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# R&D AND INNOVATION

**Francesco Colotta** Senior Corporate VP and Chief Medical Officer

# IN VITRO DIAGNOSTICS: BASICS

**IN VITRO DIAGNOSTICS**

**DETECTION IN BIOLOGICAL FLUIDS...**

E.G.

**BLOOD, URINE, CSF,...**

**...OF A "MOLECULE" ...**

E.G.

**PROTEINS**

**NUCLEIC ACIDS**

**SMALL MOLECULES**

**IMMUNODIAGNOSTICS**

**MOLECULAR DIAGNOSTICS**

**CLINICAL CHEMISTRY**

**DETECTION BY ANTIBODIES...**

**DETECTION BY DNA...**

**DETECTION BY  
CHEMICAL REACTIONS**

**...BY A LIGHT-EMITTING MOLECULE**

**...BY A FLUORESCENCE-EMITTING  
MOLECULE**

**..."RELATED" TO A DISEASE**

**INFECTIOUS DISEASES**

**INFECTIOUS DISEASES**

**ELECTROLYTES**

**ONCOLOGY**

**ONCOLOGY**

**GLUCOSE**

**HORMONOLOGY**

**OTHERS**

**CHOLESTEROL**

**AUTOIMMUNITY**

**CARDIOLOGY**

**HEPATIC ENZYMES**

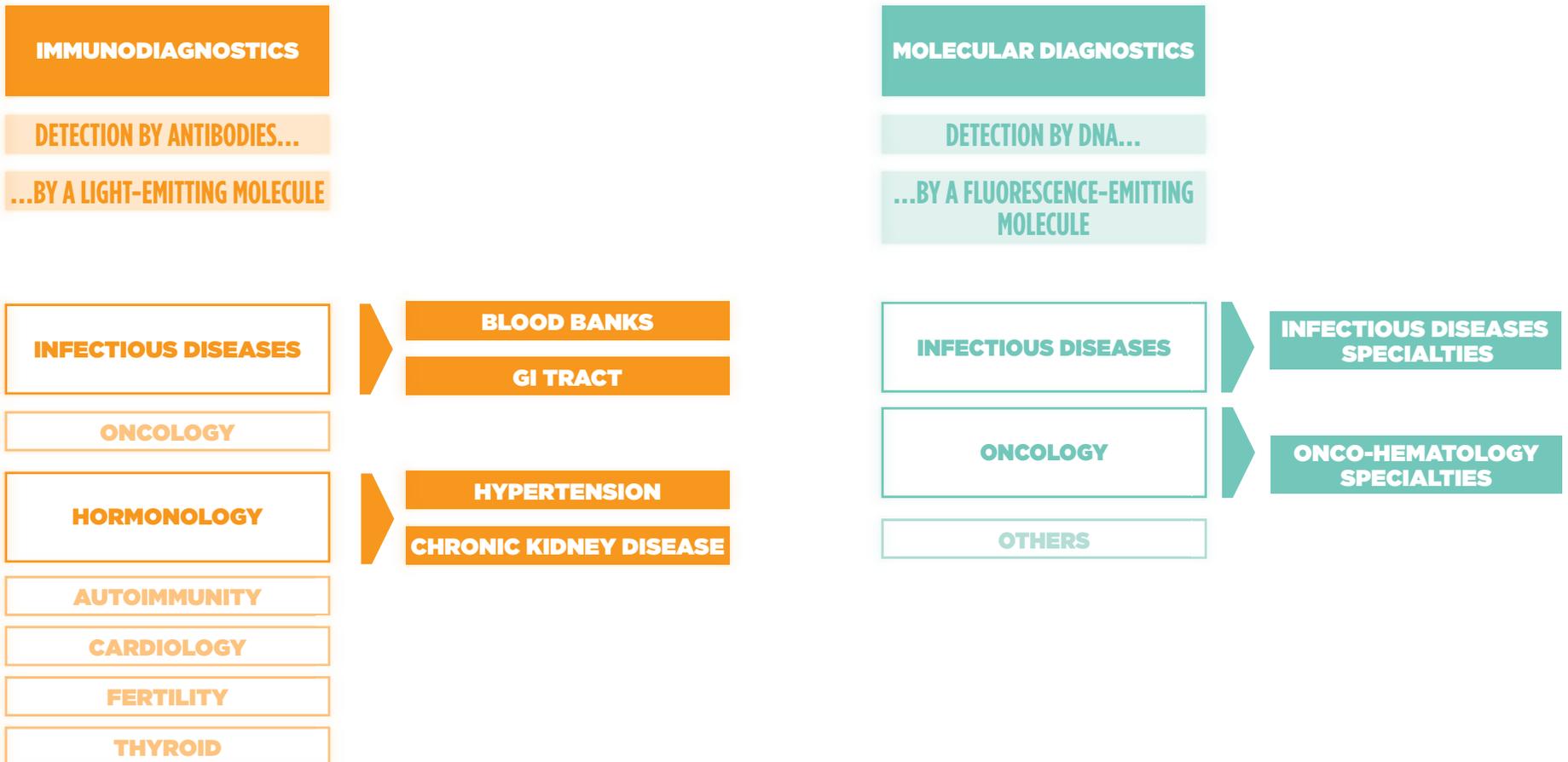
**FERTILITY**

**THYROID**

**OTHERS**

# AREAS TO BE A FRONT RUNNER IN LAB TESTING

- STRENGTHEN OUR LEADERSHIP IN IMMUNOASSAY
- BECOME A NEW PLAYER IN MOLECULAR DIAGNOSTIC



R&D STRATEGY BASED ON 2 LEGS: LEADERSHIP ON IMMUNOASSAY + MOLECULAR DIAGNOSTIC ENTRANCE

# BLOOD BANKS DEVELOPMENT PROGRAM

**LEVERAGE DIASORIN EXPERIENCE AND REPUTATION IN IDS**

**LEVERAGE DIASORIN FULL MENU AVAILABILITY**

**T. pallidum**

**HBsAg**

**HCV**

**HIV**

**HTLV I-II**

**Chagas**

**HIV HT**

**BLOOD  
BANKS**

**LIAISON XL**

 In development

# NEW AUTOMATED SYSTEM IN STOOL TESTING

**SET UP OF OPTIMAL ASSAY CONDITIONS  
WITH LIAISON AND LIAISON XL**



**COMPANION ONE-STEP SIMPLE SAMPLE  
PREPARATION DEVICE**

## GI INFECTIONS

C. DIFFICILE TOXINS A&B

ENTEROHEMORRAGIC E. COLI

C. DIFFICILE GDH

ROTAVIRUS

H. PYLORI

ADENOVIRUS

## GI INFLAMMATORY/AUTOIMMUNE DISEASES

CALPROTECTIN

LACTOFERRIN

LIPASE

## FECAL OCCULT BLOOD



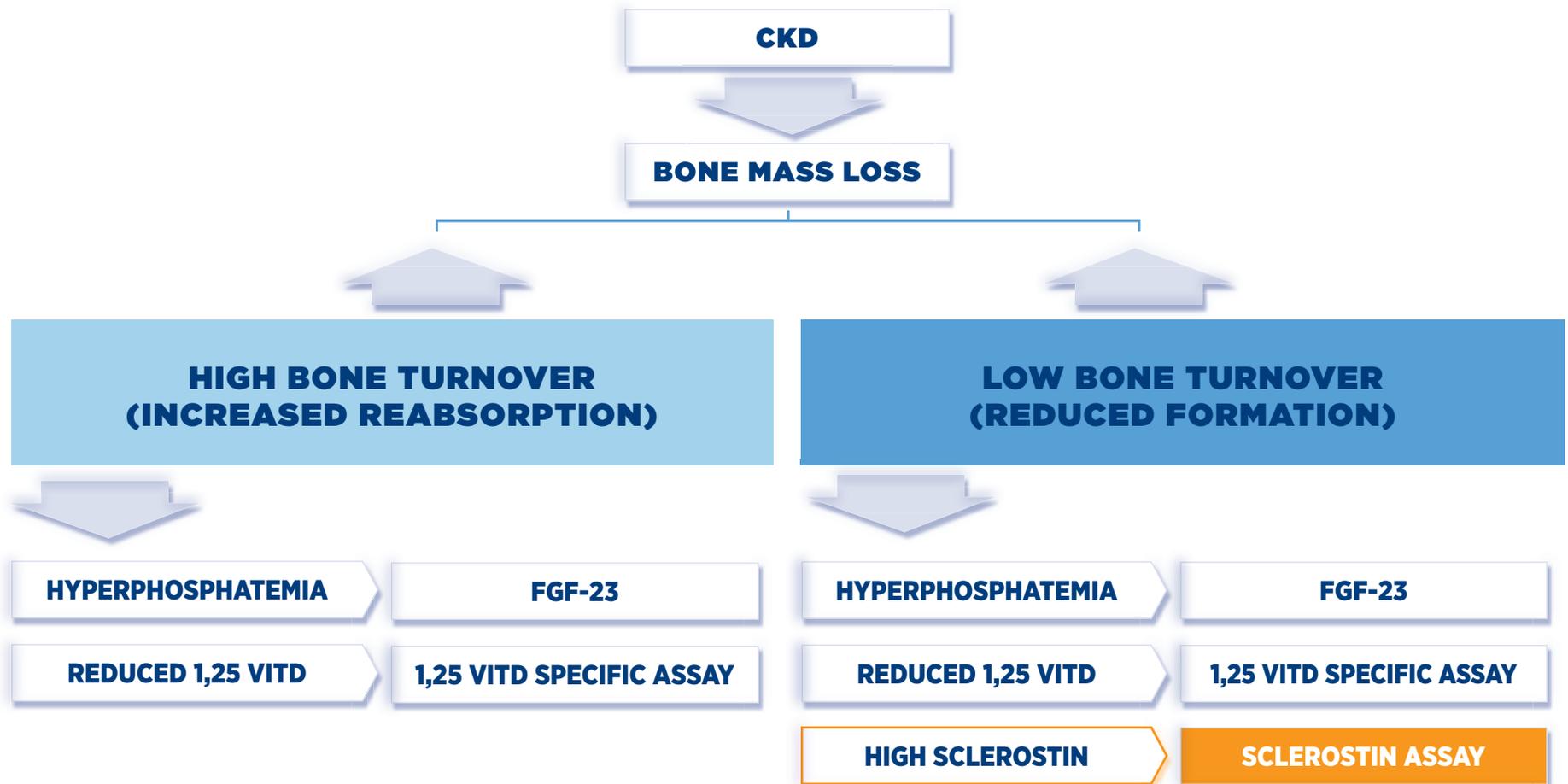
**LIAISON® STOOL  
CLEAN-UP DEVICE**

**DEVELOP AN INNOVATIVE IMMUNODIAGNOSTIC CHEMILUMINESCENT SYSTEM CHARACTERIZED BY:**

- **BIOLOGICAL MATRIX CURRENTLY POORLY AUTOMATED**
- **WIDE APPLICABILITY**
- **INTEGRABLE WITH MOLECULAR DIAGNOSTICS**

# LEVERAGE ON BONE METABOLISM FRANCHISE

## CHRONIC KIDNEY DISEASE (CKD) AND BONE METABOLISM



# HYPERTENSION: A FULL PANEL ON LIAISON SYSTEMS

DIASORIN MENU: A UNIQUE OFFER FOR THE DETECTION OF THE KEY HYPERTENSION MARKERS ON A FULLY AUTOMATED PLATFORM

## DIFFERENT "TYPES" OF HYPERTENSION

RENOVASCULAR HYPERTENSION

RENIN-SECRETING TUMORS

HIGH RENIN ESSENTIAL HYPERTENSION

LOW RENIN ESSENTIAL HYPERTENSION

PHEOCHROMOCYTOMA

PRIMARY ALDOSTERONISM

DRUGS-INDUCED HYPERTENSION

Renin and aldosterone are differentially expressed in each specific hypertension-inducing condition



To discriminate which clinical condition is inducing hypertension in the patient, both **RENIN** and **ALDOSTERONE** must be measured

## DIASORIN STRATEGY TO PLAY THE MOLECULAR DIAGNOSTIC MARKET

# THE 3 KEY DECISIONS

AMPLIFICATION TECHNOLOGY

**LAMP**

AUTOMATED NA AMPLIFICATION  
AND DETECTION INSTRUMENT

**LIAISON IAM**

NAT MENU

**INFECTIOUS DISEASES  
AND ONCOHEMATOLOGY  
TESTS**

# LAMP TO DEVELOP A SPECIALTY MENU IN NAT

**DIASORIN LICENSED LAMP (LOOP-MEDIATED ISOTHERMAL AMPLIFICATION) TECHNOLOGY FROM EIKEN CHEMICAL COMPANY LTD IN 2008: THE DIFFERENTIATION FACTOR IN ONCO-HEMATOLOGY FUTURE MENU**

## **DIASORIN LAMP grants:**

**HIGHER SENSITIVITY**

**HIGHER SPECIFICITY**

**SIMPLER REACTION SET-UP**

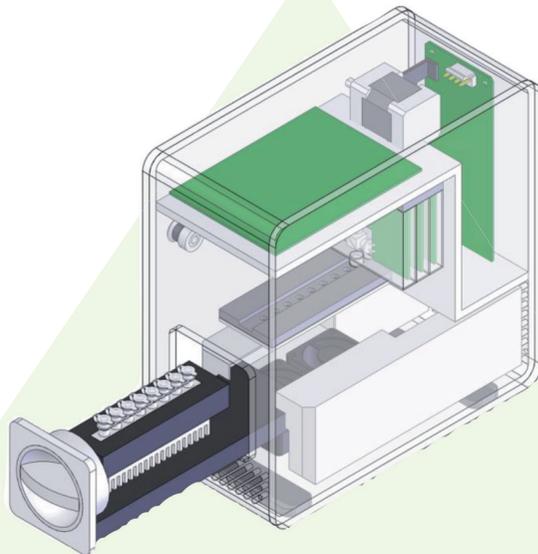
**SHORTER TIME-TO-RESULT**

**CHEAPER PRICE**

# LIAISON IAM: A SMALL AUTOMATED ANALYZER

**DIASORIN SIGNED AN AGREEMENT WITH PRECISION SYSTEM SCIENCE CO. LTD OF JAPAN (PSS) FOR THE DEVELOPMENT OF A NUCLEIC ACID TEST (NAT) ANALYZER**

## Liaison Instant Amplification Molecular (IAM)



### CLIENTS

DIASORIN MICROBIOLOGY CUSTOMERS  
DIASORIN SPECIALITIES SEROLOGY CUSTOMERS  
CUSTOMERS ALREADY USING VALIDATED EXTRACTION METHOD

### FEATURES

- **SMALL:** BENCH TOP, 150(w) X 300(h) X 300(d), <6kg
- **FAST:** REAL TIME; ONE RUN <60MIN.
- **PRECISE:** FLUORESCENCE QUANTITATION
- **FLEXIBLE:**
  - **THROUGHPUT:** FROM 1 TO 8 REACTIONS/INSTRUMENT; UP TO 48 REACTIONS (WITH 6 INSTRUMENTS)
  - **RANDOM ACCESS:** BY USING DIFFERENT INSTRUMENTS
  - **MULTIPLEX CAPABILITY:** 3 FLUORESCENT DYES
  - DIFFERENT ASSAYS CAN BE PERFORMED IN THE SAME RUN
- **FULL TRACEABILITY:** BAR CODE READER USE FOR SAMPLER AND REAGENTS
- **CONNECTIVITY:** TO LIS
- **CLOSED SYSTEM:** FOR ONLY ISOTHERMAL LAMP REACTION
- **LOW RISK OF CONTAMINATION:** PLASTIC STRIP CAN'T BE RE-OPENED AFTER CLOSURE
- **EASY TO USE:** INTUITIVE SOFTWARE

DIASORIN DEVELOPING ITS NAT ANALYZER, FOCUSED ON SPECIALTY TESTS

# NAT MENU: FOCUS ON SPECIALTIES

**LEVERAGE DIASORIN EXPERIENCE AND REPUTATION IN INFECTIOUS DISEASES**

## **INFECTIOUS DISEASES SPECIALTIES**

**EPSTEIN-BARR VIRUS (EBV)**

**CYTOMEGALOVIRUS (CMV)**

**PARVOVIRUS (PARVO)**

**TOXOPLASMOSIS (TOXO)**

**BK VIRUS (BKV)**

**VARICELLA ZOSTER VIRUS (VZV)**

**PROVIDE THE SPECIALIST WITH A COMPLETE PANEL**

## **ONCO-HEMATOLOGY SPECIALTIES**

**MYELOPROLIFERATIVE NEOPLASMS (MYELO NEOPL)**

**ACUTE LYMPHOBLASTIC LEUKEMIA (ALL)**

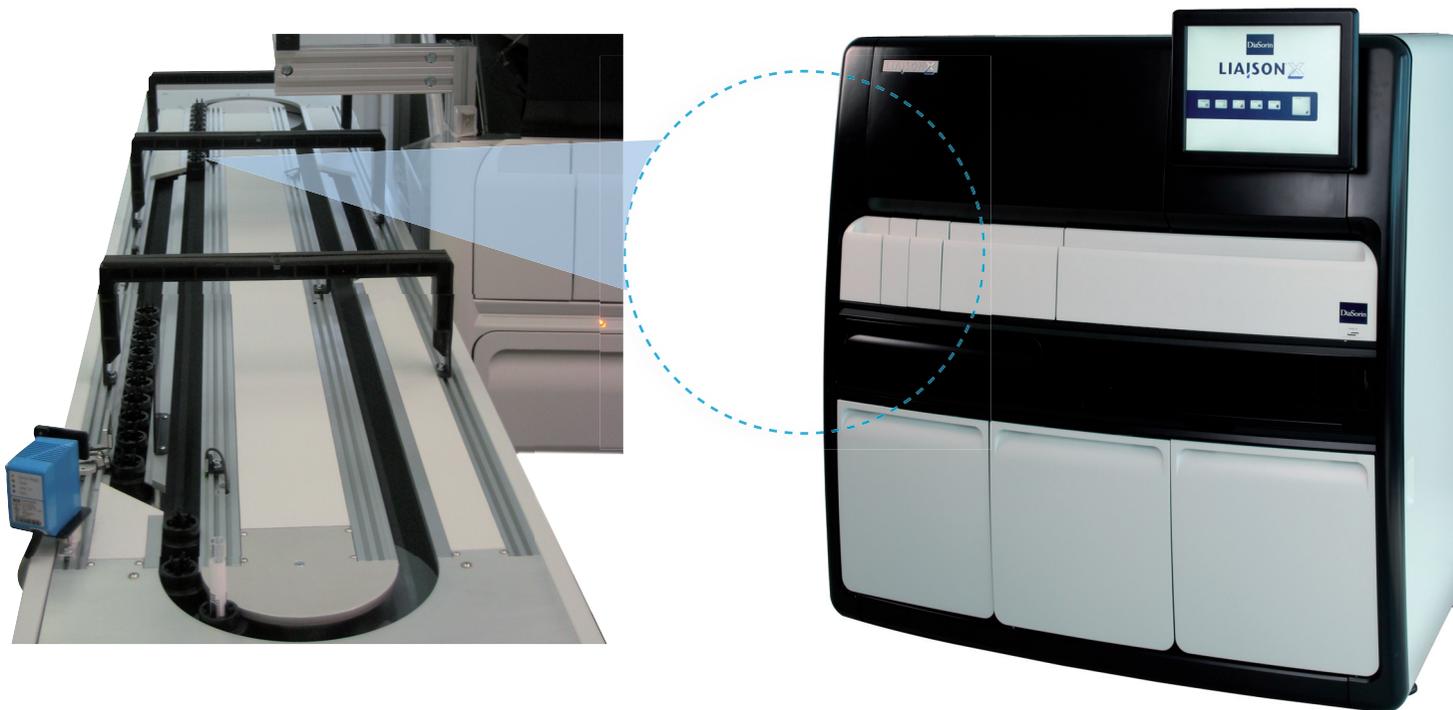
**ACUTE MYELOID LEUKEMIA (AML)**

**ACUTE PROMYELOCITIC LEUKEMIA (APL)**

**CHRONIC MYELOID LEUKEMIA (CML)**

# LAS CONFIGURATION AND LIAISON XL

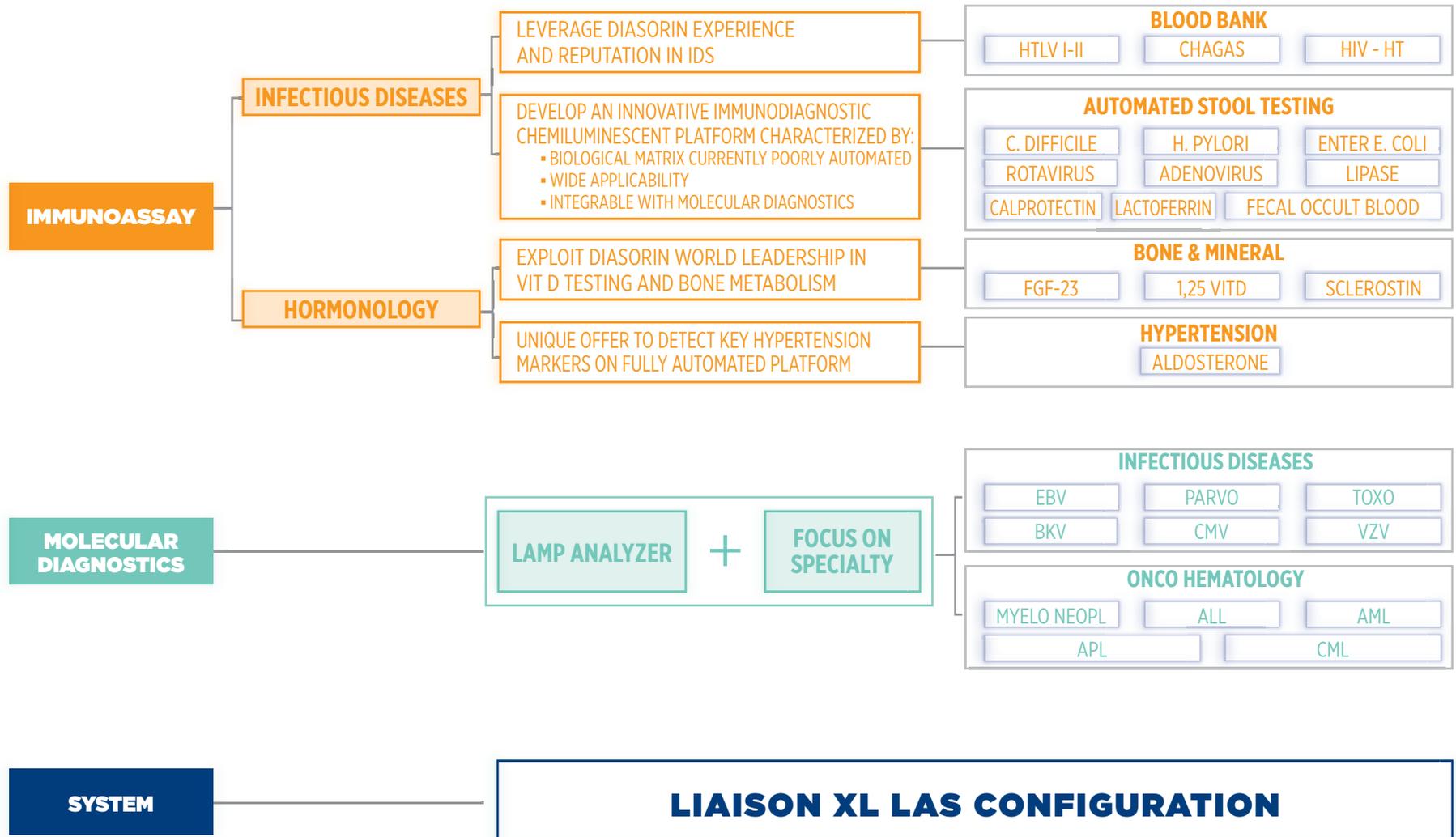
**LAS BRINGS LIAISON XL INTO THE MOST ADVANCED, HIGH THROUGHPUT AND AUTOMATED DIAGNOSTIC LABS, TO FULFILL FLEXIBILITY AND EFFICIENCY OF THE NEW ANALYZER**



## **DEVELOPMENT PLAN:**

- **UPGRADE SW AND HW TO INTEGRATE LIAISON XL INTO AUTOMATED PATIENT SAMPLE PROCESSING: LABORATORY AUTOMATION SYSTEM (LAS)**
- **PROTOTYPE SW AND HW READY**

# DIASORIN: R&D PIPELINE 2011 - 2015



AN IMPORTANT R&D PIPELINE TO ADDRESS OPPORTUNITIES AND ENFORCE OUR RECOGNITION AS THE DIAGNOSTIC SPECIALIST