diasorin acquires Siemens Healthineers' ELISA business.



Diasorin acquires the US company Luminex Corporation for \$1.8bn, thus gaining multiplexing technology for molecular diagnostics and entering in the Licensed Technology field.

Diasorin launches the Lyme test in partnership with QIAGEN and the MeMed BV test in partnership with MeMed.



Diasorin sells all the assets related to the Flow Cytometry & Imaging (FCI) business unit to Cytek® Biosciences.

Diasorin collaborates with Gilead Sciences to develop an automated assay for HDV detection





Diasorin, the diagnostics division of SORIN Group, is sold to the multinational **American Standard** International.



On July 19, Diasorin is listed on the Italian stock exchange (Piazza Affari, Milan).



Diasorin enters the molecular diagnostic sector by acquiring the American Focus Diagnostics, now Diasorin Molecular, adding to the Group's competence and excellence.



Diasorin signs an exclusive license agreement with TTP for the development of LIAISON NES.

Launch of 5 COVID tests.



Diasorin furthers its collaborations with **BARDA** to support clinical validation and FDA 510(k) clearance of the LIAISON® NES.

Diasorin and B-R-A-H-M-S partner on MR pro-ADM, a new immunodiagnostic solution for emergency departments to improve patient management.



Diasorin receives FDA 510(k) clearance of its **LIAISON PLEX®** together with the respiratory panel and the blood culture yeast assay.





# **Diasorin worldwide**

### **NORTH AMERICA**

**50%** of Group Revenues\*

### **EUROPE**

35% of Group Revenues\*

### **REST OF WORLD**

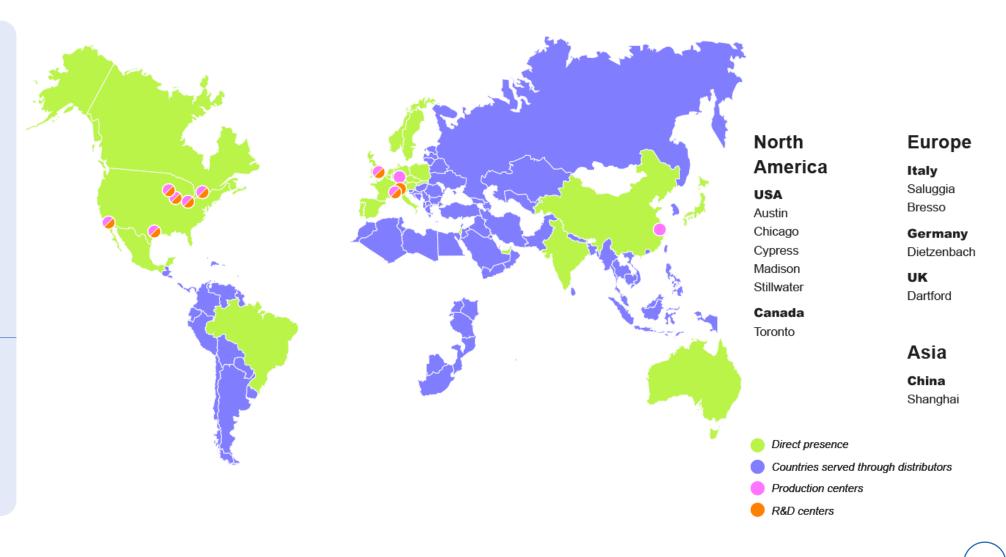
15% of Group Revenues\*



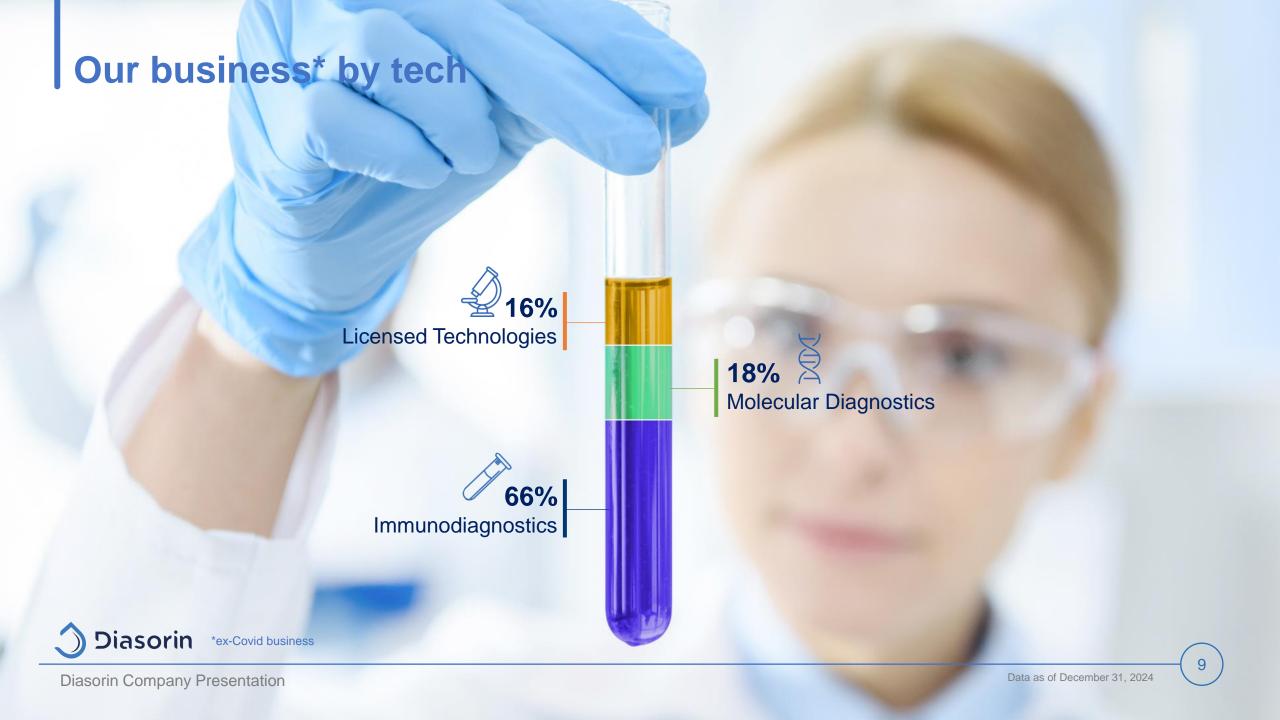
3271 **Employees** 

\*data as of December 31, 2024









# **M&A** and Partnerships





LIAISON NES platform



MR-proADM test

2020 - Today







Molecular Diagnostics & Licensed **Technologies** 

Sale of Flow Cytometry & Imaging business



Hepatitis & Retrovirus

COULTER

QuantiFERON Technology

**QIAGEN** 

2015 - 2019



Molecular **Diagnostics**  **ELISA Business** 



meridian BIOSCIENCE®

GI Stool testing

**ELISA Hepatitis** & Retrovirus

2010 - 2014

(ullet)



Roche)

Connectivity for

lab automation



**PARTNERSHIPS** 

M&A

**Byk Sangtec** 

**Biotrin** 

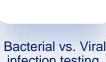
2000 - 2009

lacksquare

CLIA immunodiagnostic platforms

Parvovirus test

















# **Our Immunodiagnostic Systems**



### **DISEASE AREAS**

- Infectious diseases
- Endocrinology
- Gastrointestinal diagnostics
- Autoimmunity
- Hypertension
- Emergency/Sepsis

- Bone & mineral
- Oncology



# The LIAISON® XL assay menu



### METABOLIC DISORDERS

25-OH Vitamin D TOTAL 1,25 dihydroxyvitamin D

1 - 84 PTH

N-TACT® PTH Gen II

FGF 23

BAP OSTASE® Osteocalcin

Ferritin

Folate

Vitamin B12



### **TUMOR MARKERS**

CFA Free PSA

PSA

PSA II Gen

CA 15-3®

CA 125 II™

CA 19-9™

TPA®-M

NSE

S100

AFP hCG/ß-hCG

ß2-Microglobulin

TK

Calcitonin



### **GASTROINTESTINAL DISEASES**

Calprotectin

Elastase-1 Meridian H. pylori SA

H. pylori IgG

C. difficile GDH

C. difficile Toxin A/B Campylobacter Ag

Adenovirus

Rotavirus

tTG IqA



### **HEPATITIS AND RETROVIRUSES**

Anti-HAV

HAV IgM

HBsAq Qual HBsAg Quant

HBsAg Confirmatory test

Anti-HBs

Anti-HBs plus

Anti-HBc

HBc IgM

HBeAg Anti-HBe

Anti-HDV

Anti-HEV IgG Anti-HEV IgM

HIV Ab/Ag

HIV Ab/Ag HT HCV Ab

HTLV I/II



### **ENDOCRINOLOGY**

TSH Free T3 Free T4

Т3

T4

Anti-Tg Tg Gen II

Anti-TPO

Androstenedione

DHEA-S

Estradiol

FSH hCG

Progesterone

Prolactin Prolactin xt

SHBG Testosterone

Testosterone xt



C-Peptide

Direct Renin

Aldosterone

Insulin

hGH

IGF-I

ACTH

Cortisol

### **ENDOCRINOLOGY INFECTIOUS DISEASES**

MeMed BV®

SARS-CoV-2 TrimericS IgG SARS-CoV-2 Ag

QuantiFERON®-TB Gold Plus

Mycoplasma pneumoniae IgM Mycoplasma pneumoniae IgG

Bordetella pertussis Toxin IgG

Bordetella pertussis Toxin IqA BRAHMS PCT® II Gen

BRAHMS MR-proADM™

Legionella Urinary Ag S. pneumoniae Urinary Ag

LymeDetect®

Borrelia burgdorferi IgG

Borrelia burgdorferi IgM II

Borrelia burgdorferi IgM Quant



### INFECTIOUS DISEASES

Toxo IgG II Toxo IgM

Toxo IgG Avidity

Rubella IgG II

Rubella IgM

CMV IgG II CMV IgM II

CMV IgG Avidity II

HSV-1/2 IgG

HSV-1 IgG

HSV-2 IgG

HSV-1/2 IgM Parvovirus B19 IgG

Parvovirus B19 IgM

Parvovirus B19 IgG Plus

Parvovirus B19 IgM Plus

EBV IgM

VCA IgG

EBNA IgG

EA IgG

Treponema Screen

Chlamydia T. IgG

Chlamydia T. IgA

Measles IgG

Measles IaM

Mumps IgG

Mumps IgM

VZV IgG

VZV IgM VZV IgG HT

Zika Capture IgM II

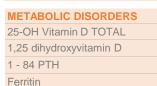
Chagas IgG



Trademarks: QuantiFERON® (QIAGEN Group), LIAISON®, LymeDetect® (Diasorin)

# The LIAISON® XS assay menu







TUMOR MARKERS CEA Free PSA PSA II Gen CA 15-3®



Calprotectin
Elastase-1
Meridian H. pylori SA
C. difficile GDH
C. difficile Toxin A/B
Campylobacter Ag
Adenovirus

Rotavirus

**GASTROINTESTINAL** 



HEPATITIS AND
RETROVIRUSES

Anti-HAV
HAV IgM
HBsAg Qual
HBc IgM
Anti-Hbe
Anti-HEV IgG
Anti-HEV IgM
HTLV I/II



**ENDOCRINOLOGY** TSH Free T3 Free T4 Т3 T4 Anti-Tg Tg Gen II Anti-TPO FSH hCG Prolactin xt hGH IGF-I Direct Renin Aldosterone ACTH Cortisol



INFECTIOUS DISEASES
MeMed BV®
SARS-CoV-2 TrimericS IgG
QuantiFERON®-TB Gold Plus
Mycoplasma pneumoniae IgM
Mycoplasma pneumoniae IgG
BRAHMS PCT® II Gen
BRAHMS MR-proADM™
Legionella Urinary Ag
S. Pneumoniae Ag
LymeDetect®
Borrelia burgdorferi IgG
Borrelia burgdorferi IgM II
Borrelia burgdorferi IgM Quant



The LIAISON® XS is a single completely automated system with efficient design and reduced dimensions for specific pathologies and ad hoc areas.



▲ Trademarks: QuantiFERON® (QIAGEN Group), LIAISON®, LymeDetect® (Diasorin)

# **Our Molecular Diagnostic Systems**

\* To be launched



Single-low Plex Platforms

Detects the presence of up to 5 pathogen agents starting from a single sample



Multiplexing Platforms
Simultaneously detects the presence of up to 40 different pathogens from a single sample

### **CLINICAL AREAS**

- Respiratory Infections
- Herpes viruses
- Meningitis/Encephalitis

- Hospital Acquired Infections
- Vector borne
- Bloodstream Infections

- Transplant
- Women's/Neonatal Health
- Genetics/Cystic Fibrosis



# LIAISON® NES

The LIAISON® NES is a new molecular platform to address the growing diagnostic decentralization trend that is driving the need for fast and accurate testing in laboratory and near-patient settings.

The LIAISON® NES will offer high quality, cost effective low-plex testing, generating results in approximately 15 minutes.

The LIAISON® NES will be initially registered as a professional-use only platform in the EU and a Point-of-Care (POC) platform in the USA.



\* To be launched



# LIAISON® MDX and LIAISON® MDX Plus



The LIAISON® MDX is an innovative and powerful thermocycler with two consumable disc options: the 8-well Direct Amplification Disc for sample-to-answer testing and the 96-well Universal Disc for higher volume testing.

Supported by an expanding menu of molecular assays, the LIAISON® MDX is flexible allowing you to run real-time PCR for qualitative, quantitative and multi-analyte detection. The instrument can perform both IVD as well as Laboratory Developed Tests.

The LIAISON® MDX software provides easy to understand results with the ability to check amplification curves after a run. The software also plots QC Charts and can be bi-directionally interfaced with LIS for easy integration into any lab workflow. You can also access and navigate the software during a run.

The instrument is compact with an extremely small footprint measuring only 12" by 8" by 12" so that it can fit into laboratories of any size.





\* To be launched



# The LIAISON® MDX and ASRs/RUO menu



single low plex			
	LIAISON® MDX	LIAISON® MDX	
	(DAD kits)	(UD kits)	ASR(s)/RUO
Respiratory			
Bordetella	X	X	X
Group A Strep	X		X
Flu A/B & RSV	X		X
COVID-19 & Flu A/B	X		X
Flu A/B & RSV+SARS-CoV -2	X		X
Influenza A H1N1 (2009)		X	X
SARS-CoV-2	X		X
SARS-CoV-2 variants			X
C. Pneumoniae			X
Strep group C and group G			X
hMPV			X
Klebsiella			
pneumoniae			X
Legionella			X
M. Pneumoniae			X
L. Pneumoniae			X
Мрох			X
Parainfluenza			X

single low plex			
	LIAISON® MDX (DAD kits)	LIAISON® MDX (UD kits)	ASR(s)/RUO
Hospital			
Acquired			
Infections			
C. difficile	X	X	X
MRSA			
Norovirus			X
C. auris	X		X

Transplant

Adenovirus

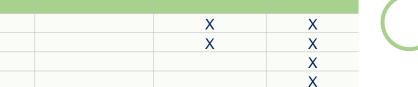
Enterovirus 8VHH HHV6 JCV

P. Jirovecii Parvovirus Toxoplasma

gondii

**CMV EBV** 

BKV





Χ





# The LIAISON® MDX and ASRs/RUO menu



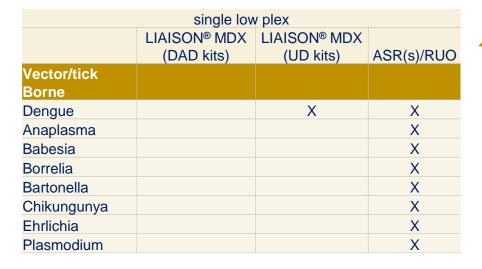
	single low	v plex	
	LIAISON® MDX (DAD kits)	LIAISON® MDX (UD kits)	ASR(s)/RUO
Women's Health			
HSV 1&2	X		X
VZV (SWAB)	X		X
HSV 1/2 & VZV		X	X
GBS	X		X



CNS		X
HSV 1&2	X	
VZV (CSF)	X	X
Parechovirus		Χ



Neonatal		
Congenital CMV	X	



Genetics	
MTHFR	X
Factor II	X
Factor V	X





# **MAGPIX**®



This compact multiplexing unit performs up to 50 different tests in a single reaction volume and reads a 96-well plate in just 60 minutes. MAGPIX<sup>®</sup> features self-cleaning routines and magnetic bead compatibility (with MagPlex<sup>®</sup> beads), making the instrument easy to learn and easy-to-use.

The MAGPIX® System features an innovative design based on imaging technology that allows for a more compact, robust system. It's also easy to operate and maintain with streamlined start-up and shutdown protocols and easy-to-perform preventative maintenance. MAGPIX® is supported by a broad menu of commercially available assay kits, as well as reagents to build your own assays.

# **LUMINEX® 200**



The Luminex® 200™ System is a flexible analyzer based on the principles of flow cytometry that enables you to multiplex (simultaneously measure) up to 100 analytes in a single microplate well, using very small samples. The system delivers fast and cost-effective bioassay results on many assay formats including nucleic acid assays, receptor-ligand assays, immunoassays, and enzymatic assays.

The Luminex 200 System is the combination of three core xMAP® Technologies. The first is xMAP microspheres, a family of fluorescently dyed micron-sized polystyrene microspheres that act as both the identifier and the solid surface to build the assay. The second is a flow cytometry-based instrument, the Luminex 200 analyzer, which integrates key xMAP detection components, such as lasers, optics, fluidics, and high-speed digital signal processors. The third component is the xPONENT® Software, which is designed for protocol-based data acquisition with robust data regression analysis.

# **VERIGENE®**



The VERIGENE® System instrumentation consists of a VERIGENE® Reader and one or multiple VERIGENE® Processor SPs. The VERIGENE® Reader manages sample information, reads results from processed cartridges, and allows for result printing, internal data storage, and LIS connectivity without the need for an external PC. The VERIGENE® Processor SP is a modular, easy-to-use benchtop analyzer that combines automated nucleic acid extraction, purification, amplification, and hybridization in each module. These advanced capabilities allow users to run VERIGENE® tests on-demand in response to testing requirements, without the need for batch processing, instrument-specific training, or specialized facilities. The system is scalable, allowing throughput customization to meet the size and testing demands of each laboratory.

The VERIGENE® System rapidly and accurately detects infectious pathogens and their associated drug resistance markers—without relying on time-consuming culture methods. Delivery of this time-critical information enables clinicians to provide targeted patient care more quickly, potentially leading to improved patient outcomes, lower costs, optimized antibiotic therapy, and reduced spread of antibiotic resistance. VERIGENE®'s ease of use and automation-friendly workflows make it a valuable system for use in both hospital-based and reference laboratories. Tests run on the VERIGENE® platform are designed to target infections in the bloodstream, respiratory tract, and gastrointestinal tract.

# LIAISON® PLEX

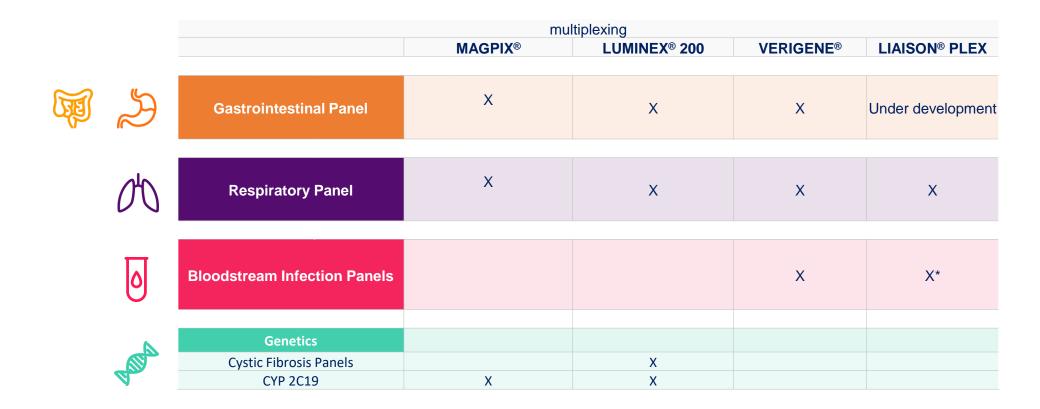
The LIAISON® PLEX System is a sample-to-answer molecular diagnostic platform capable of performing multiplex testing on a single sample. The system is fully-integrated and performs extraction, amplification, hybridization, and detection-all in one cartridge. Its proprietary *Flex*® Software enables users to test and pay only for the targets ordered by the clinician, with the option to unmask additional results as needed. This unique capability provides laboratories and clinicians with a cost-effective diagnostic tool that is designed to improve clinical outcomes.

### LIAISON® PLEX





# MAGPIX®, LUMINEX® 200, VERIGENE® and LIAISON® PLEX menu





<sup>\*</sup>The LIAISON PLEX® Blood Culture portfolio consists of 3 panels: LIAISON PLEX® Yeast Blood Culture Assay (U.S. FDA cleared); LIAISON PLEX® Gram-Negative Blood Culture Assay; LIAISON PLEX® Gram-Positive Blood Culture Assay.

# Our Licensed Technologies Systems









### **Licensed Technologies Group**

### MAIN APPLICATIONS

- Allergy Testing
- Neurodegenerative Disease
- Autoimmune Disease
- Biodefense/Environmental
- Cancer Markers
- Cardiac Markers
- Cellular Signaling
- Cytokines, Chemokines and Growth

### **Factors**

- Endocrine
- Gene Expression Profiling
- Genotyping
- HLA Testing
- Immunogenicity
- Infectious Disease
- Isotyping

- Metabolic Markers
- Neurobiology/Brain and Nervous System Markers
- Plant & Food Safety
- Sepsis Markers
- Transcription Factors/Nuclear Receptors
- Toxicology
- Vaccine Testing



# Licensed Technologies: Luminex xMAP INTELLIFLEX® platform



# Reliable, sensitive results Customization and flexibility Maximum data/answers

500 analytes per well; up to 2 parameters per analyte





Diasorin S.p.A. www.diasorin.com



