CHALENGES TO TRANSLATING RESEARCH: Lessons Learned from the Philippine Research Landscape

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Translational Research

Or sirings from basic science to enhance human health and well-being.

Science from "bench to bedside"

• In a medical **research** context, it aims to "translate" findings in fundamental **research** into medical and nursing practice and meaningful health outcomes.

But.....

- In the Philippines, there is a disconnect between basic science and clinical science research
- Dearth of clinician-scientist in the Philippines

So.....

 Strategic partnership with the basic scientists seems to be the logical approach

Doing research in the Philippines

Starts with asking a question of relevance





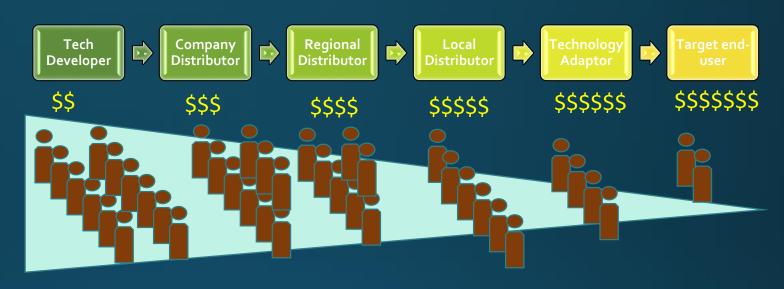
THE LONG VALUE CHAIN



THE DECLINING ACCESS



THE LONG VALUE CHAIN



THE DECLINING ACCESS



The cost-limiting nature of molecular tools for diagnosing infectious diseases in the Philippines led to the creation of the Molecular Diagnostic Program in Biotech-Manila



Molecular Diagnostic Program

Target	Source of Funding	Platforms	Stage of Development
Vector Borne Diseases (Dengue & Chik)	DOST	RT-PCR LAMP NGS	NEAR MARKET
ТВ	EST	RT-PCR LAMP	NEAR MARKET
MDRO	NRCP	PCR SEQUENCING	RESEARCH
HIV Drug Resistance Profiling	DOST	RT-PCR SEQUENCING	CLINICAL SERVICES
Influenza	DOST	PCR LAMP	PRE-CLINICAL
NTD	DOH	PCR LAMP	NEAR MARKET
Waterborne Parasites	DOST	RT-PCR MICROARRAY	FIELD TESTING

Creating the environment

"I've learned that dreams are necessary to transform realities"



Finding a role model



Finding Meaning



"Diseases of Poverty"

"Top ten causes of morbidity and mortality"

"Cancer in the family"

"because its cool!"

The Value of Persistence



"How long does it take you to procure your reagents?"

Sometimes you start alone..





Biotech-Manila

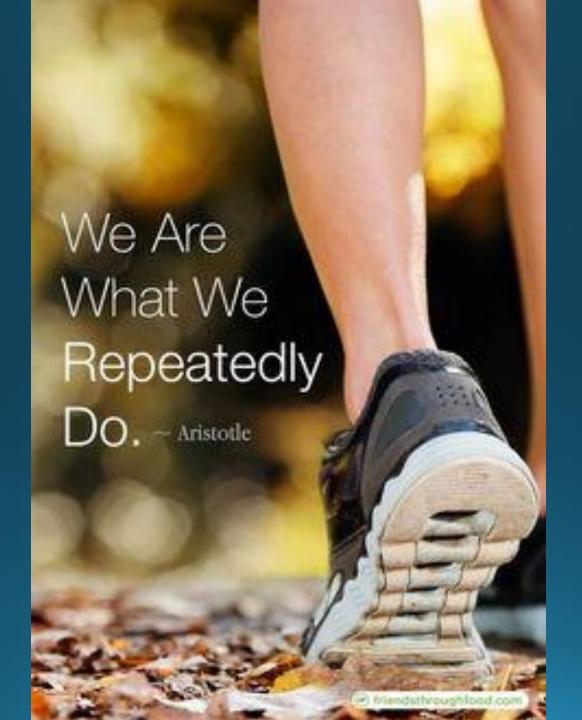
Me, myself and I And my 87\$



- Local and International full-time and visiting faculty
- Publications of ISI journals, modules, advisories and Patents
- Over 100 students mentored
- > 300 M of grants
- Molecular diagnostic services for marginalized sectors



"Researchers are not born, they are nurtured and developed."





Braving the unknown..





The **first private, SEC registered** R&D company on Health Biotechnology in the Philippines that is focused on developing and providing affordable diagnostic technologies for communicable and non-communicable disease

THE LONG ROAD



REASEARCH & DEVELOPMENT 1



REASEARCH & DEVELOPMENT 2



REASEARCH & DEVELOPMENT 3

ASSAY DEVELOPMENT

PRE-CLINICAL TESTING

CLINICAL VALIDATION

FDA APPROVAL

TECHNOLOGY ADAPTATION

- ✓ Analytical and Clinical Sensitivity and specificity testing
- ✓ Limit of detection
- ✓ Miniaturization
- ✓ Stability
- ✓ Packaging and storage
- **✓** SOP
- ✓ QC Parameters

- Will they use our technology?
- Will someone be bold enough to invest?
- What is the best strategy to meet our objectives?

Customized Isothermal Heaters



Customized LED trans illuminators



Our Technology Solution



Biotek-MTM Dengue Kit

Biotek-MTM TB Kit

Biotek-MTM Salmonella Kit

Biotek-MTM Chikungunya Kit

Biotek-MTM Influenza Kit

Biotek-MTM Malaria Kit

Biotek-MTM Schisto Kit

Our 4 Pillars

DIAGNOSTIC SERVICES

2015

ISOTHERMALTECHNOLOGIES

PCR TECHNOLOGIES

Avian-Derived TECHNOLOGIES

2016 2017

2018

TB (RIFr) PCR

EBV Viral Load

PCP PCR

Pillar 1: Diagnostic Services

CMV Viral Load

CHIK PCR

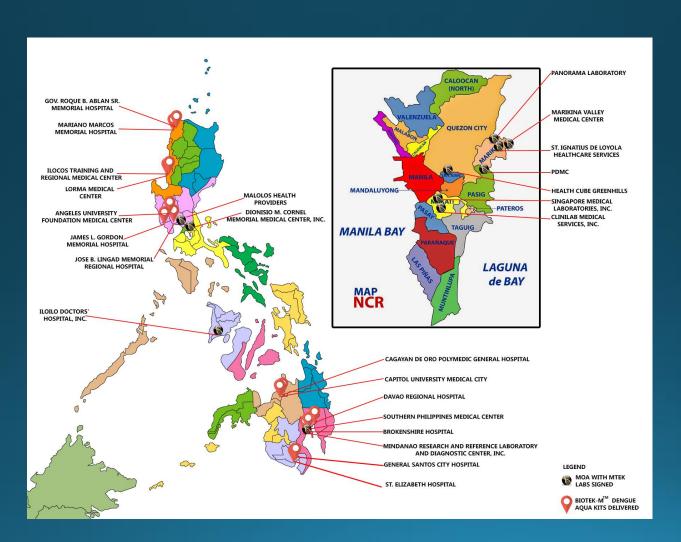
HCV Viral Load

HIV Viral Load

EGFR MUTATION
TEST

HBV Viral Load

Hospitals and stand-alone labs currently using our technology



2017 NSTW Outstanding Technology Commercialization Award (Gregorio Zara Medal)

NAST-DOST

SECTIONS Friday, March 3, 2017

INQUIRER.NET

TODAY'S PAPER Q

TECHNOLOGY / SCIENCE, HEALTH AND RESEARCH 951 SHARES 1 951 SHARES





Microbiologist vs dengue leads science awardees

By: Jocelyn R. Uy - Reporter / @mj_uyINQ Philippine Daily Inquirer / 03:26 AM July 31, 2016



A microbiologist who developed a portable kit that can detect within an hour the presence of dengue virus in the blood and a University of the Philippines (UP) professor who used computer programs to develop designer drugs against tuberculosis were among the winners of this year's





TRENDING



Gunmen kill people's doctor



Family of slain rural doctor cries for justice



Duterte renews attack on Church as he defends war on





Kris Aquino hints at TV

Intellectual Property



CONFIRMATION COPY

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OFFICE OF TECHNOLOGY TRANSFER AND BUSINESS DEVELOPMENT

Ground Floor, National Institute of Molecular Biology And Biotechnology, National Science Complex University of the Philippines Diliman, Quezon City PREVIOUSLY SENT
VIA E-MAIL
Date Will Philipping 15
03 November 2015
By: Mandar 2015
Date: 11 27 2015
Date: 11 27 2015
By: Mandar 2015
By: Mand

Attention: DR. LUIS SISON

Re: Philippine Utility Model Registration Nos. 2-2015-000237 and 4-2015-000236 both for "DETECTION OF PATHOGENS" both in the Name of the UNIVERSITY OF THE PHILIPPINES Our Refs.: 6.6156(B)/UM and 6.6156(C)/UM

Gentlemen:

We are pleased to inform you that the Philippine Intellectual Property Office ("IPO") has issued its Notices of Issuance of the Certificates of Registration ("Notices") both bearing mailing date of 28 September 2015, stating that the Certificates of Registration for the subject utility models have been issued.

The subject registrations have a term of seven (7) years from the date of filing, or until 19 May 2022.

With our best regards.

Very truly yours,

DIVINA GRACIA E. PEDRON

ROWANIE A. NAKAN

Encl.: a/s

6.6156(B)/6.6156/(C)/UM/DEP/RAN/CTM SR NOI OR (UTILITY MODEL)_6156(B)_6156(C)(DETECTION OF PATHOGENS)UP@KYLE

It Received FDA Approval



Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



CERTIFICATION

To Whom This May Concern:

This is to certify that the BIOTEK-MTM DENGUE AQUA KIT is currently not required to be registered with this Office because the new Food and Drug Administration (FDA) Guidelines for the registration of medical devices has not yet been issued.

This certification is issued upon the request of MANILA HEALTHTEK INC. with business address at 109 Gil Fernando Avenue, Sta. Elena, Marikina City for whatever legal purpose this may serve.

This certification is automatically cancelled or revoked upon the issuance of the pertinent health products registration guidelines. This certificate cannot be used for advertising purposes in whatever medium and neither can this certificate be construed as an endorsement by the Center for Device Regulation, Radiation Health, and Research.

Done this 20th September 2016 at Alabang, Muntinlupa.

ENGR. BAYANI C. SAN JUAN, MSc, MNSA, CESE

Center for Device Regulation, Radiation Health, and Research

Not valid without DOH Seal

: 0774754

: PhP 2,550.00 (5 Products) : 22 August 2016

LRD/CDRRHR EXEMP-2016-8025

DTN: 20160822150114



Republic of the Philippines Department of Health FOOD AND DRUG ADMINISTRATION



CERTIFICATION

To Whom This May Concern:

This is to certify that the BIOTEK-MTM LAMP HEATER is currently not required to be registered with this Office because the new Food and Drug Administration (FDA) Guidelines for the registration of medical devices has not yet been issued.

This certification is issued upon the request of MANILA HEALTHTEK INC. with business address at 109 Gil Fernando Avenue, Sta. Elena, Marikina City for whatever legal purpose this may serve.

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Done this 20th September 2016 at Alabang, Muntinlupa.

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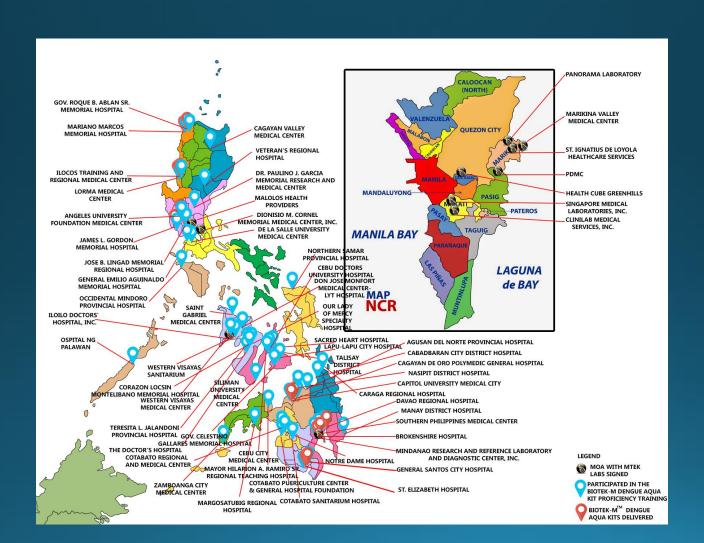
: 0774754

: PhP 2,550.00 (5 Products)

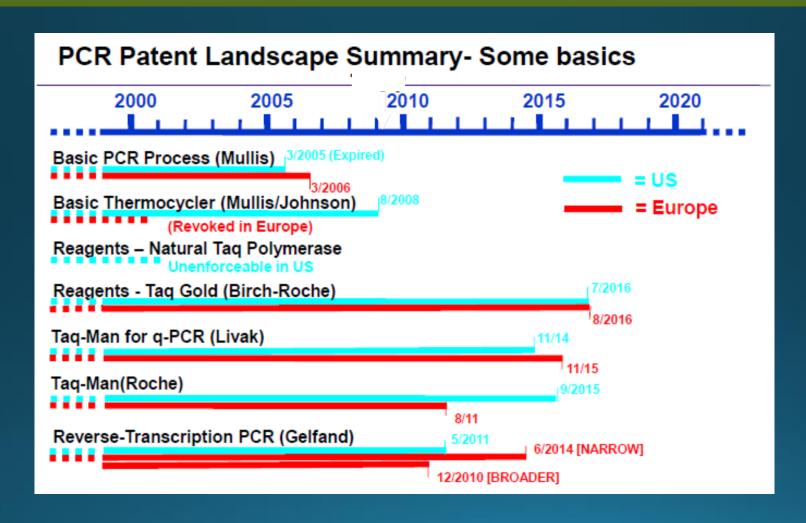
: 22 August 2016 LRD/CDRRHR EXEMP-2016-8029

DTN: 20160822150114

This is the number of hospitals we already trained



Pillar 3: PCR Technologies



GenAmplify

Dengue-ChikV PCR Detection Kit Salmonella PCR Detection Kit

TB/MDR PCR Detection Kit
Pneumocystis jerovici PCR Detection Kit
HBV-DNA PCR Detection Kit

A quality Philippine Product of



TM



Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION



CERTIFICATION

To Whom This May Concern:

This is to certify that the GENAMPLIFYTM VIRAL RNA PURIFICATION KIT is currently not required to be registered with this Office because the new Food and Drug Administration (FDA) Guidelines for the registration of medical devices has not yet been issued.

This certification is issued upon the request of MANILA HEALTHTEK INC. with business address at 109 Gil Fernando Avenue, Sta. Elena, Marikina City for whatever legal purpose this may serve.

This certification is automatically cancelled or revoked upon the issuance of the pertinent health products registration guidelines. This certificate cannot be used for advertising purposes in whatever medium and neither can this certificate be construed as an endorsement by the Center for Device Regulation, Radiation Health, and Research.

Done this 20th September 2016 at Alabang, Muntinlupa.

ENGR. BAYANI C. SAN JUAN, MSc, MNSA, CESE

Center for Device Regulation, Radiation Health, and Research

Not valid without DOH Seal

OR No. : 077475

mount : PhP 2,550.00 (5 Products)

Date : 22 August 2016 LRD/CDRRHR EXEMP-2016-8028

DTN: 20160822150114

/ddd

Pillar 4: Avian-derived IgY Technologies



Diagnostics and Therapeutics

Our new brand



- FDA Certification as R&D facility
- FDA Certification as Special Clinical Molecular Laboratory
- FDA Certification as a Manufacturing Facility

Our first technology Adaptor

• DEPARTMENT OF HEALTH

MENT MEMORANDUM 0353

ALL UNDERSECRETARIES; ASSISTANT SECRETARIES;
DIRECTORS OF BUREAUS, DOH REGIONAL OFFICES AND
SERVICES (REGION I, VI AND IX); EXECUTIVE
DIRECTORS OF SPECIALTY HOSPITALS; CHIEFS OF
MEDICAL CENTERS; AND OTHERS CONCERNED

CT: Interim Guidelines for Initial Implementation of Nucleic Acid
Amplification Test -Loop Mediated Isothermal Assay (NAATLAMP) as One of Dengue Confirmatory Tests to Support Dengue
NS1 Rapid Diagnostic Test (RDT)

2016 the Administrative Order No. 2016-0043 "Guidelines of antation of Dengue NSI Rapid Diagnostic Test (RDT)" was of retary of Health. This approval paves way on the availability of the diagnostic test for dengue at the Rural Health Units (RHUs) are meday diagnosis making early detection, prompt treatment, as moscible. Although the Dengue Rapid Diagnostic Test (Rural Research)

Summary of Lessons

Researchers must ask the question of relevance.

Researchers need to address unmet medical needs

Know your technology development landscape.

Creating an Enabling Environment

Do not be afraid engaging with technology adaptors.

Re-tool yourself.

Share your blessings.

Acknowledgements

- The team would like to acknowledge
 - the grant support provided by PCHRD-DOST, TAPI-DOST, VENTURES-DOST
 - DOH-NEB for assisting us identifying testing sites
 - the panel of evaluators who has provided us a wealth of advice and constructive challenges
 - The Philippine Genome Center for helping us find and defend all our funding applications
 - The NIH-UP Manila administration for the research environment
- May this project meet its aim to provide affordable technology for the Filipino people.

Thank you.