


# The NABIT

Nucleic Acid Barcode  
Identification Tool





**How can democratizing genetics  
protect the planet and its inhabitants?**

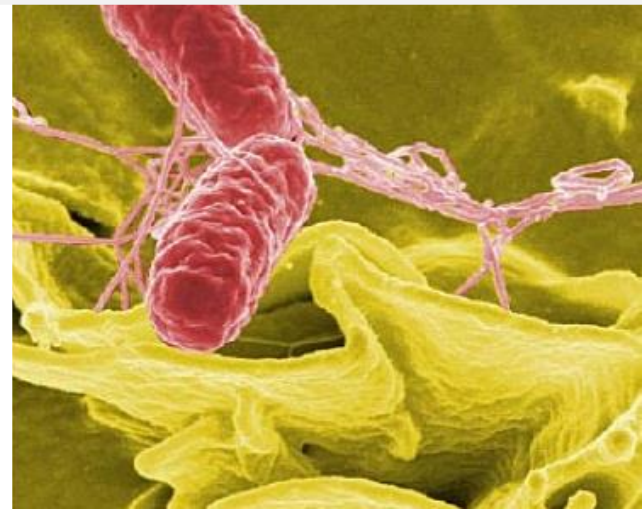


**Some products are easy  
to identify...**





**Others aren't.**



# NABIT

Nucleic Acid Barcode  
Identification Tool

**Genetic ID  
anywhere, by  
anyone, at  
any time**



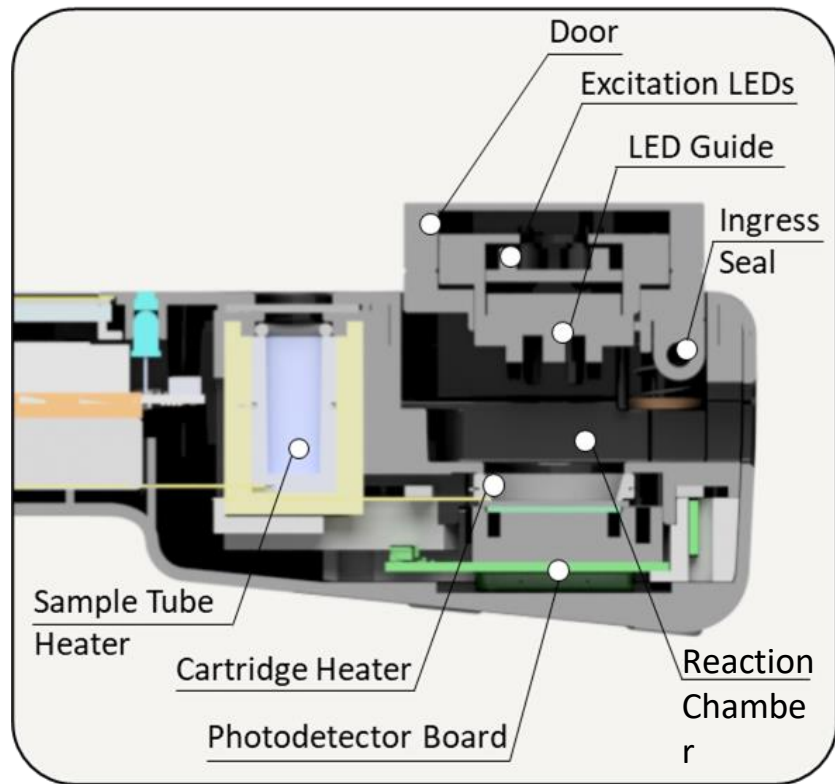
THYLACINE BIOSCIENCES

# Workflow Summary

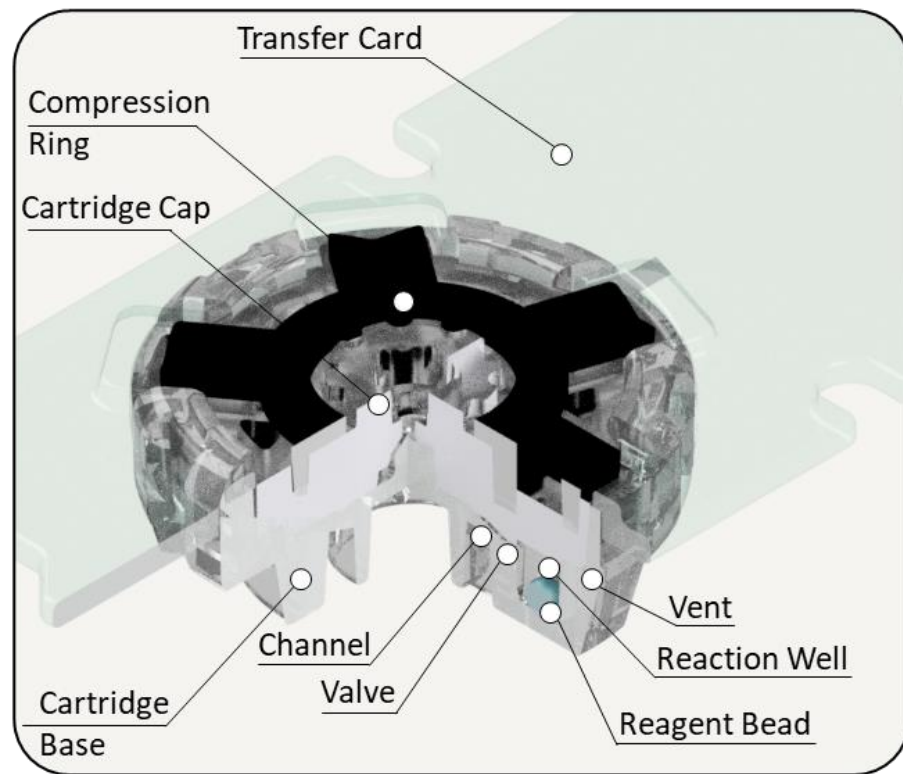
- Designed for CLIA-waiver. Review by FDA consultants under the auspices of NIH's RADx program found it to be consistent with criteria for CLIA-waiver.
- The sample is deactivated by the lysis buffer (included in each kit as a prefilled tube) and heating by the instrument prior to transfer.
- All manipulation of the samples occurs in the specially-designed test kit to reduce any potential for contamination.
- If starting from DNA/RNA there is 1 step (load cartridge with prepared sample and insert cartridge into device).
- Test kits also include the ability to do full sample-to-results in 2 steps by adding the sample extraction/preparation step.
- The test kit includes a loading guide that facilitates cartridge loading within the packaging, reducing error and contamination.



## KEY FEATURES



**NABIT**



**Cartridge**

# NABIT - DETAILED SPECIFICATIONS

Feature	Capability
Display	3.5" LCD Touchscreen
Processor	4x Arm® Cortex-A35 (1.2 GHz) 1x M4 Core
Memory	2GB DDR4 RAM 8 GB eMMC Flash
Lysis	37 – 95±2°C
Reaction	37 - 80±0.5°C 5-Channel 510 – 530nm λ
Barcode Scanner	1D or 2D Codes Center cross hair w/ 'Green Spot'
Dimensions	3"x3"x9" 3lbs
Data Transfer	USB-A, USB 2.0
Battery	4900 mAh Li-polymer
Charging	2.5A USB-C





# NABIT – PERFORMANCE CONDITIONS

Condition	Designed For
Temperature	-20 – 40 °C (-4 to 104 °F)
Humidity	5 – 95% RH
Altitude	3050 m operating 12,200m storage
Ingress Protection	IP 54
Drop	4ft unprotected 8ft protected
Shock/Vibration	1.04 Grms, 2 – 500Hz

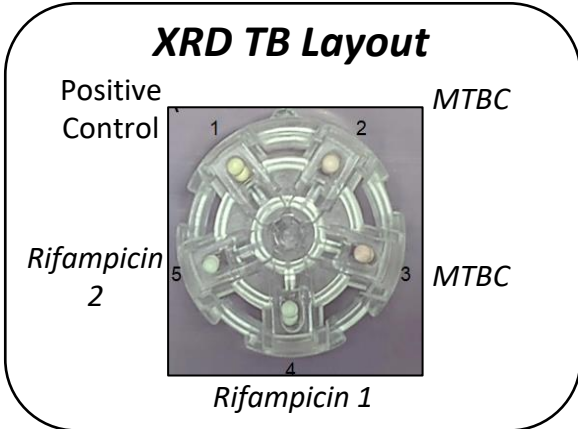
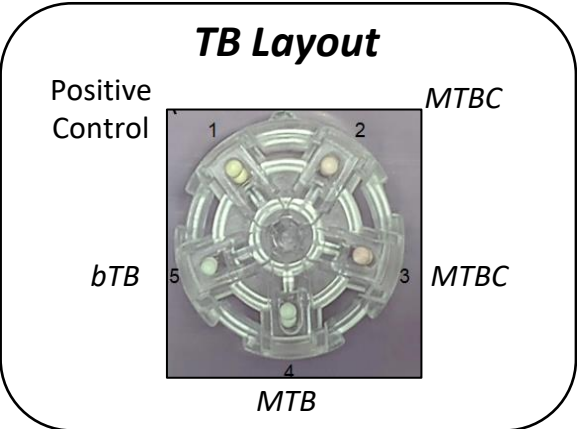
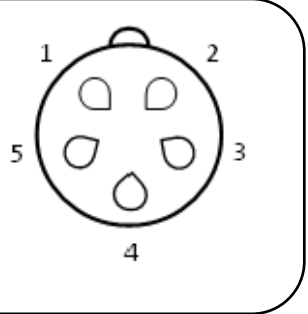




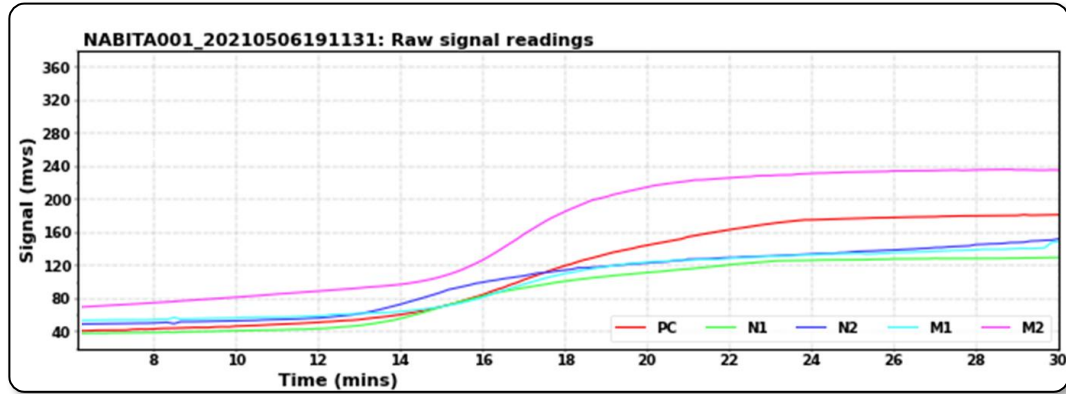
Layout allows for multiple targets or redundancies for increased

- Lyophilized reagents for **room temperature stability**
- Cartridge distributes sample into **5 reaction wells**
- Enables **integrated positive control**
- Kit assembly process makes **layout changes easy**

**Covid-19 Layout**  
1 – Positive Control  
2 – Assay Gene M  
3 – Assay Gene M  
4 – Assay Gene N  
5 – Assay Gene N



- Lyophilized reagents for room temperature



- Entire reaction is recorded like qPCR
- Proprietary algorithm automatically interprets results from signal behavior
- Displays easy-to-understand result to the screen
- All data stored on-board

- 1 – Positive Control
- 2 – Assay Gene M
- 3 – Assay Gene M
- 4 – Assay Gene N
- 5 – Assay Gene N

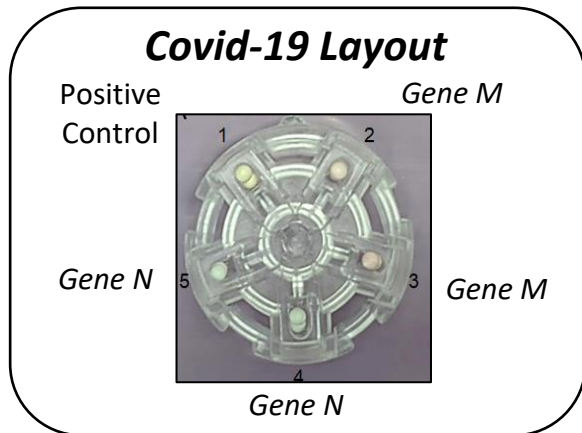


# COVID-19 Assay

## LoD Performance

Analytical testing performed by independent laboratories

- Final in-well LoD of <math><1\text{ copy}/\mu\text{L}</math>
- Two 2 gene targets (Gene M and Gene N) detects all known variants to-date
- Assays maintain performance for over 1 year when stored at room temperature



Input Swab Viral Load (copies/swab)	Final In-Well Concentration (copies/mL)	Results
38,250	23,813	POS (3/3)
19,150	11,922	POS (3/3)
9,550	5,946	POS (3/3)
4,780	2,976	POS (3/3)
2,390	1,488	POS (3/3)
1,195	744	POS (3/3)
600	374	NEG (2/3)
300	187	Untested
150	93.5	Untested
-	-	NEG (0/3)

Testing performed independently by Atlanta Center for Microsystems Engineered Point-of-Care Technologies (ACME POCT) at Emory University using gamma-irradiated virus and human nasal wash.

# Development & Production

- RADx participant – selected as one of 40 out of 2400 applicants (we continue to be supported by RADx).
- Working with FIND on TB and diagnostics development (invited to respond to RFI in anticipation of Unitaid grant for TB diagnostics).
- Third-party testing of the NABIT has been performed by Johns Hopkins University (Manabe Lab), Emory University (ACME lab of POCTRN), and MRI Global.

## Manufacturing and Production

- Design-locked instrument and SARS-CoV-2 test.
- Fully implemented quality management system (QMS).
- Small-batch manufacturing in-house.
- Quotes for manufacturing of devices, test kits, and lyophilized beads in-hand. Scaled production is ready to begin.



# Molecular Development Kit

Partnerships with research labs to easily translate thousands of lab-based assays to the NABIT

## Initial Development Partners:

- **Covid-19:** MitoLab (Broad Institute spin-out)
- **Tomato spotted wilt virus:** NC State
- **Foulbrood:** USDA ARS
- **Pan-coronavirus:** One Health Institute, UC Davis

**A Software Development Kit for biology**



# Test Kit Development PROCESS OVERVIEW

## PHASE 1 - DEFINITION

*Determine test targets, sample types, and assay feasibility*



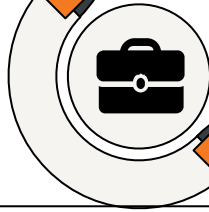
## PHASE 2 – DEVELOPMENT

*Develop assay recipes and sample workflows*



## PHASE 3 – TRANSLATION

*Conversion to stable assay beads and integrated test kits*



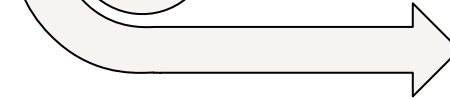
## PHASE 4 – VALIDATION

*Performance verification and field/application validation*



## PHASE 5 – MANUFACTURE

*Translation to controlled operations for recurring or on demand production*



*Our development process ensures use case needs are met and mitigates risk*

# MDK User Story



WildTechDNA is a conservation technology company combating illegal trafficking of big cats.

They have developed an assay to detect snow leopard in trace samples or wildlife products.

They have the capacity and skillsets to translate, deploy, and manage tests and are interested in having us host their test on the NABIT.

We will provide support as needed to help them translate their test on our platform, and provide contract manufacturing services and management if needed. They will manage sales and distribution of test kits, we will provide NABIT sales and distribution to their customers as well as technical support on the NABITs.

For hosting their test we will receive:

- Added user base from their customers
- Facilitating the field-transfer of an existing IWT prevention assay
- Additional data from their users can guide deployment and impact measurement of efforts
- Revenue from NABIT sales





Ovipost is an insect farm with sites in Florida and Mississippi

They are interested in having a test to detect denzoviruses in their stocks.

They do not have the capacity or facilities to develop their own tests or manage production, nor can they pay the full cost of test development at our standard rates. However, they can pay for some development costs or support testing on their sites.

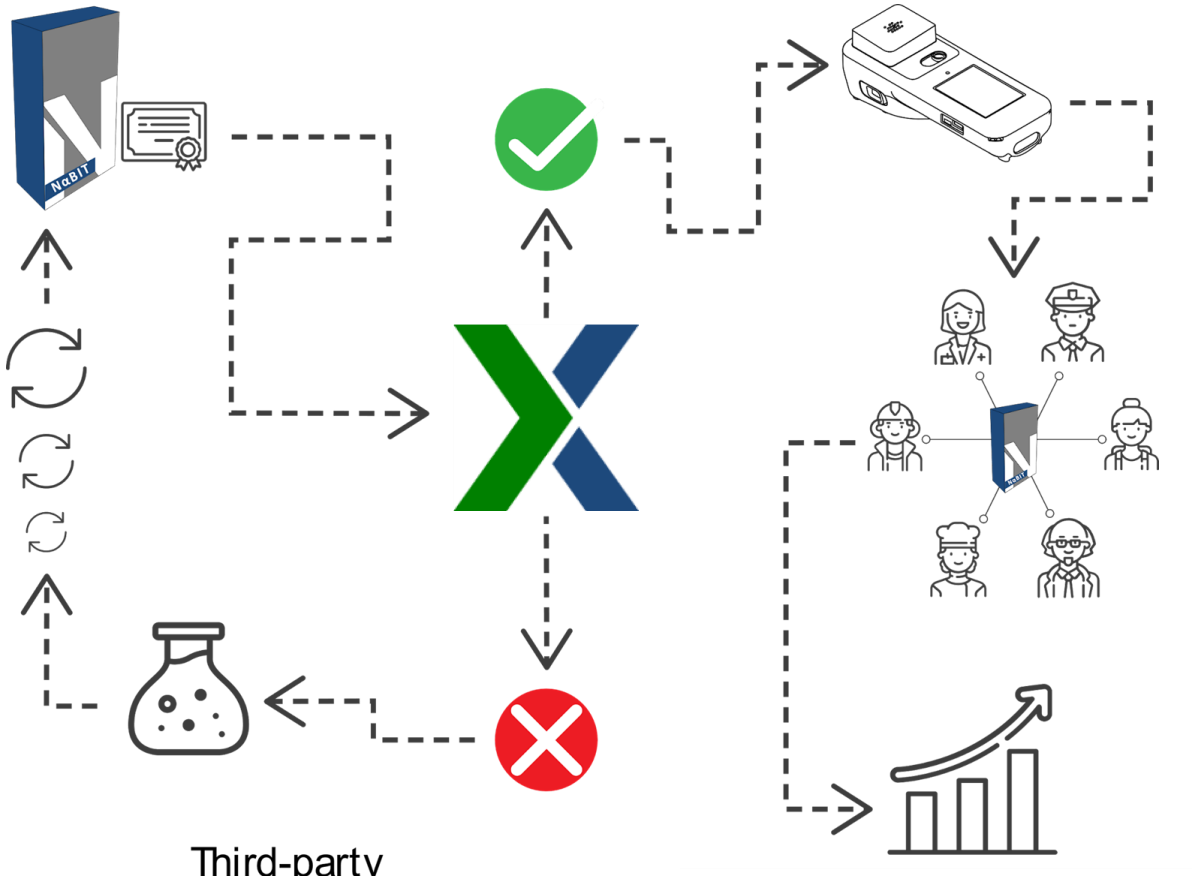
They will be a regular customer of this kit following its completion.

In exchange for our investment of their test kit we will receive:

- **100% of revenue from test kit sales**
- **Revenue from NABIT sales**
- **Added user base from their network**
- *Additional data from their customers*



# MDK Concept



Third-party  
Molecular Developer



Like the Apple App Store or Google Play, our platform will host third party development of new kits

We will review third party kits for compatibility, safety, and reliability and host approved tests on the NABIT and make them accessible to our entire community.

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# REDUCE ENVIRONMENTAL FRAUD



## Wildlife & Timber Trafficking

US \$30 to \$100 Billion



## Seafood Fraud

US \$15 Billion in the  
United States in 2015



## Invasive Species

US \$1.4 Trillion – Five  
percent of the global  
economy

**Sources:** Oceana, 2017. UNEP, 2012. Pimentel et al. 2001.

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# Agricultural Pathogens

- **Crop & Livestock Fungal Pathogens**
- **Livestock Disease Diagnosis**
- **Threats to New Agriculture**
- **Aquaculture Disease Detection**







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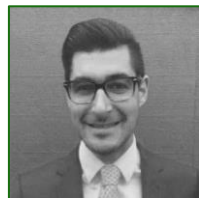
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**Dr. Hal Holmes**  
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Moore Inventor Fellow  
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**Molecular Innovations Director**  
M.Sc. Population Genetics  
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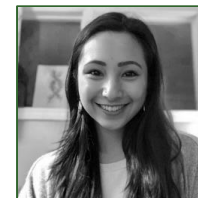
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**THANK YOU VERY MUCH!**  
**- THYLACINE TEAM**

