

MDRG

Thomas Barry Ph.D.

- 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

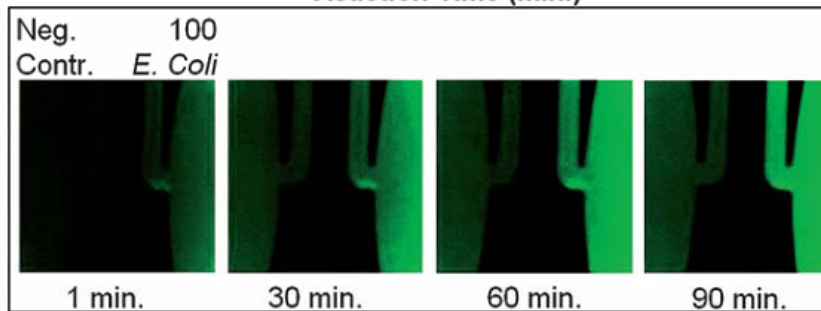
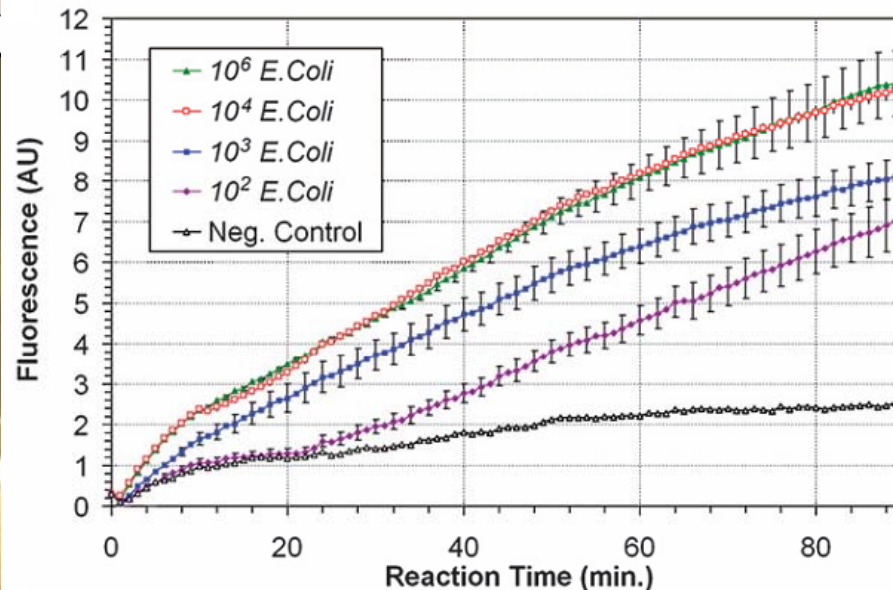
- **Cancer** (Breast)

Will detect molecular indicators of Breast Cancer

Will aid in chemotherapy regimens



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



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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