

# MDRG

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- Principal Investigator

**Nucleic acid tests based on novel biomarkers  
(Bacteria + Fungi) for use in**

- Clinical - Infectious Disease
- Food Pathogens
- Environmental - Water contamination



QuickTime™ and a  
decompressor  
are needed to see this picture.



NUI Galway  
OÉ Gaillimh

Molecular Diagnostics Research Group

# Infectious Disease Diagnostics Drivers

Traditional methods slow, require highly skilled personnel, complex, manual, poor integration, slow turn around time and not near patient

Nucleic Acid Testing - the impact in the near future:

- Near patient rapid high throughput capacity and turn around time testing capability
- Fully automated integrated solutions for multiple routine molecular infectious disease diagnostics testing, moderate skill complexity required

”Sample in → Result out”



# MDRG

- **bringing better health to the people more quickly!**

**T1** "T1 translational research" may include **laboratory-based research** aimed at clarifying mechanisms of disease; **developing** measures or **markers of disease presence**, severity, or improvement; and developing drugs, devices, or interventions to treat disease or to improve health.

**T2** "T2 translational research" generally **identifies community, patient, physician, and organizational factors** that **serve as barriers and facilitators to translation**; develops novel intervention and implementation strategies to increase translation, such as quality improvement programs or policies; and evaluates the impact of strategies to increase translation of relevant healthy behaviours and processes of care.



# MDRG Strategy

“T1” - Typical laboratory type research - Biomarker discovery / Assay development  
Resulting in “[Laboratory Developed Diagnostics Tests or Home Brew tests](#)”

Q: Are these tests that your clinical laboratory uses / developed for routine patient care **approved** (FDA / CE)?

FDA approved tests (**very, very few**) – Infectious Disease

Chlamydia, Neisseria, Trichomonas, Strep A, B, Mycobacterium Tuberculosis, Legionella, MRSA.

Influenza A, CMV, Enterovirus, HCV, HIV, HPV



# Biodiscovery and Test Design R+D - T1

## Molecular target bio-discovery

- Intellectual Property Portfolio



- Proof of principle



**Industry Compliant**

## NAD test design and development

- Assay design, optimisation and validation



DNA or RNA targets  
Primer, Probe design,  
Specificity, Sensitivity,  
ISC design




Ongoing research programmes: New **targets** and **assays** for integration with next generation diagnostics systems





# MDRG Strategy - T2

"T2 translational research" generally identifies community, patient, physician, and **organizational factors** that serve as barriers **and facilitators to translation**

Toward "T2" - Assay Validation

Is there documentation that the laboratory has performed validation studies to establish the performance characteristics of laboratory-developed assays? - **MDRG** 

Do validation studies include specimens representing each of the possible reportable results (genotypes / serotypes)? - **MDRG** 

Were validation studies with an adequate number and representative (reasonable) distribution of samples performed for each type of specimen expected for the assay (e.g. blood, fresh/frozen tissue, paraffin-embedded tissue, prenatal specimens)? - **MDRG** 





# MDRG / BCBL Case Study 2008 - 2012



- MDRG is currently collaborating with Beckman Coulter Biomedical Limited (BCBL)
- A company that has a presence in Ireland - manufacturing facilities in Galway and Clare
- 4 year R+D programme
- License and R+D Agreement(s) which has seen the creation of a team of 11 researchers based at NUIG
- Collaborative in nature: BCBL have in place 4 of its researchers working together with the NUIG team (technology and know-how transfer)
- 24 Diagnostics assays for detecting infectious pathogens - bacterial / fungal



# MDRG/ UCHG / BDI – Developing POC Integrated IVD Systems (2010 – 2015) - SFI CSET

**Bringing together** Chemists, Physicists , Molecular Biologists, Bioinformaticists  
Clinicians, Engineers and Industry

## **Near Patient Systems for Use in Low Resource Settings**

- **Sepsis / Meningitis**– use in GP's Office / A+E

Will detect and identify rapidly specific infectious pathogens in blood

Allow for appropriate antibiotic treatment

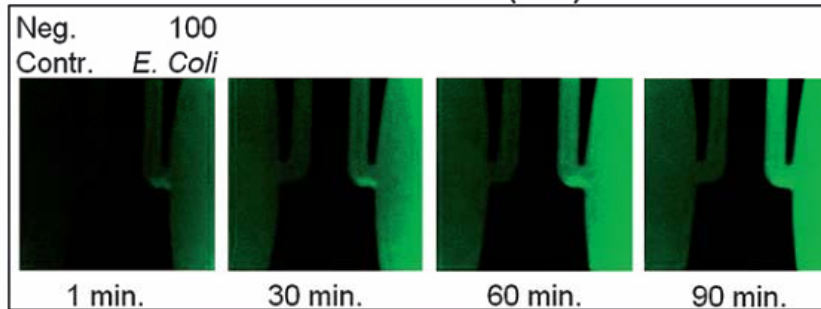
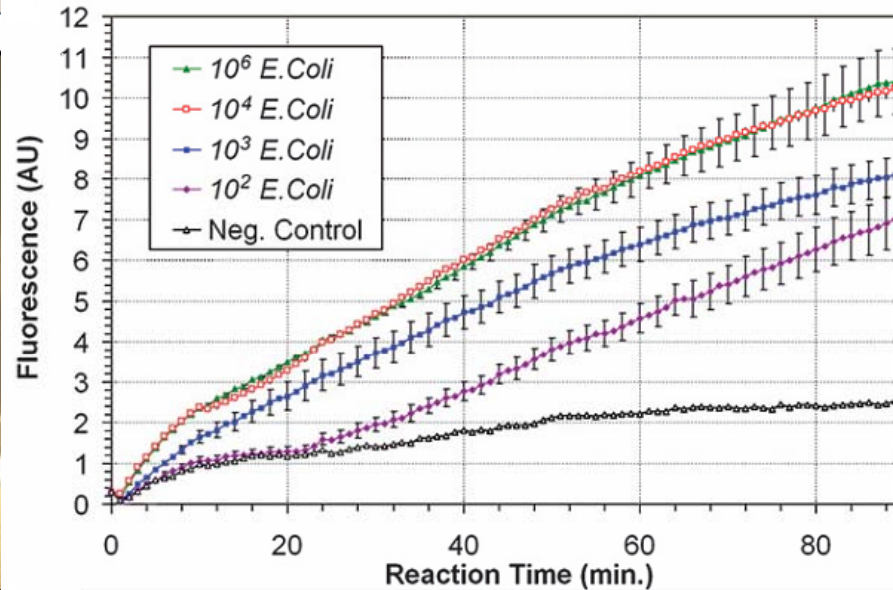
- **Cancer** (Breast)

Will detect molecular indicators of Breast Cancer

Will aid in chemotherapy regimens



# Integrated Micro-Fluidic Real-Time Prototype Device for POC Molecular Diagnostics



(20 s)



# MDRG - “The Support”

## Intellectual Property and Licensing Agreements:

- Technology Transfer Office, NUIG / Enterprise Ireland



## R+D Funding:

- Enterprise Ireland  
Proof of Concept  
Commercialisation  
Innovation Partnership
- IDA
- Firm
- SFI
- EU



EUROPEAN REGIONAL  
DEVELOPMENT FUND



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