

# Our new opportunity: **Molecular Diagnostics**



## **Analyst Day**

**October 2012**

**10** Wed **Dublin**

**DiaSorin**

The Diagnostic Specialist

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# Q-LAMP

the 2<sup>nd</sup> Generation LAMP,  
Isothermal Evolution  
in Molecular Diagnostics

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

# AIM OF THE PRESENTATION

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**A**

Q-LAMP technology:

- **HIGHLY PERFORMING**
- **SIMPLE WORKFLOW**
- **FAST TIME TO RESULTS**
- **COST SAVING**

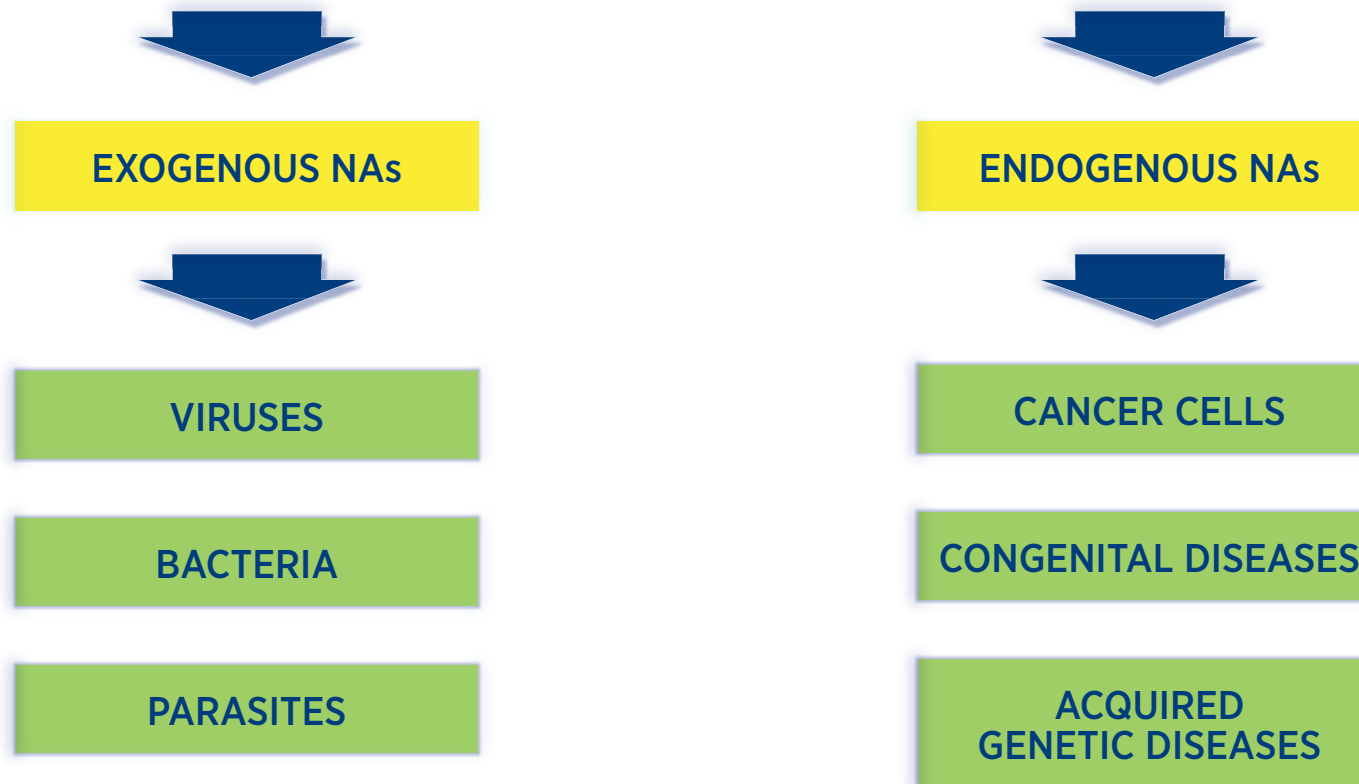
**B**

Strategic directions for:

- **NEXT WAVES OF PRODUCTS**
- **INSTRUMENTS**
- **CONSOLIDATED OFFER TO CUSTOMERS**

# HUMAN MOLECULAR DIAGNOSTICS

## DETECTING NUCLEIC ACIDS (NAs) IN THE HUMAN BODY





# DNA

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# EBV SPECIFIC DNA STRETCH

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**GAGAACATTGCAGAAGGTTTAAGACTTCTC**



# MOLECULAR DIAGNOSIS OF EBV

**GAGAACATTGCAGAAGGTTTAAGACTTCTC**



**GAGAACATTGCAGAAGGTTTAAGACTTCTC**  
GAGAACATTGCAGAAGGTTTAAGACTTCTC  
GAGAACATTGCAGAAGGTTTAAGACTTCTC  
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GAGAACATTGCAGAAGGTTTAAGACTTCTC  
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GAGAACATTGCAGAAGGTTTAAGACTTCTC



**INFECTED**

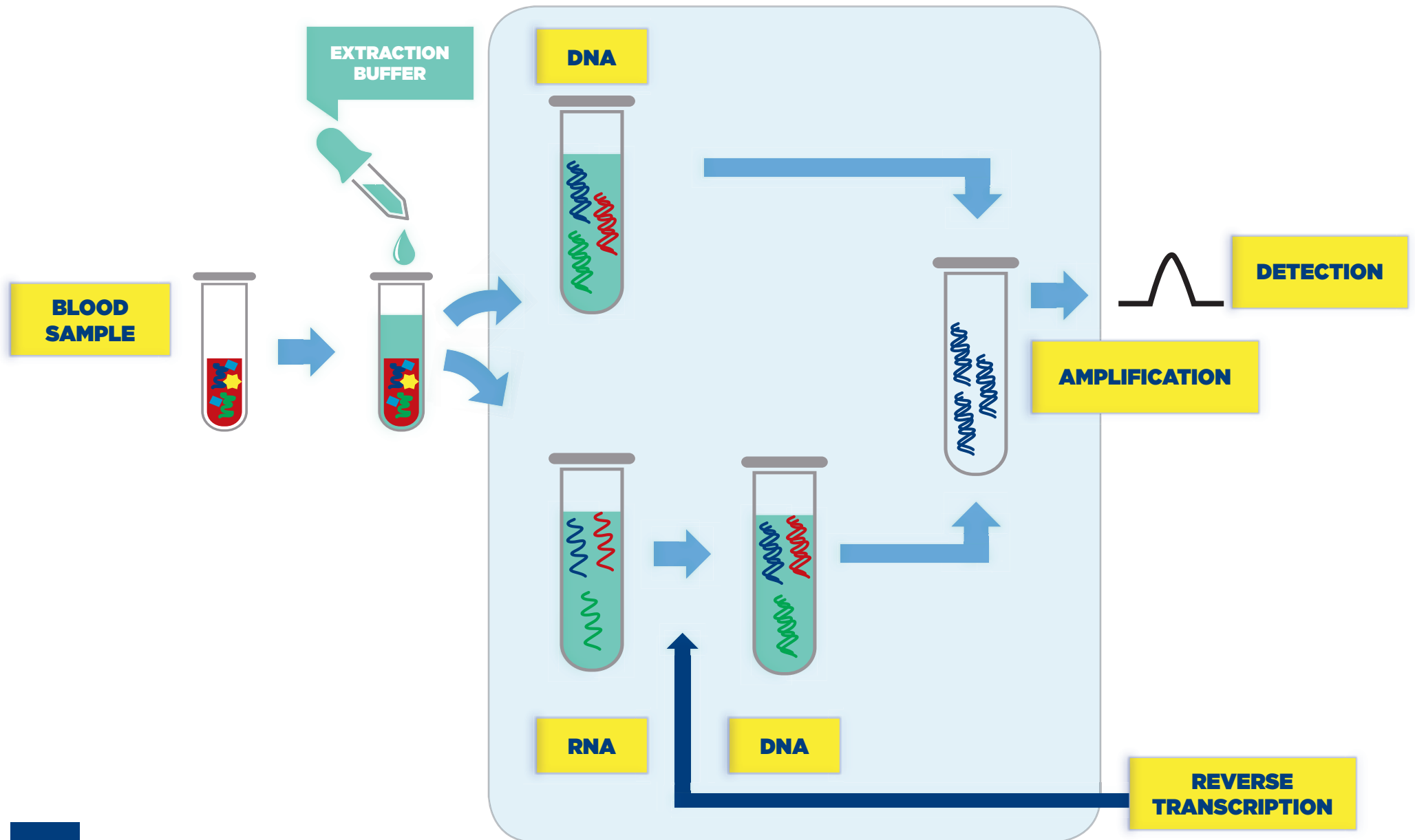


**NO AMPLIFICATION**

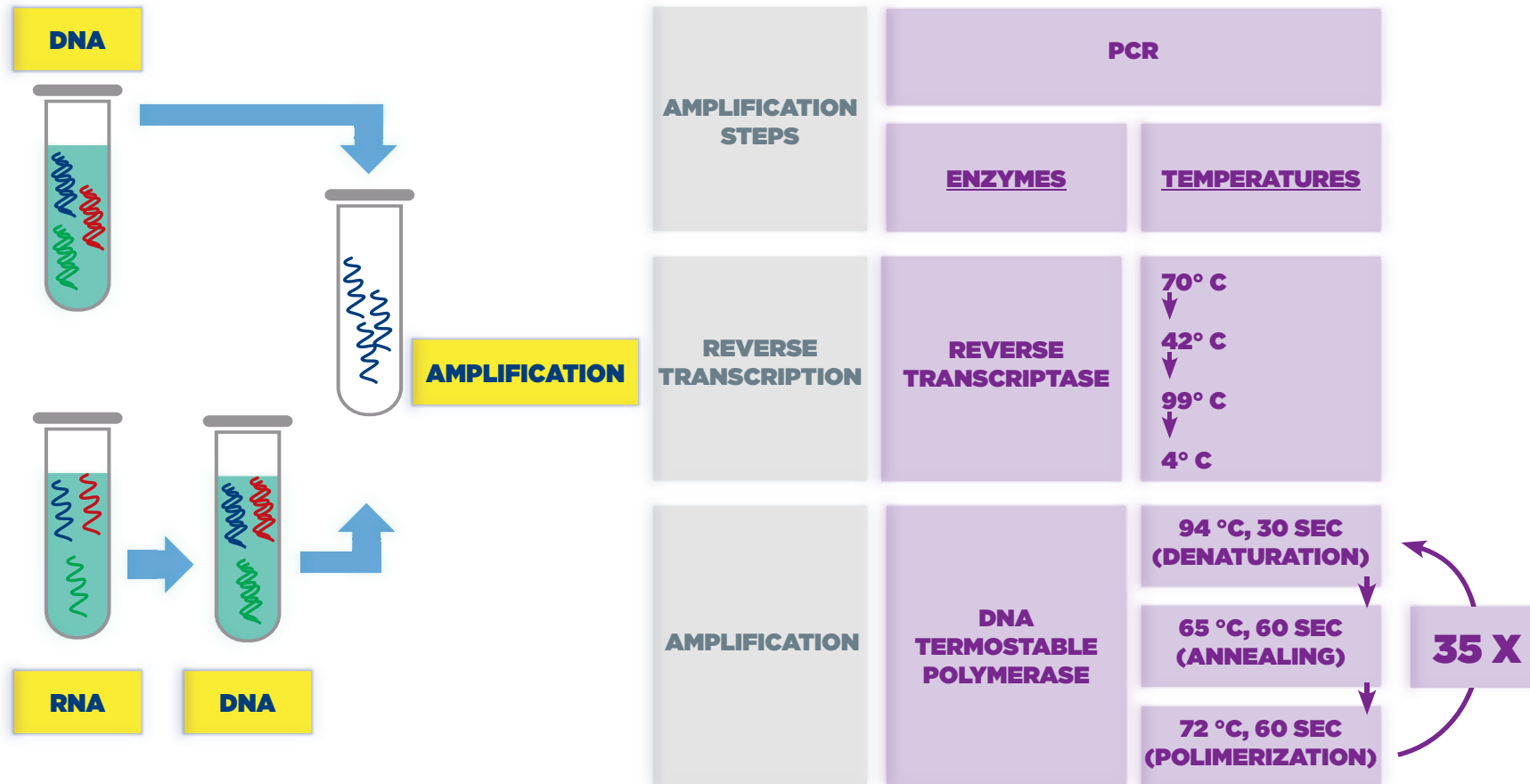


**HEALTHY**

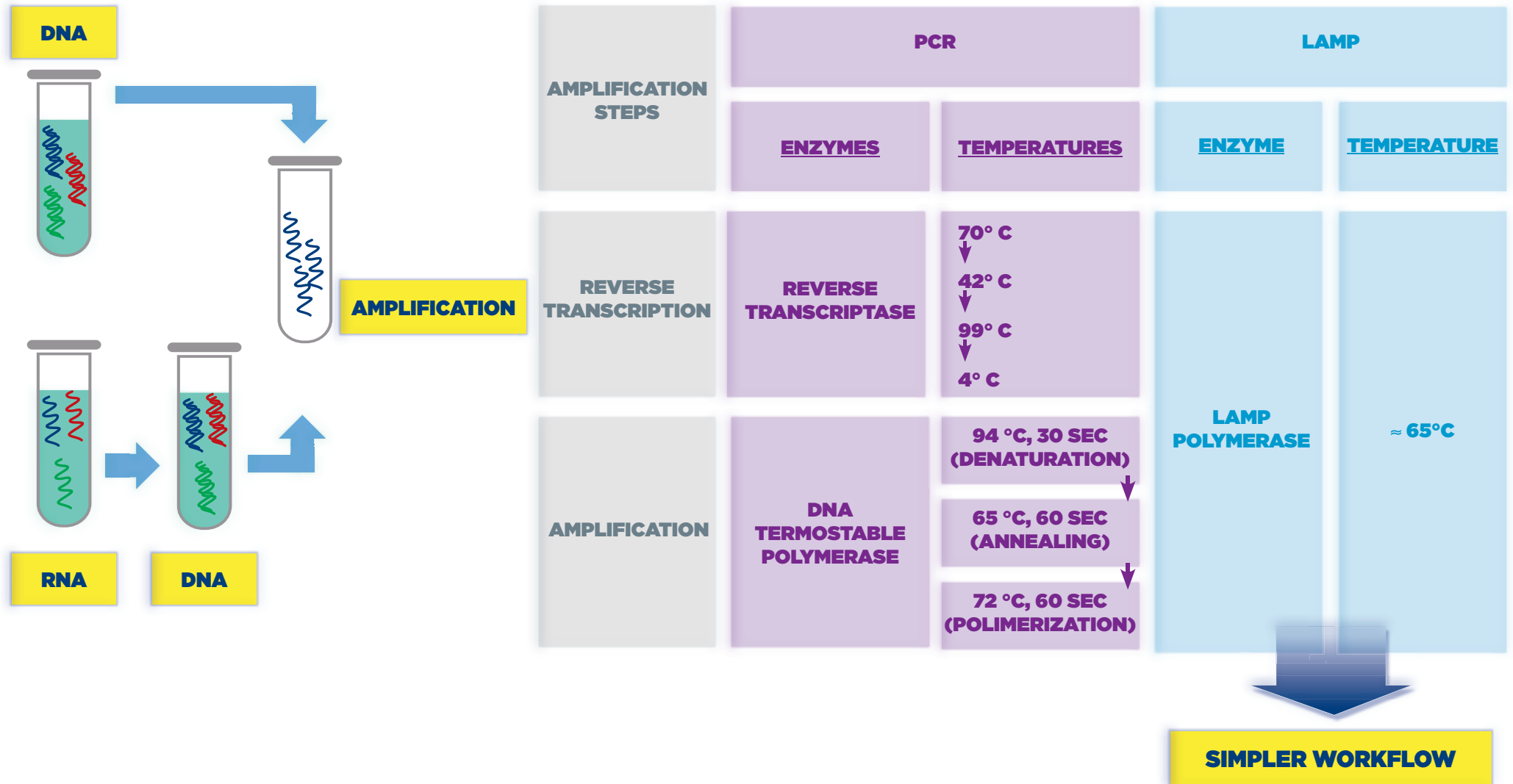
# EXTRACTION AND AMPLIFICATION



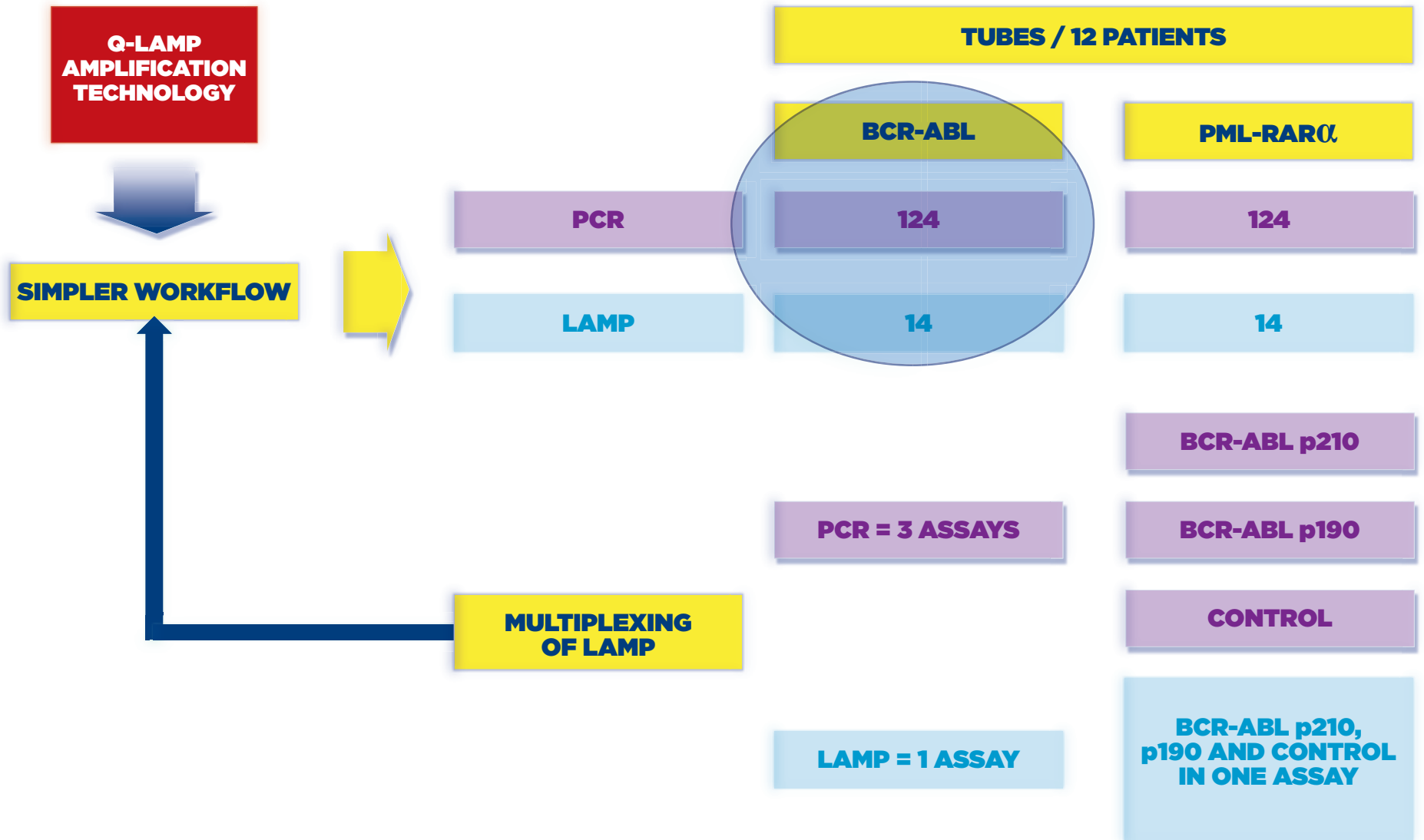
# AMPLIFICATION W/ PCR



# AMPLIFICATION W/ PCR AND LAMP

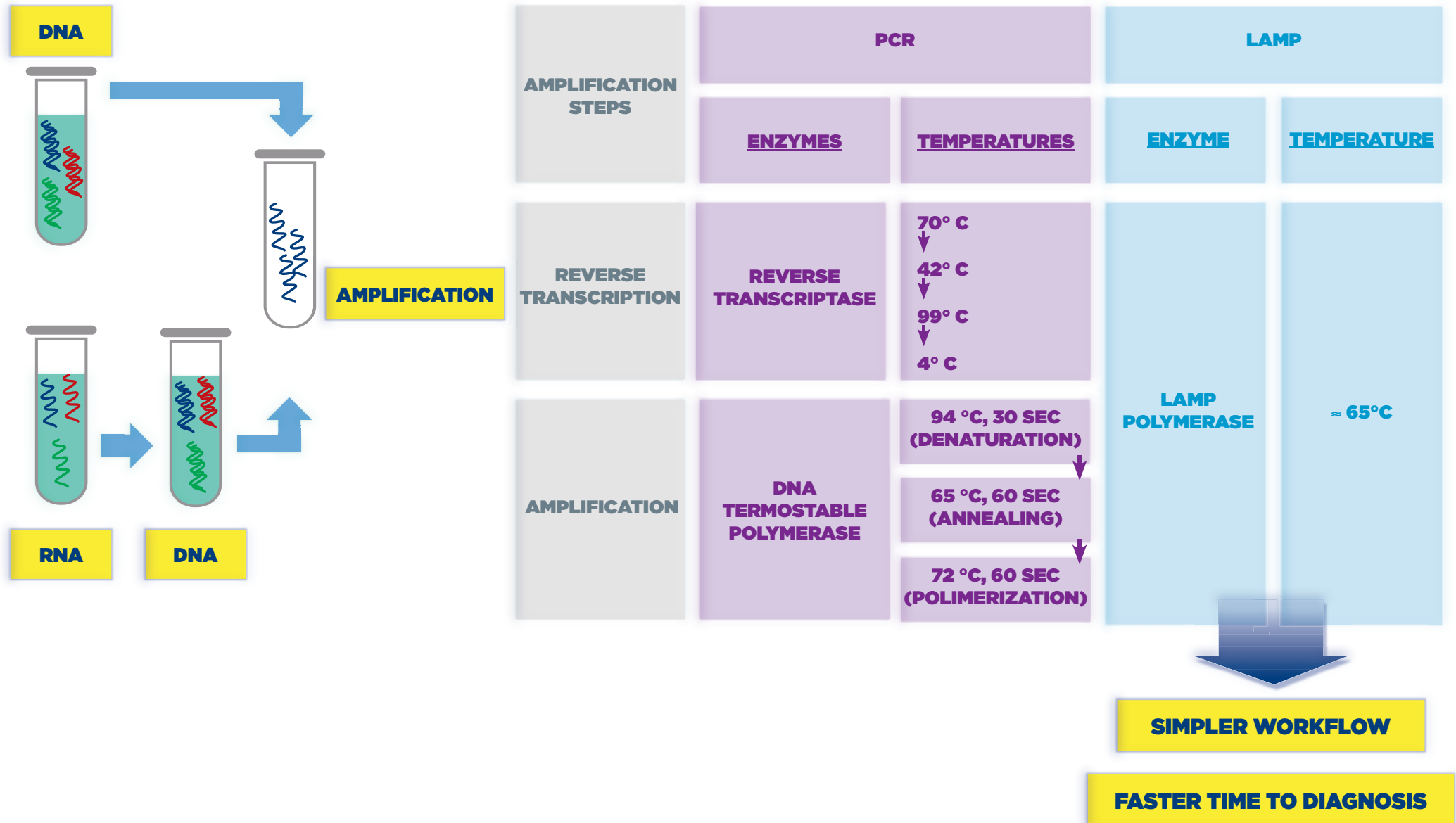


# MULTIPLEXING OF LAMP

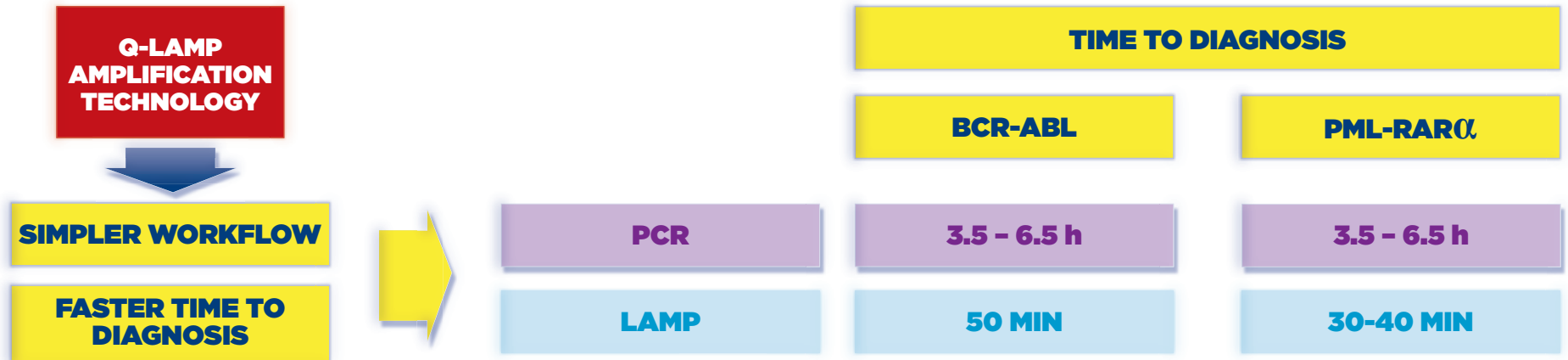




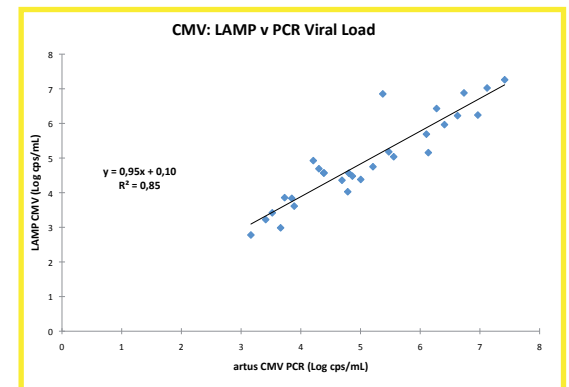
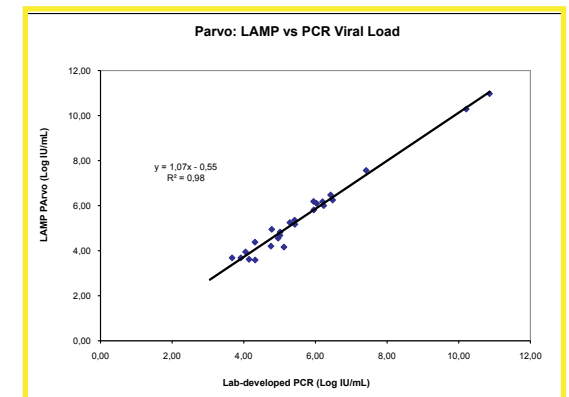
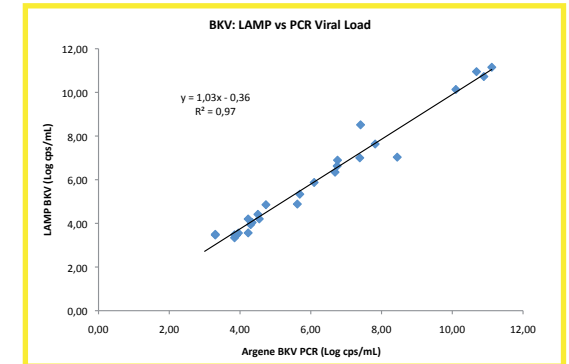
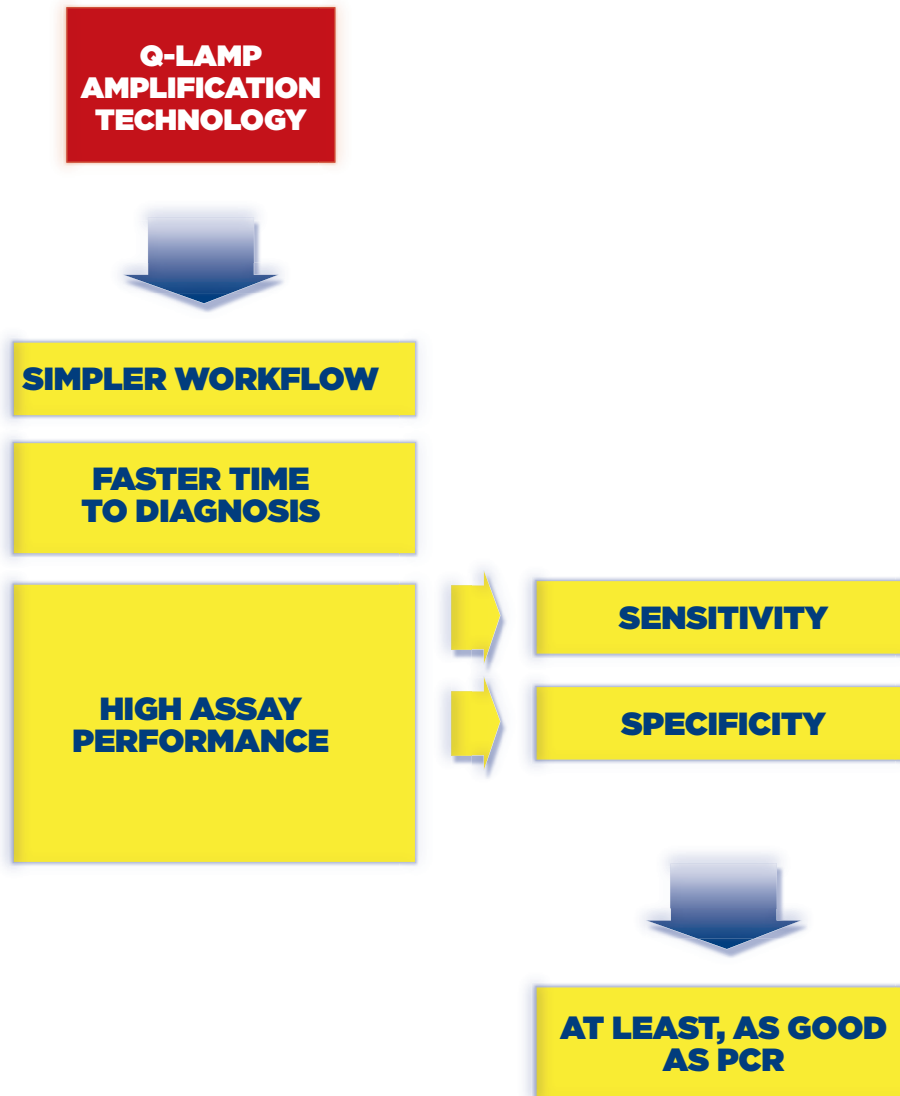
# AMPLIFICATION W/ PCR AND LAMP



# RAPIDITY OF TIME TO DIAGNOSIS



# ASSAY PERFORMANCE - IDs



# ROBUSTNESS TO MATRIX INHIBITORS

**Q-LAMP  
AMPLIFICATION  
TECHNOLOGY**



**SIMPLER WORKFLOW**

**FASTER TIME  
TO DIAGNOSIS**

**HIGH ASSAY  
PERFORMANCE**



**SENSITIVITY**

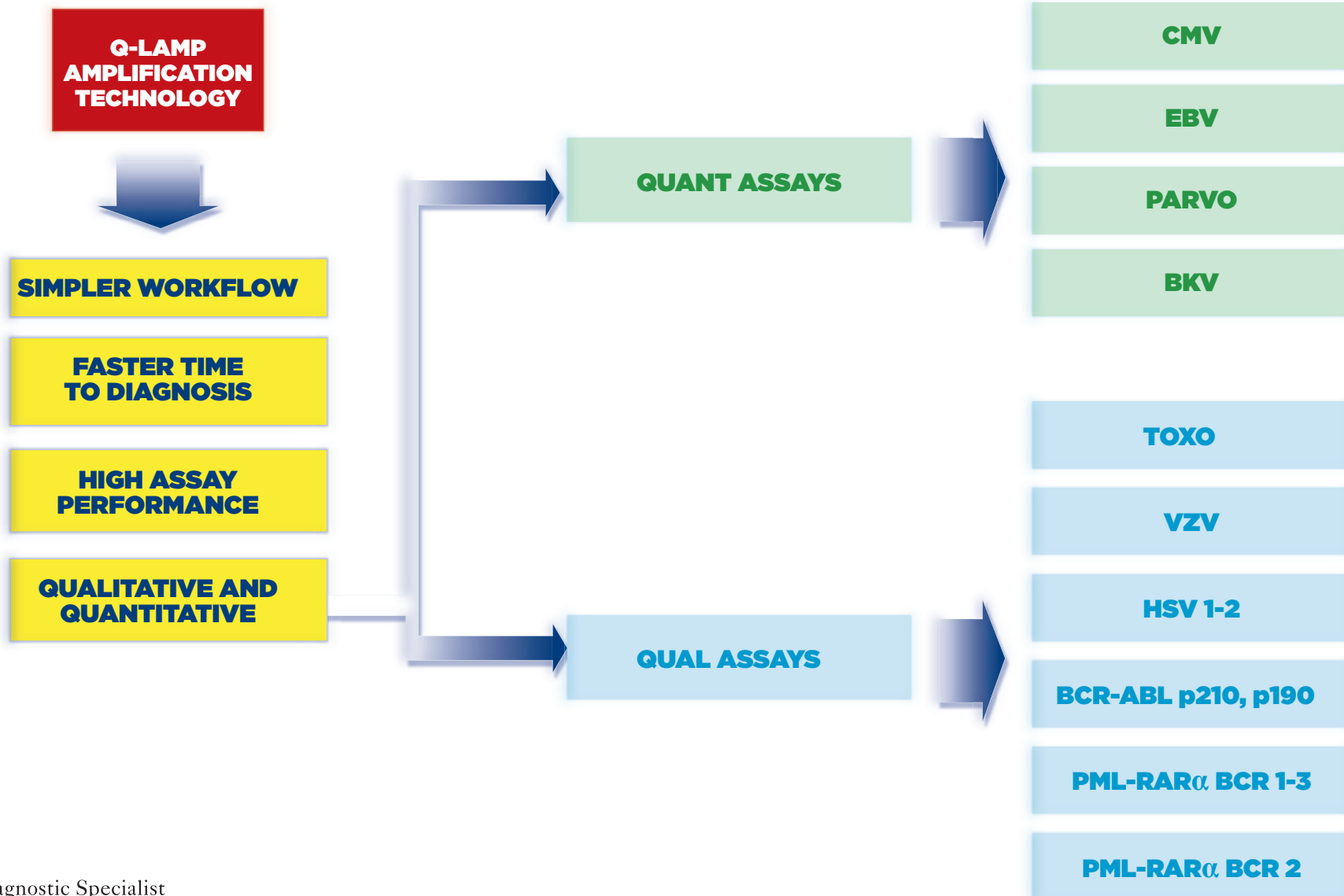
**SPECIFICITY**

**ROBUSTNESS**

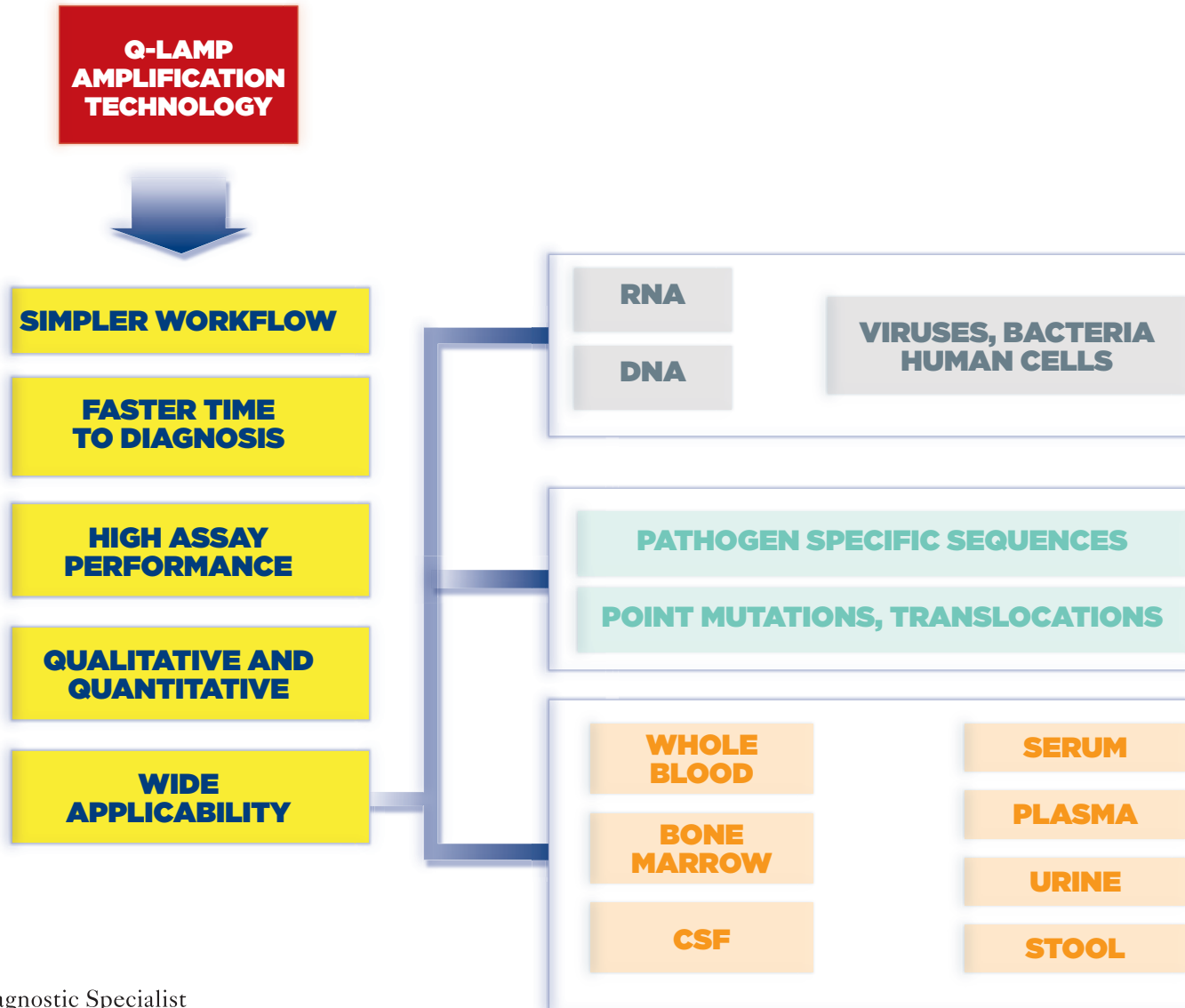
**2 PATIENTS REQUIRED PRE-TREATMENT WITH HEPARINASE TO BE DETECTED BY PCR.  
THIS PRE-TREATMENT WAS NOT REQUIRED FOR DETECTION BY LAMP.**

		<b>HOME BREW PCR (BIOMED)</b>	
		<b>+</b>	<b>-</b>
<b>LAMP BCR-ABL</b>	<b>+</b>	79	0
	<b>-</b>	0	54
<b>AGREEMENT</b>		<b>100%</b>	<b>100%</b>

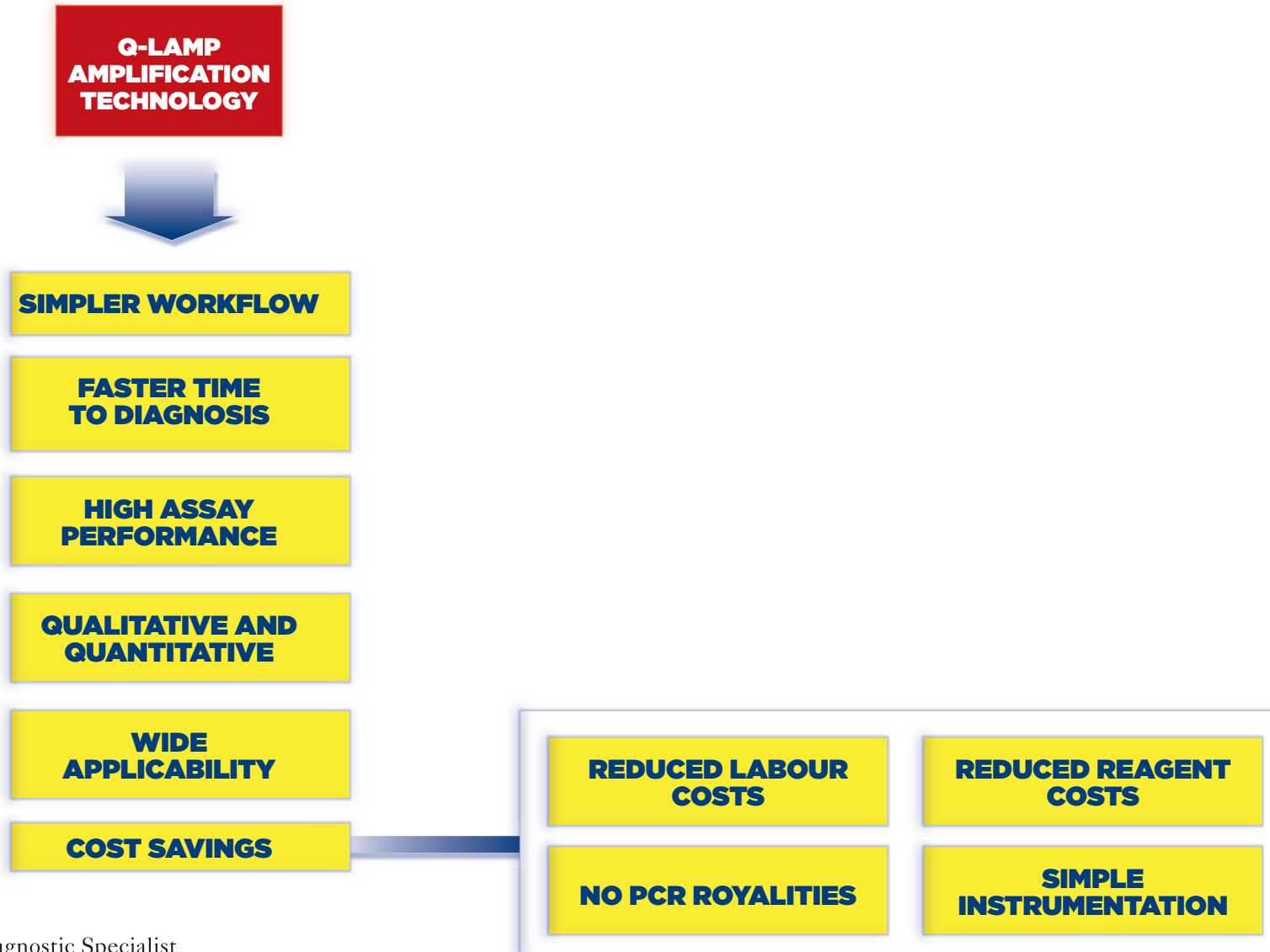
# AMENABLE TO QUALITATIVE AND QUANTITATIVE ASSAYS



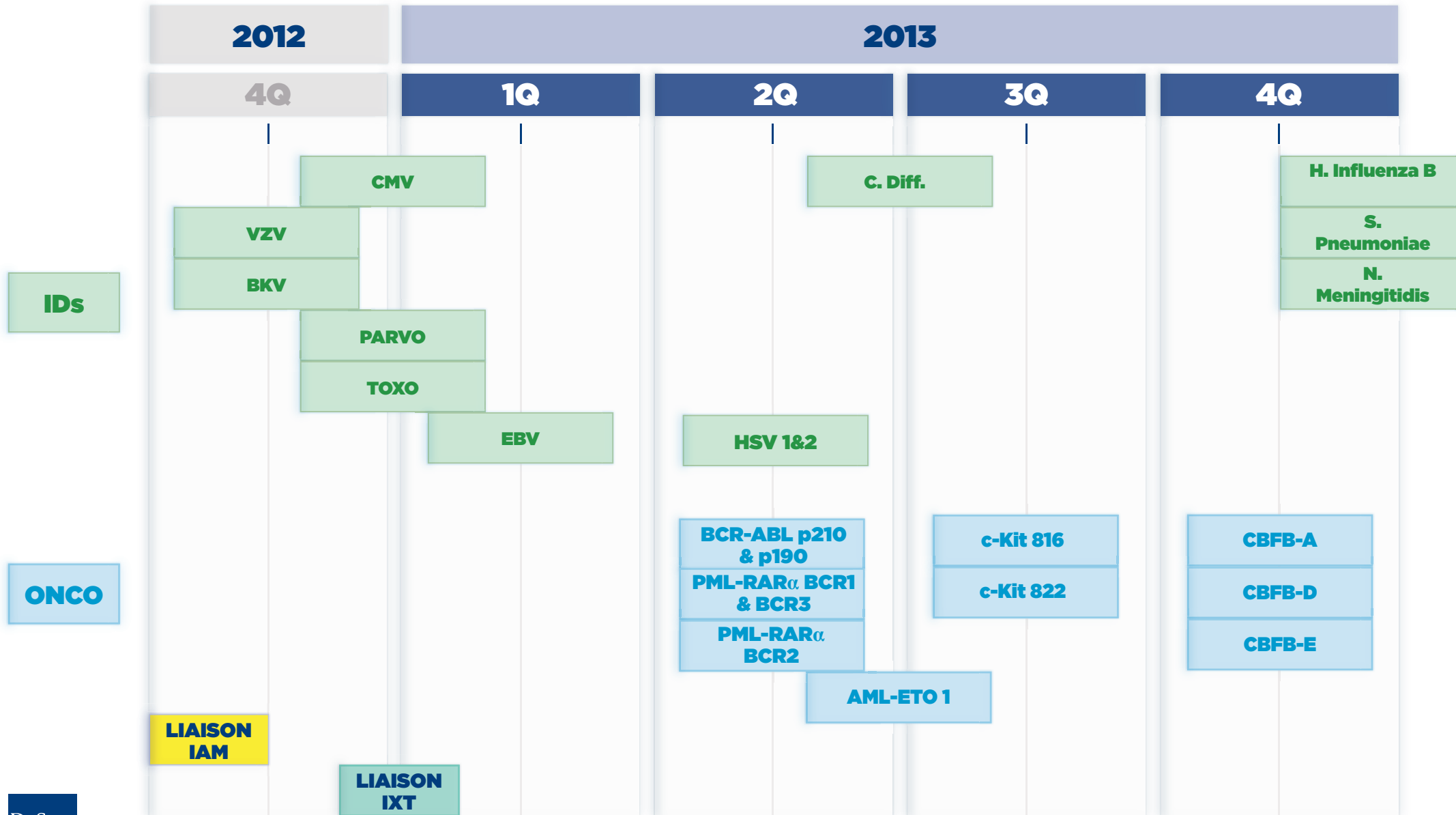
# WIDE APPLICABILITY



# ALLOWING COST SAVINGS FOR LABS



# MOLECULAR DIAGNOSTICS PRODUCT PORTFOLIO





# LIAISON<sup>®</sup> *Iam* : GETTING THE BEST OUT OF LAMP

- ▶ SMALL BENCH TOP INSTRUMENT
- ▶ VERY ACCURATE TEMPERATURE CONTROL
- ▶ THREE DETECTION CHANNELS (GREEN, YELLOW, ORANGE)
- ▶ TWO ALTERNATIVE DETECTION MODES:
  - MULTIPLEX FLUORESCENCE
  - ANNEALING ANALYSIS
- ▶ SAFE PLASTIC STRIP-TUBES



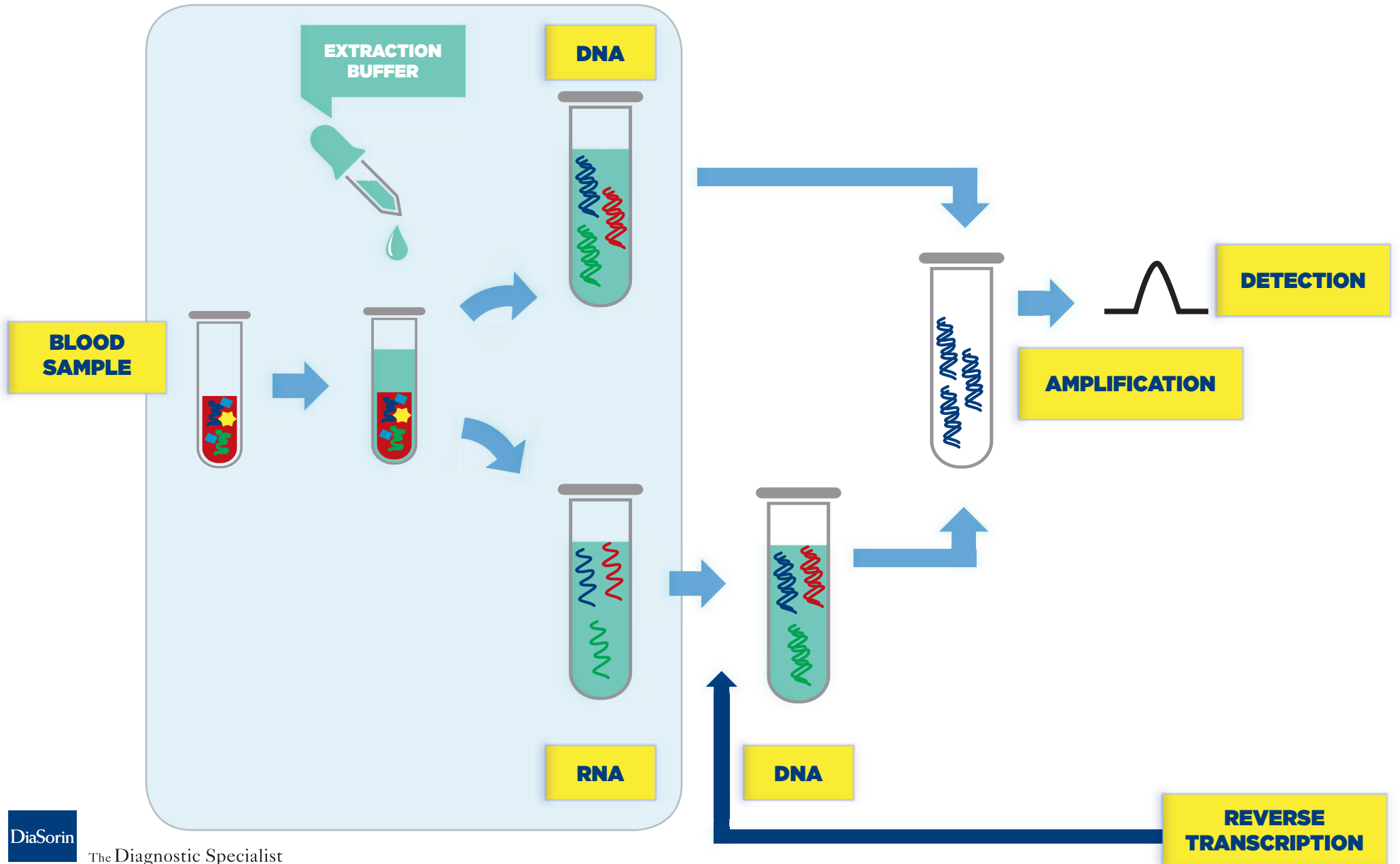
# LIAISON<sup>®</sup> Jam : GETTING THE BEST OUT OF LAMP



## ▶ A DEDICATED SOFTWARE EASY TO USE AND LOADED WITH FEATURES

- AUTOMATED DATA ANALYSIS
- BARCODE READER TO TRACE REAGENTS AND SAMPLES
- CONNECTIVITY TO LIS
- CONNECTIVITY OF UP TO 6 INSTRUMENTS
- USER FRIENDLY REPORT GENERATION

# EXTRACTION AND AMPLIFICATION

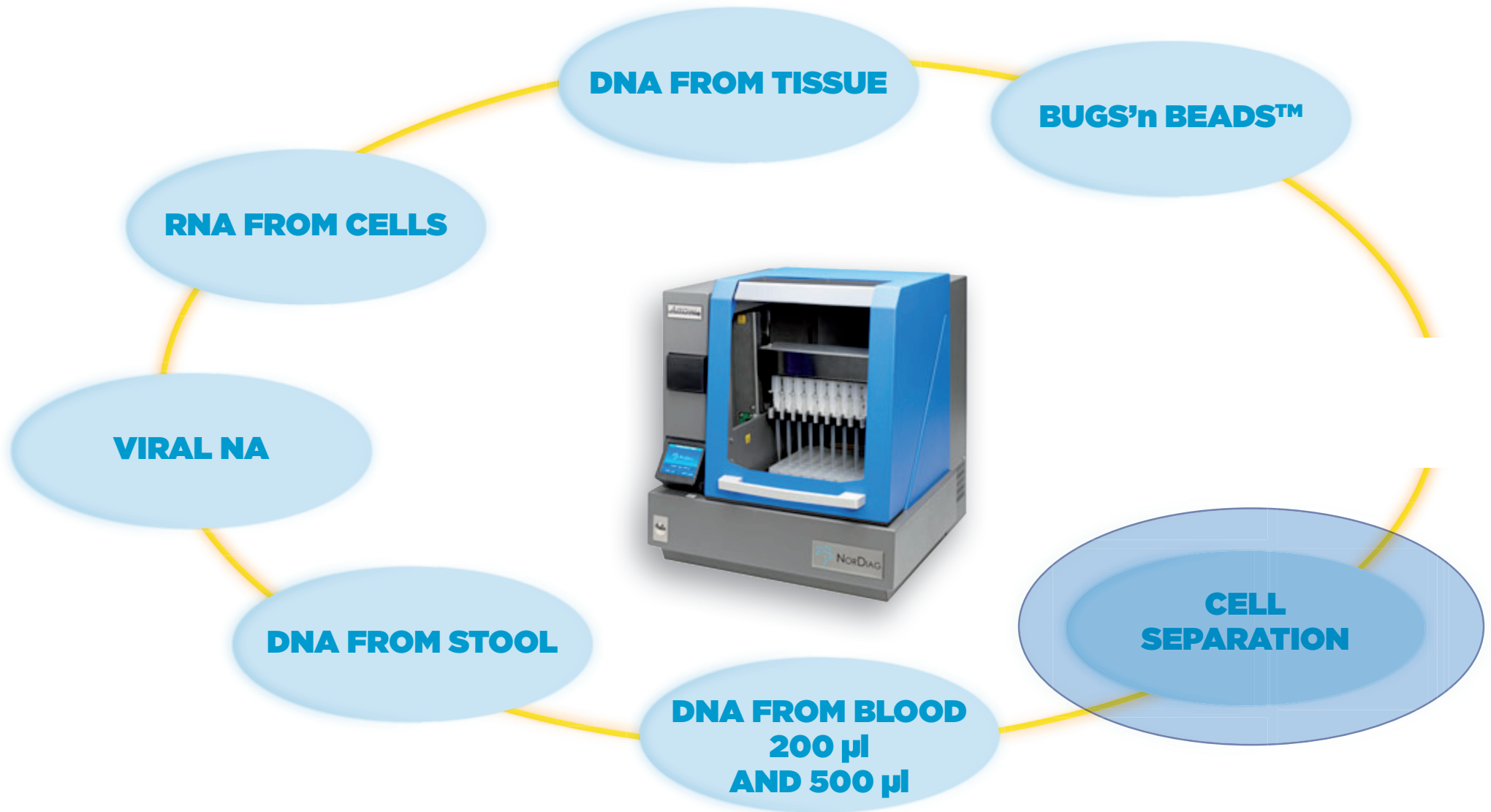


# LIAISON<sup>®</sup> *Ixt* MAKING EXTRACTION SIMPLE



- NOVEL PIPETTING SYSTEM
- UV STERILIZATION
- 1-12 SAMPLES PROCESSED WITH PREFILLED REAGENTS
- COST EFFECTIVE
- WIDE RANGE OF SAMPLE TYPES
- EASE OF USE

# LIAISON IXT - AVAILABLE TESTS



# CONCLUSIONS - TODAY

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## ▶ **DiaSorin Q-LAMP technology made:**

- **Simple**
- **Fast**
- **Highly performing**
- **Quantitative**
- **Cost convenient**

## ▶ **DiaSorin LAMP characteristics adequate to support a business model focused on decentralized Labs**

### ▶ **1<sup>st</sup> wave:**

- **7 kits in IDs**
- **3 kits (detecting 5 molecular markers) in Onco-Hematology**
- **Automated DNA extraction and Cell separation instrument and kits (Liaison Ixt)**
- **Automated LAMP amplification and detection instrument (Liaison Iam)**

# CONCLUSIONS - TOMORROW

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## Growth

- **30 molecular products by 2015**
- **New automated and integrated instrument for NA extraction and amplification**
- **New cell separation kits targeting HLA labs on Liaison IXT**

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# Molecular Diagnostics A Market Perspective & Opportunity

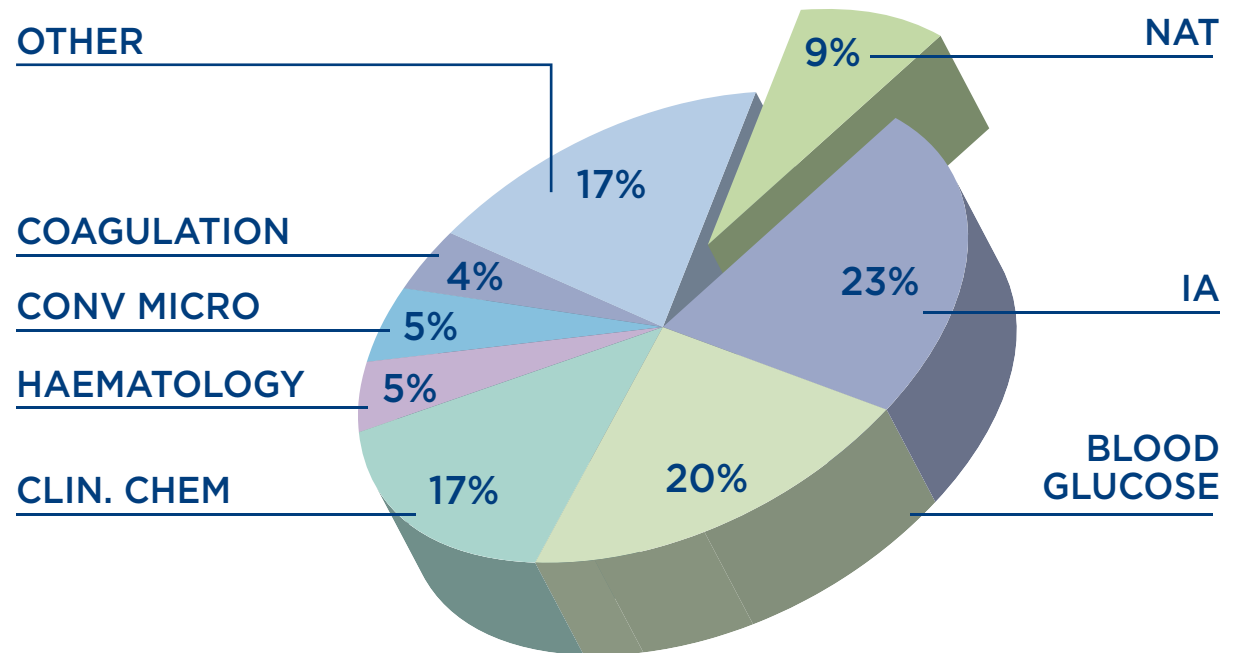
**Paul Eros** Global VP Marketing Molecular



# MOLECULAR DIAGNOSTICS MARKET OVERVIEW

- ▶ In 2011 the MDx IVD market grew 11% to \$4.1 billion
- ▶ Continued strong growth expected
- ▶ MDx is the fastest growing segments in the In Vitro Diagnostics market
- ▶ Health care reforms embracing innovative molecular technologies in targeted disease areas (e.g. Cancer, Infectious Disease, Screening)
- ▶ Nine companies share 75% of the Molecular Diagnostics business
- ▶ Market polarising between consolidation and decentralisation

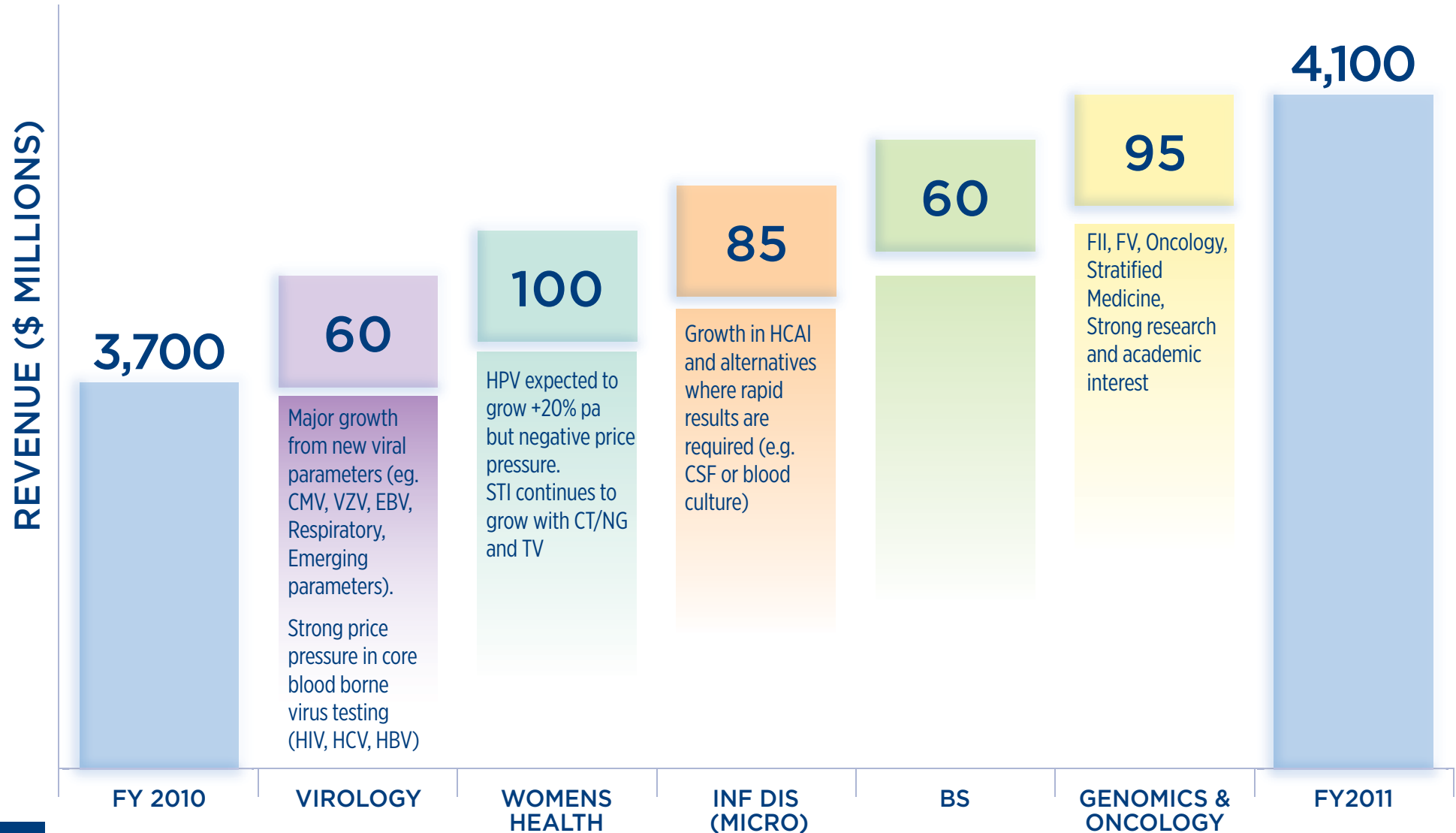
**TOTAL IVD MARKET: \$44 BILLION**



Source: Boston Consulting Group

# WHERE THE GROWTH COMES FROM

## INCREMENTAL REVENUE PER SEGMENT



# DRIVERS OF OVERALL IVD MARKET ALSO DRIVE MDx

## SOCIAL

- ▶ Increased patient awareness
- ▶ More patient self testing
- ▶ Global Baby Booming populations
- ▶ Rapid spread of Infectious Disease
- ▶ Ageing population
- ▶ Improving healthcare in developing regions

## TECHNOLOGICAL

- ▶ Increasing laboratory test menus
- ▶ Need to improve time to result
- ▶ Less complexity associated with lab
- ▶ Cost of pathology services
- ▶ Decentralization to “point of impact”

## HEALTHCARE CHALLENGES

- ▶ Increased disease burden
- ▶ Health challenges in developing regions
- ▶ Acute Infectious Disease issues
  - ▶ Respiratory, HCAI, STI's
- ▶ Increase in chronic disease conditions
  - ▶ Cancer, Diabetes, Cardiovascular

# MOLECULAR DIAGNOSTICS AND INFECTIOUS DISEASE

## 60% of the Molecular Diagnostics market is Infectious Disease Testing

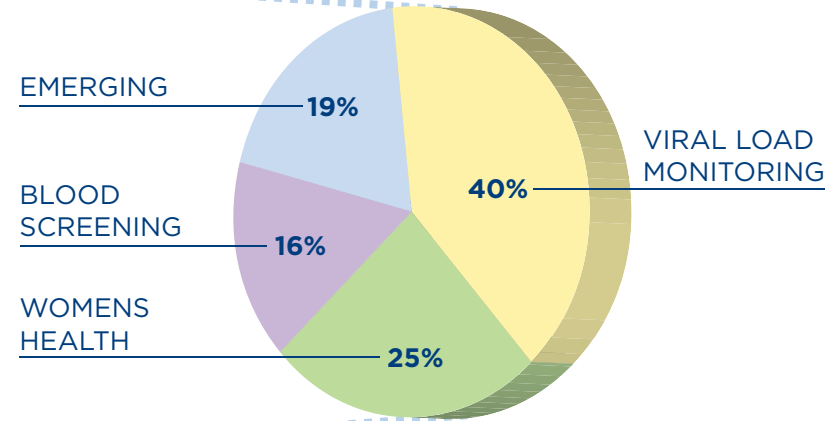
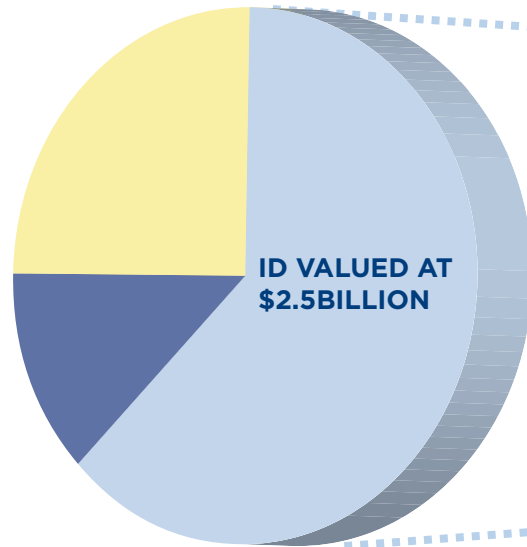
- ▶ HIV
- ▶ HPV
- ▶ HBV/HCV
- ▶ CT/NG
- ▶ Blood Screening
- ▶ Gastro intestinal/Stool
- ▶ Healthcare Acquired Infections
- ▶ Respiratory
- ▶ Transplantation
- ▶ Confirmatory testing
- ▶ Therapy monitoring

Qualitative identification and profiling of the Infectious Disease agent

Quantification of the pathogens to monitor disease progression, tailor treatment and determine response to therapy

Source: Report by "Markets and Markets" January 2012

# INFECTIOUS DISEASE MARKET



■ INFECTIONOUS DISEASE ■ ONCOLOGY ■ GENETICS & PRENATAL

Source: Report by "Frost and Sullivan" 2010

## INFECTIOUS DISEASE GROWTH DRIVEN BY

- Respiratory parameters
- Herpes virus panel
- Healthcare associated infections
  - C.diff, VRE, MRSA
- Gastro intestinal parameters
- CT/NG
- HPV
- Trichomonas
- Bacterial targets (e.g. TB, GBS etc)

# MOLECULAR DIAGNOSTICS - GROWTH TRENDS

**Four areas of future rapid growth for Molecular Diagnostics testing**

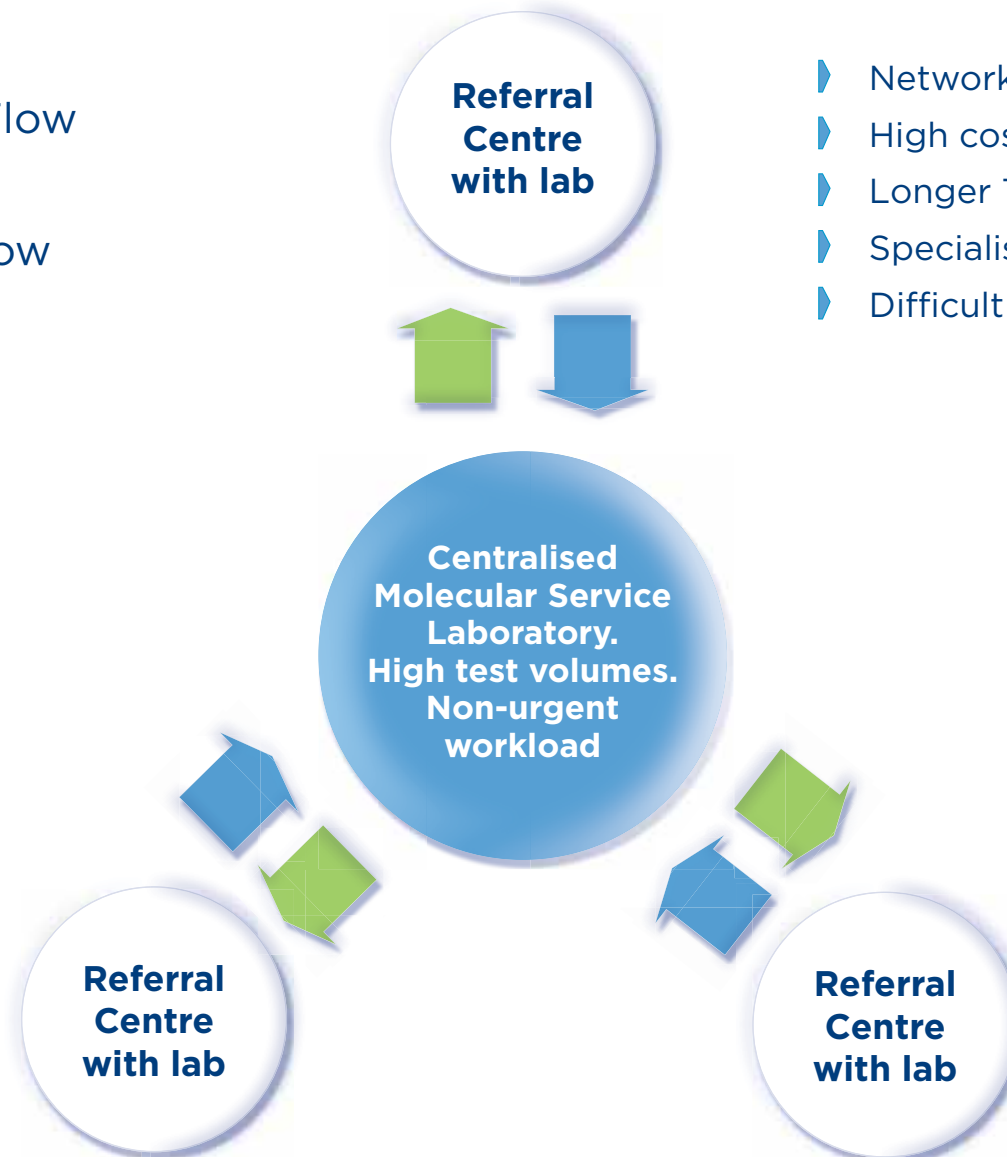
Decentralized  
“Point of Impact” testing

Cancer Diagnostics

Prenatal Diagnostics & Genetic Testing

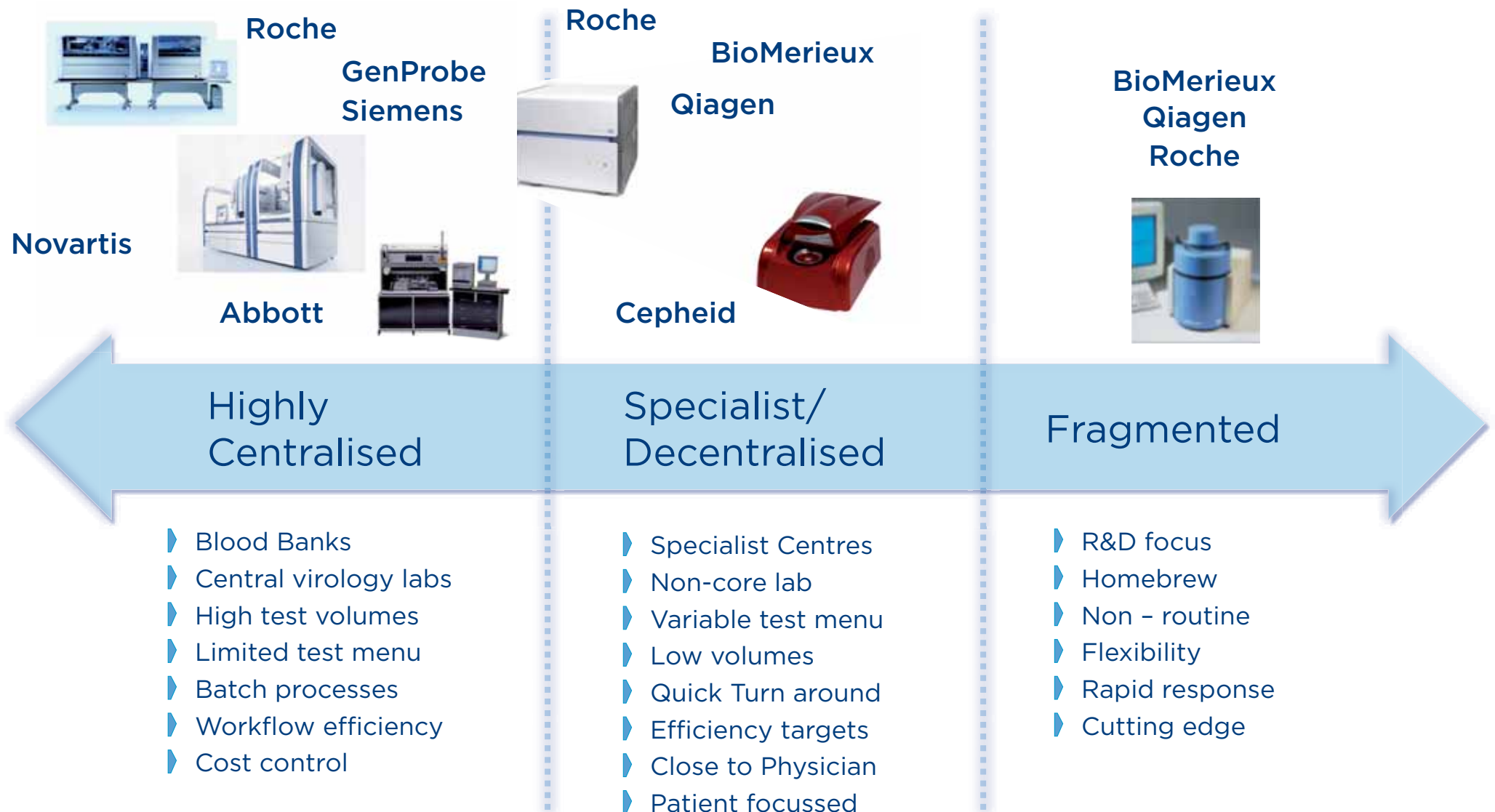
Source: Report by “Frost and Sullivan” 2010

# MOLECULAR LAB NETWORKS AND CENTRALISATION



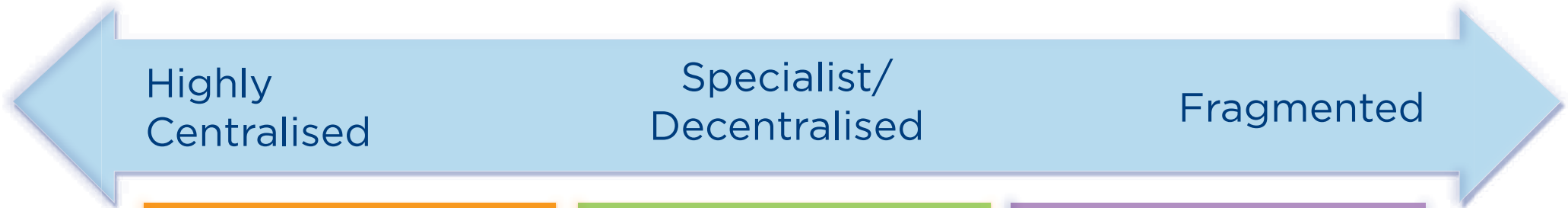
- ▶ Networked/referral lab approach
- ▶ High cost to referring lab
- ▶ Longer TAT
- ▶ Specialist services not catered for
- ▶ Difficult to request new tests





# CENTRALISED, DECENTRALISED AND FRAGMENTED APPROACHES TO MDx



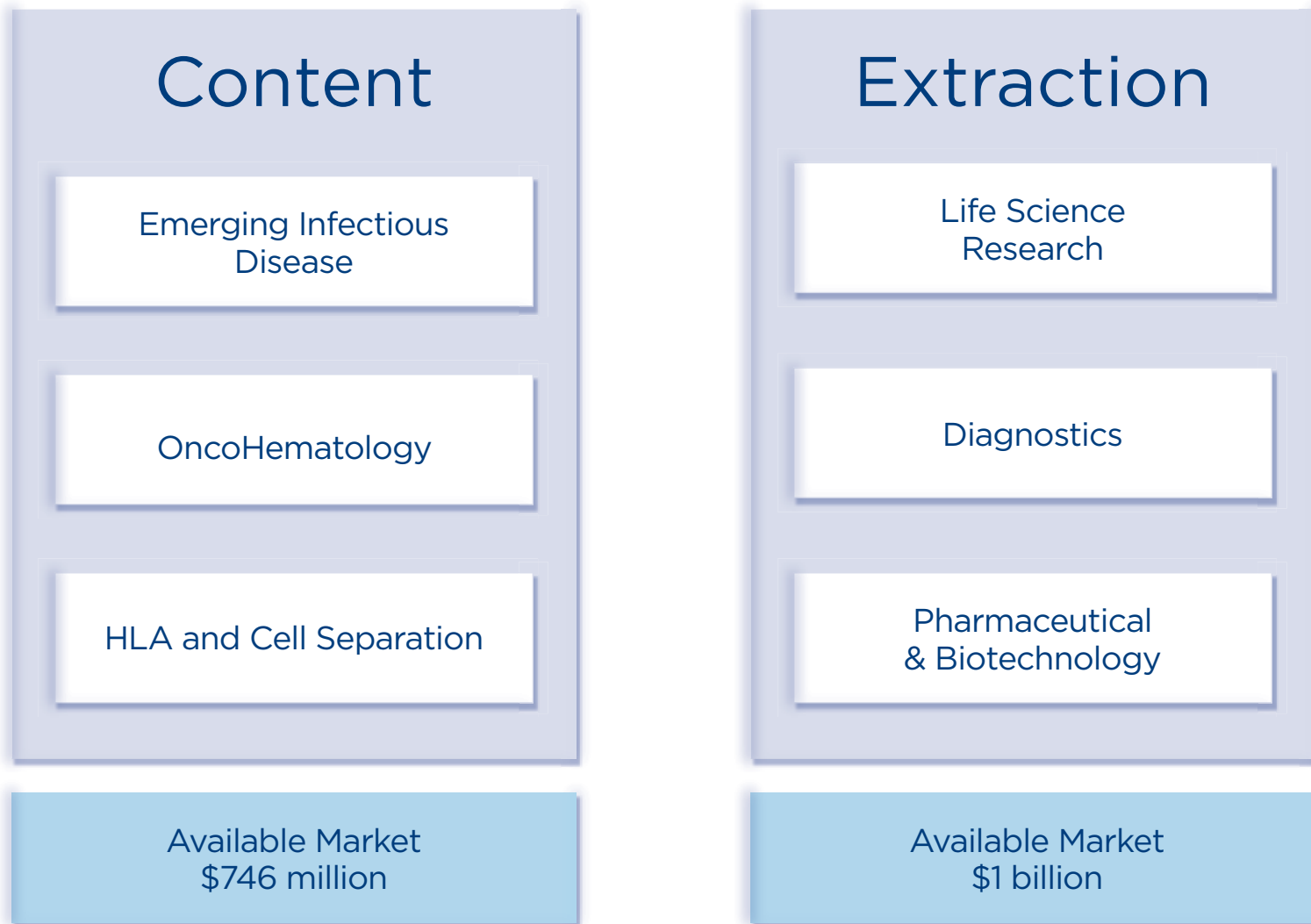


# PRIMARY FOCUS

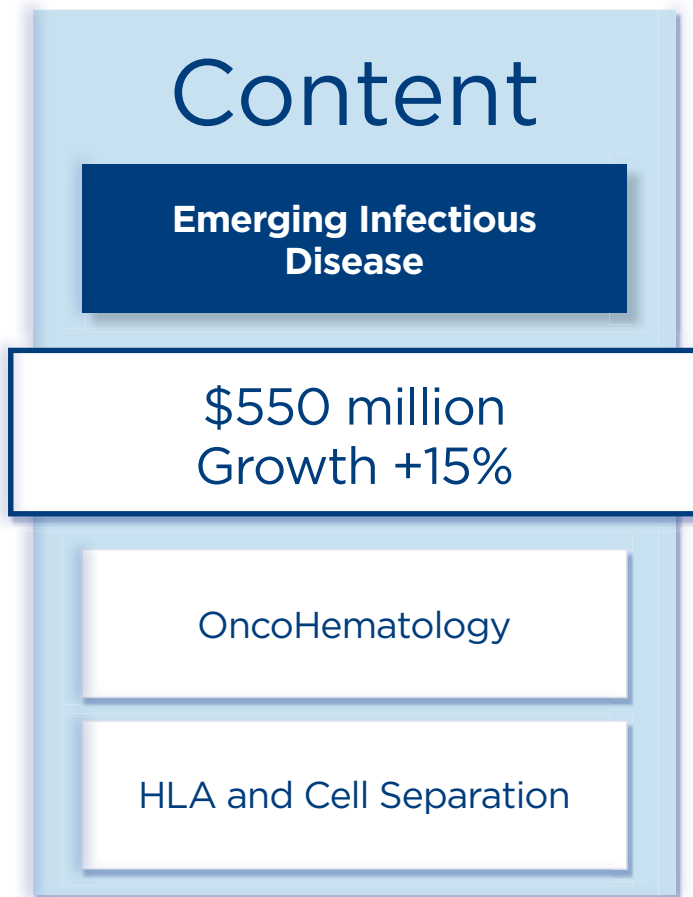


<b>HIGHLY OPPORTUNISTIC (ALMOST NEVER)</b>	<b>PRIMARY FOCUS (ALWAYS)</b>	<b>OPPORTUNISTIC (SOMETIMES)</b>
<p>Alongside high volume systems for additional content</p> <p>For urgent samples</p> <p>When system is occupied</p> <p>Rapid turn around required</p> <p>Serving specialist centres</p> <p>Open extraction</p> 	<p>DiaSorin Serology Customers</p> <ul style="list-style-type: none"><li>- MDx for confirmatory</li><li>- MDx to differentiate service</li></ul> <p>Specialist Centres</p> <ul style="list-style-type: none"><li>- Transplantation</li><li>- Oncology centres</li><li>- Paediatrics</li><li>- Elderly care</li></ul>  <p><b>DRIVEN BY CONTENT</b> <b>10-20 TESTS PER DAY</b></p>	<p>Extraction and cell separation</p>  <p>Low Volumes</p>  <p>Lge Vol open Extraction</p>

# DIASORIN TWIN PILLAR STRATEGY



# DIASORIN CONTENT PILLAR



Optimised assays with extraction

First phase launch  
7 assays aligned with DiaSorin serology portfolio

Follow up launch of C.Diff assay (FDA & CE-IVD)

Additional assays launched  
2013/2014 and 2015

Target decentralised testing

# DECENTRALISED “POINT OF IMPACT” TESTING - LIAISON IAM



- ▶ Small footprint
- ▶ Isothermal reaction
  - No thermal cycling
- ▶ Less complexity
- ▶ Less to go wrong
- ▶ Cost effective
- ▶ Small batches
- ▶ Modular
- ▶ Unique software
- ▶ Linking instruments
- ▶ Grow with workload

# DIASORIN CONTENT PILLAR

## Content

Emerging Infectious  
Disease

**OncoHematology**

\$136 million  
Growth +12%

HLA and Cell Separation



Large unmet need for diagnosis  
and monitoring of therapy

Launch 2013  
BCR-ABL (p190 & p210)  
PML-RAR $\alpha$  (BCR 1, 2 & 3)

Portfolio expansion  
2013/2014/2015

# DIASORIN CONTENT PILLAR

## Content

Emerging Infectious  
Disease

**OncoHematology**

\$136 million  
Growth +12%

HLA and Cell Separation

Complete solutions to diagnose  
and monitor leukaemia

Rapid, Economical, Efficient  
and Approved assays



# FIRST WAVE LAUNCH INFECTIOUS DISEASE & ONCOLOGY

Liaison Ixt extraction system  
&  
Liaison lam Q-LAMP system

## Infectious Diseases assays

- Epstein-Barr Virus (EBV)
- Cytomegalovirus (CMV)
- Parvovirus (PARVO)
- Toxoplasmosis (TOXO)
- BK Virus (BKV)
- Varicella Zoster Virus (VZV)
- Herpes Simplex Virus (HSV 1-2)

## Onco Haematology assays

- Chronic Myeloid Leukemia (CML)
  - BCR-ABL p190
  - BCR-ABL p210
- Acute Promyelotic Leukemia (APL)
  - PML-RAR $\alpha$  1
  - PML-RAR $\alpha$  2
  - PML-RAR $\alpha$  3

- ▶ **Liaison lam/Liaison Ixt combination allows full control**
- ▶ **Liaison lam kits validated for other extractions**

# DIASORIN CONTENT PILLAR

## Content

Emerging Infectious  
Disease

OncoHematology

**HLA and Cell Separation**

\$60 million  
Growth +5%



Unique position in cell separation using  
specially designed reagent kit

Lymphocyte  
prep for HLA  
typing

Cell prep for  
OncoHematology  
Diagnostics

Cell separation  
for research  
applications  
and cell culture



# DIASORIN CONTENT PILLAR

## HLA TYPING CELL PREPARATION

### Content

Emerging Infectious  
Disease

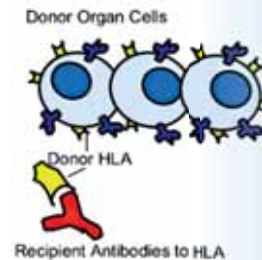
OncoHematology

**HLA and Cell Separation**

\$60 million  
Growth +5%



**Liaison Ixt/ Arrow  
HLA cell separation  
and cross - matching**



Donor HLA antibodies in transplant recipients can lead to hyper acute graft rejection

Cross matching carried out to ensure good organ donor match

Multiple cross matches performed per transplant

Donor lymphocytes need to be isolated  
- Ficoll separations



# DIASORIN CONTENT PILLAR

## HLA TYPING CELL PREPARATION

### Content

Emerging Infectious  
Disease

OncoHematology

**HLA and Cell Separation**

**\$60 million  
Growth +5%**



- ▶ Arrow, CellSep kit & Ab bound Mag Beads displaces the use of time consuming techniques like Ficoll / Dextran density gradients
- ▶ Arrow capable of 12 preps in 45 min
- ▶ Vastly simplifies the isolation process for the lab
- ▶ For kidney transplants require 5 - 12 cross matches / patient
- ▶ Arrow approved for use in USA and Europe

# DIASORIN CONTENT PILLAR

## HLA TYPING CELL PREPARATION

### Content

Emerging Infectious  
Disease

OncoHematology

**HLA and Cell Separation**

\$60 million  
Growth +5%

### NUMBER OF TRANSPLANTS PER ANNUM IN USA

KIDNEY	16,898
LIVER	6,291
PANCREAS	350
KIDNEY/PANCREAS	828
HEART	2,333
LUNG	1,770
HEART/LUNG	41
INTESTINE	151
<b>TOTAL</b>	<b>28,662</b>

# DIASORIN CONTENT PILLAR

## HLA TYPING CELL PREPARATION

### Content

Emerging Infectious  
Disease

OncoHematology

**HLA and Cell Separation**

\$60 million  
Growth +5%

### HLA TYPING CELL PREPARATION WORLDWIDE ESTIMATES

NUMBER OF SOLID ORGAN TRANSPLANTS P.A. 55,000

NUMBER OF BONE MARROW TRANSPLANTS 40,000

MEAN NUMBER OF CRASS MATCHES / TRANSPLANT 8

TOTAL AVAILABLE MARKET (HLA ONLY) \$23 MILLION

# DIASORIN EXTRACTION PILLAR

**BULLET**



Installed Base:  
44 instruments

**ARROW**



Installed Base:  
382 instruments

OEM supply  
contracts

**Specialist extraction kits:  
Blood, gDNA, RNA, Stool, Viral NA, Bacterial NA**

**Revenues 2011: \$3.8 million**

## Extraction

**Life Science  
Research**

**Diagnostics**

**Pharmaceutical &  
Biotechnology**

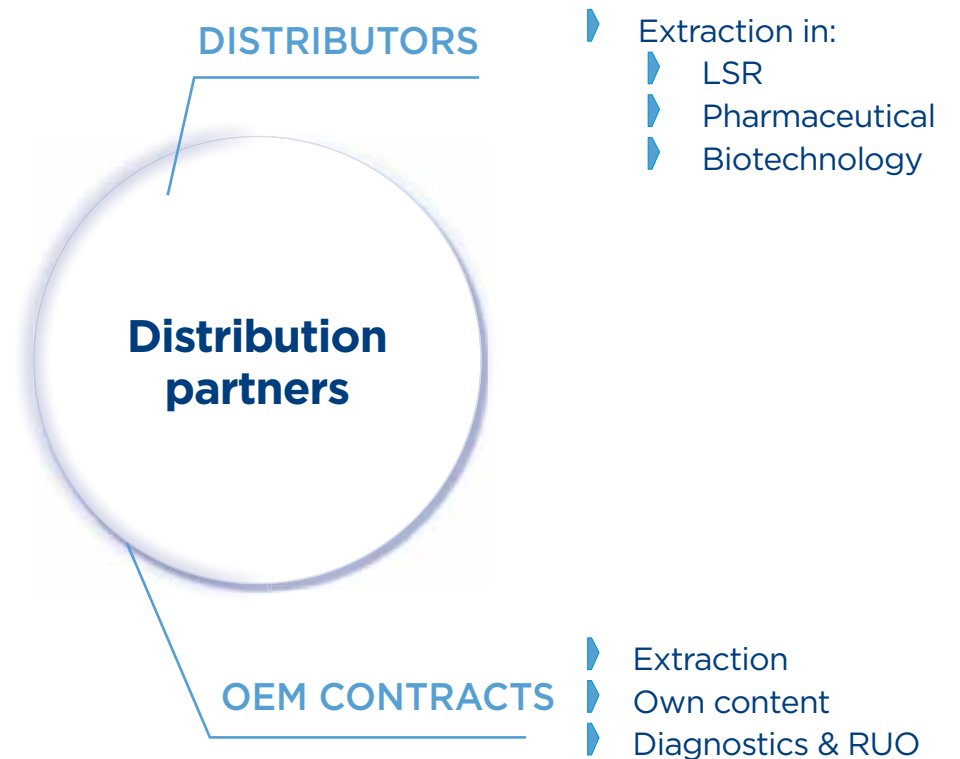
Available Market  
\$1 billion

# STRATEGY EXECUTION

## CONTENT DRIVEN



## EXTRACTION OPPORTUNITIES



# GROWTH STRATEGY

## STRATEGY LOOKING FORWARD



TARGETING  
DECENTRALIZED LABS

INSTRUMENTS AND ASSAYS TO MAKE MOLECULAR  
DIAGNOSIS SIMPLER, FASTER, COST EFFECTIVE AND  
HIGHLY PERFORMING

EXPLOITING SYNERGIES  
BETWEEN NA EXTRACTION,  
CELL SEPARATION AND  
GENETIC TESTING

MICROBIOLOGY  
LABS

HEMATOLOGY  
LABS

HLA TYPING

AUTOMATION

NEXT GENERATION AUTOMATED & INTEGRATED NA EXTRACTION AND LAMP AMPLIFICATION

AUTOMATED CELL SEPARATION

MDx KITS

ACUTE INFECTIONS  
REQUIRING FAST  
DIAGNOSIS FOR THERAPY  
(BUT MULTIARRAY  
UNNECESSARY)

LEUKEMIA PANELS

GENETIC TESTING

RESISTANCE TO  
ONCO-THERAPY

HEMATOLOGY TESTS

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# Molecular Diagnostics drivers

**Riccardo Fava** Head of IR and Media



# WHERE WE WILL BE DIFFERENT



## COMPETITORS

### BUSINESS OPPORTUNITY

#### Strictly linked to our Immunoassay offer:

- Confirmatory results (doubtful results on Immunoassay tests)
- Differentiation of service (2<sup>nd</sup> step of the diagnostic process on a patient found infected with the immunoassay technology)

### FOCUS

Always driven by **content** = DiaSorin, The Diagnostic Specialist

#### Infectious Diseases

- Epstein-Barr Virus (EBV)
- Cytomegalovirus (CMV)
- Parvovirus (PARVO)
- Toxoplasmosis (TOXO)
- BK Virus (BKV)
- Varicella Zoster Virus (VZV)
- Herpes Simplex Virus (HSV 1-2)

#### + new additional pipeline

#### HLA and Cell Separation

- Lymphocyte prep for HLA typing
- Cell prep for Haem/Onc Diagnostics
- Cell separation for research applications and cell culture

#### Oncology

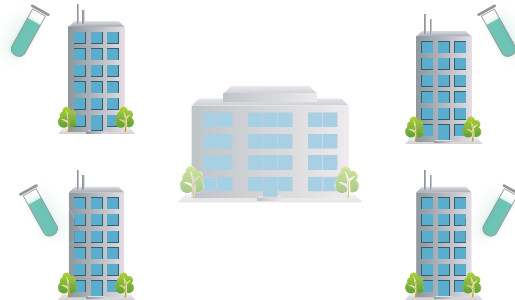
- Chronic Myeloid Leukemia (CML)
  - BCR-ABL p190
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- Acute Promyelotic Leukemia (APL)
  - PML-RAR $\alpha$  1
  - PML-RAR $\alpha$  2
  - PML-RAR $\alpha$  3
- Acute Myeloid Leukemia (AML)
- Acute Lymphoblastic Leukemia (ALL)
- Myeloproliferative Neoplasms (MYELO NEOPL)

#### + new additional pipeline

Driven by:

- financial opportunity
- drugs / pharma focus
- track systems positioning

### POSITIONING AND CLIENTS



#### Targeting decentralized labs:

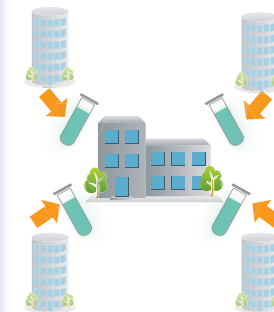
- microbiology labs
- hematology labs
- HLA typing

having:

- variable test menu
- quick turn around

being:

- patient focused
- close to physician



#### Targeting centralized labs:

- blood banks
  - Central virology labs
- having:
- limited test menu
  - high test volumes
- being:
- efficient on the workflow

# WHERE WE WILL BE DIFFERENT



## COMPETITORS

### AMPLIFICATION TECHNOLOGY

**LAMP ...** ...to make molecular diagnosis:

- Adequate sensitivity → **equivalent to PCR**
- Adequate specificity → **simpler faster**
- Simpler reaction set-up → **cost effective**
- Shorter time-to-result → **complete and accurate = unique**
- Low manufacturing costs → **complete and accurate = unique**
- Quantitative → **complete and accurate = unique**
- Qualitative → **complete and accurate = unique**



### PCR

### EXTRACTION TECHNOLOGY

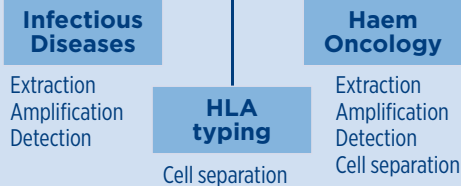
- Low manufacturing costs → **cost effective**
- Wide range of sample types → **specialist extraction kits:** ■ Blood ■ DNA ■ RNA ■ Stool ■ Viral NA ■ Bacterial NA
- Ease of use → **simple**
- Different targets → **market penetration:** ■ Life Science Research ■ Diagnostics ■ Pharmaceutical & Biotechnology



### STRATEGY EXECUTION

#### Content Driven

#### Direct Sales



#### Extraction opportunities

#### Distributors



LIAISON *Iam*



LIAISON *Ixt*



**NEW INSTRUMENT**

Extraction  
Amplification  
Detection  
Reporting + Integrated  
cartridges +

Simple to operate  
Sample in result out  
No specialist molecular biology skills required  
Robust system for use in "point of impact" setting  
Plug'n'Play  
Compatible with batch and single sample testing  
LIS compatibility

# THE “3W” COMMUNICATION STRATEGY

WHEN	WHERE *	WHAT
2011 OCT 17-20	Investor Day Presentation (Milan, London, New York)	<ul style="list-style-type: none"> <li>Market size and the players</li> <li>DiaSorin purpose and strategy</li> <li>2015 Revenues potential = € 15-20 mln</li> </ul> <ul style="list-style-type: none"> <li>The 3 key decisions                             <ul style="list-style-type: none"> <li>- Amplification technology: LAMP (Eiken Chemical)</li> <li>- Liaison IAM: a small automated analyzer (PSS)</li> <li>- Menu focused on specialties</li> </ul> </li> </ul>
MAR 9	FY'11 Results Presentation	<ul style="list-style-type: none"> <li>MDx FY'12 pipeline disclosure (Infectious Diseases and Onco Hematology)</li> </ul>
MAY 4	DiaSorin Press Release	<ul style="list-style-type: none"> <li>Agreement to acquire the NorDiag Group's Molecular Diagnostics assets</li> </ul>
2012 MAY 8	Media Tutorial in our R&D center (Gerezano, Italy)	<ul style="list-style-type: none"> <li>History of an Italian challenge</li> <li>LAMP vs. PCR</li> <li>7-10 new assays from 2013 every year</li> </ul> <ul style="list-style-type: none"> <li>DiaSorin LAMP characteristics:                             <ul style="list-style-type: none"> <li>- Quantitative, Qualitative, and Appropriate in “seeing” the Point Mutations (DiaSorin IP)</li> <li>- Automated</li> <li>- Highly sensible and specific</li> </ul> </li> </ul>
MAY 11	Q1'12 Results Presentation	<ul style="list-style-type: none"> <li>Our strategy on MDx</li> <li>Extraction market                             <ul style="list-style-type: none"> <li>- # DNA tests WW: 140 mln / year</li> <li>- Market Value: US\$ 4.7bn</li> </ul> </li> </ul> <ul style="list-style-type: none"> <li>NorDiag Assets acquisition                             <ul style="list-style-type: none"> <li>- Business and products</li> <li>- Arrow and Bullet in details</li> <li>- Next steps on MDx</li> </ul> </li> </ul>
JUN 30	H1'12 Financial Report	<ul style="list-style-type: none"> <li>Molecular diagnostics activities description</li> <li>NorDiag acquisition and integration into the molecular diagnostics activities</li> </ul>
AUG 3	H1'12 Results Presentation	<ul style="list-style-type: none"> <li>Analyst Day - Save the date “Our new opportunity: Molecular Diagnostics”</li> </ul>
OCT 10	Analyst Day in our Molecular Diagnostics manufacturing site (Dublin)	<ul style="list-style-type: none"> <li>Content: available mkt = US\$ 746 mln                             <ul style="list-style-type: none"> <li>- Microbiology labs = US\$ 550 mln; Growth +15%</li> <li>- Hematology labs = US\$ 136 mln; Growth +12%</li> <li>- HLA typing = US\$ 60 mln; Growth +5%</li> </ul> </li> <li>Extraction: available mkt = US\$ 1 bn</li> </ul> <ul style="list-style-type: none"> <li>Focus on the market                             <ul style="list-style-type: none"> <li>- Specialist/Decentralized (10-20 tests / day)</li> <li>- Opportunistic</li> </ul> </li> <li>Strategy execution</li> </ul>
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\* All the documents are available on our website [www.diasorin.com](http://www.diasorin.com)

# KEY POINTS AND DRIVERS

## REVENUES

**€ 15-20 mln by 2015 (ref. Investor Day, Oct 2011), considering:**

- Amplification / detection end-user price going down to a € 10-15 range per test
  - Current competitors price higher
  - Onco-hematology market homebrew; premium price for an automated solution
- Liaison IAM launch with 10-20 reactions per day

**Not considered:**

- Extraction business (Liaison IXT)
- Life Science business (Bullet)
- 2<sup>nd</sup> generation fully integrated analyzer

**LIAISON IAM : Liaison IXT ratio = 1:2 or 1:1 depending on the countries**

## R&D

Consistent and continuous pipeline implementation going forward (7-10 tests/ year)

All MDx technologies in-house and all products developed internally

Highly specialized R&D scientists

2<sup>nd</sup> generation fully integrated MDx analyzer project already started

## STRATEGY

Aggressive, serious and intense approach to the MDx market

Effective from scratch with the first step offer (Liaison IAM + Liaison IXT + Bullet)

MDx to complement Immunoassay positioning and offer

Fast and ready to seize new opportunities

High profitability expected since 2012 (standard margin in the same high range of the current CLIA products)

2015 cumulative installed LIAISON IAM base expected significant

Launch of the 2<sup>nd</sup> generation fully integrated MDx analyzer by 2015

## COSTS

Biotrin site fully converted as the only MDx manufacturing site of the Group

R&D and CAPEX to deploy the first-step execution plan already accounted in the last balance sheets

Low manufacturing costs for instruments

Royalties for LAMP as a fraction of PCR royalties

Sales costs leveraging on Liaison and Liaison XL capillarity

## S&M

Pre-marketing activity completed and highly successful

Sales force fully dedicated in the first key markets (Europe and Israel)

Enormous potential for specialties, both in Infectious Diseases and Onco-hematology (some unexploited markets)

Specialist/Decentralized approach