Innovations for Tackling Tuberculosis in the time of COVID-19

BATM

ADALTIS

ADDR DIAGNOSTICS

ABOUT

Adaltis (formerly Serono Diagnostics) is an IVD international company headquartered in Rome, Italy.

www.adaltis.com

Adaltis is owned fully by BATM -international science and technology group with H.Q in Israel that employs more than 1500 scientists and engineers world wide.

ADALTIS has 35 years of experience in developing and manufacturing in-vitro diagnostic systems and reagents to detect various infections.
All our products are IVD-CE marked.
Adaltis is an ISO 9001:2008 and ISO 13485:2004 certified company.

Dr. Zvi Marom

Chairman of Adaltis and Ador,
Founder & CEO
BATM Advanced Communications
Former Chairman Israel High Tech Association

Dr. Zvi Marom founded BATM in 1992. He graduated with excellence in electronics from the Naval Academy and with excellence from the Advanced Naval Command Course. He has a postgraduate degree in medicine from the Sackler-Goldschlager School of Medicine, Israel and an MSc in industrial electronics.
Dr. Marom is on the boards of several national and international academic committees for computing and bio-med, until 2021 served as Chairman of the Board of the Israeli Hi-Tech & Innovation Industries Association and has been awarded Israel's industry award for 2021.

Dr. Eran Zahavy

CTO, BATM

Former Head of Innovation IIBR

(Israel's Institution for Biologic Research)

Dr. Eran Zahavy has nearly 20 years of leading positions in the R&D in Chemistry, Biology, Biophysics and IVD in the government research institutes (IIBR) and industry. Dr. Zahavy had served as the Head of Innovation IIBR for the last 5 years. In this capacity he had participate in leading the COVID-19 vaccine (BriLife) development and its license to NRX. Dr. Zahavy served as CTO at Israel leading clean-tech incubator "Hutchison-Kinorot" and CTO of TACount. Dr. Eran Zahavy holds a PhD in Chemistry & Biophysics from the Hebrew University and a Post Doc from the University of TX, Austin.

RATIONAL & TARGETS OF THE NEW INNOVATION PROPOSED

STEP 1

- ✓ Enable PCR MDR/XDR testing and execute scanning of large populations using novel Algo- combinatoric system. Can be done **together** with testing other respiratory conditions like **COVID-19**

STEP 2

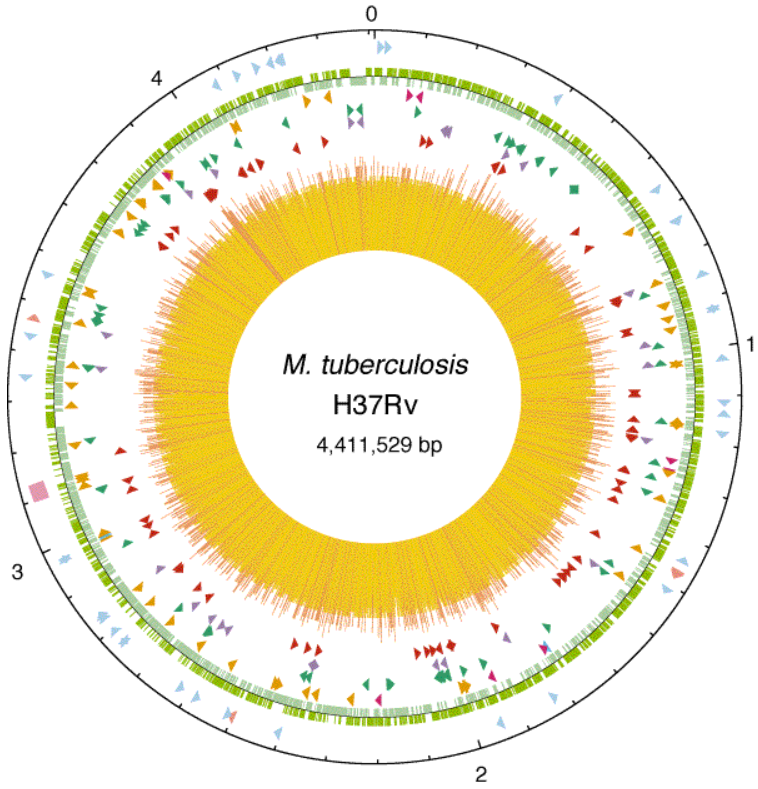
- ✓ Using Isothermal RCA test on existing equipment gives results in <30m. incl single point mutation, detecting MDR/XDR

STEP 3

- ✓ Personal \ POC-IsoThermal test enable detect Tb at places where there is no equipment and collect data via mobile

STEP 4

- ✓ Using Isothermal RCA test NATlab gives a comprehensive sample to answer POC <30 m. and gives regional/country based info



RATIONAL & TARGETS OF THE NEW INNOVATION PROPOSED

#	Method	Readiness	Remarks
1	PCR Test	Q4/2021	Yes/No/- Cheap Sub 5 EU
2	Combinatoric Algo Scanning	Q4/2021	Scanning Cost. 1:10-I.e sub 0.5 Eu\Test Tested and approved for COVID-19
3	MDR/XDR PCR	Q2/2022	Multiplexed PCR on MAX 4 wells , **can work with other multiplexed multi Respiratory panels**
4	IsoThermal personal POC kit	Q2/2022	High precision, no device needed, tested successfully with COVID-19, incl. computer report
5	IsoThermal RCA Test	Q2/2022	Works on standard Liquid handlers, results including single point mutation < 30 m.
6	POC RCA Test	Q2/2023	Comprehensive POC sample to answer solution for infectious diseases

AMPLIlab
& Other standard thermocyclers

EXTRAlab
& Other liquid handlers

NATlab

Remark: All systems(including personal and POC) are able to report to national AI or Databases -
Example : RAMZOR in Israel that handles all reporting and vaccination systems developed and implemented by BATM.

THE PCR KITS

- ✓ TB / NTM detection by rapid PCR kit
- ✓ Covering all TB and all NTM species by conserved genes
- ✓ Using automatic RCA / PCR expansion to Isoniazid, Rifampicin and Fluroquinolones

Team lead by:

Prof. Marco Favaro

Dr. Walter Mattina

Dr. Cristiano Padula

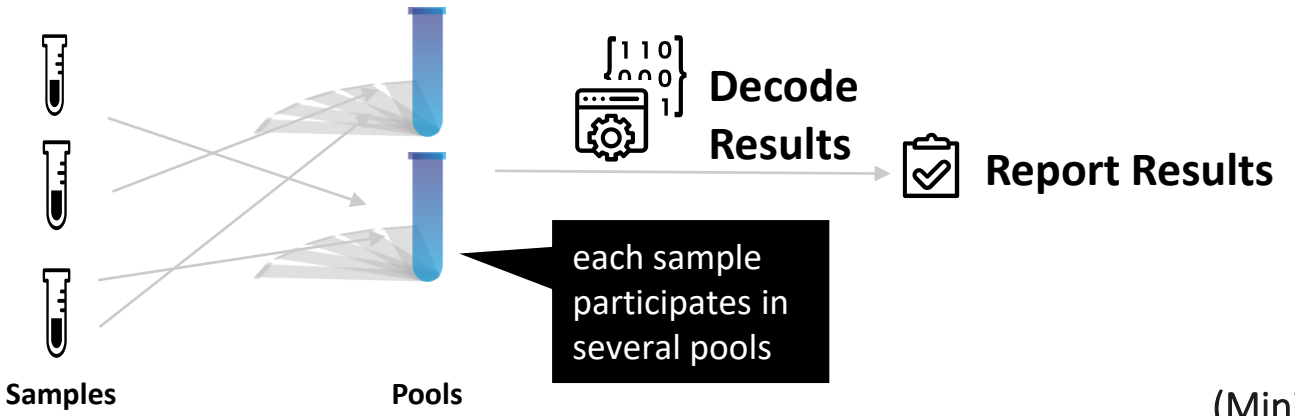
NOVELL COMBINATORIC ALGO
UNIQUE VALUE PROPOSITION

Combinatorial pooling
(Poold Diagnostics software)

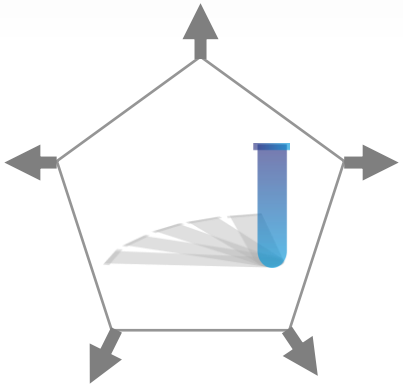
Single-stage Test

Test time:

Test mixed samples
[by mathematic formula]



Highly efficient for population screens



Optimal for multiplexed PCR tests

Saves x8 – x10 test reagent costs for prevalence <1%

Rapid integration
(Minimal disturbance to lab workflow)

Multiple testing platforms

Team Lead by:
Prof. Roy Adar
Prof. Noam Shental

SUGGESTED WORKFLOW

Combinatorial Pooling
Over EXTRAlab (Adaltis) or other liquid handlers, ~1hour

Extraction and **multiplex** PCR using TB-relevant primers

Decoding algorithm

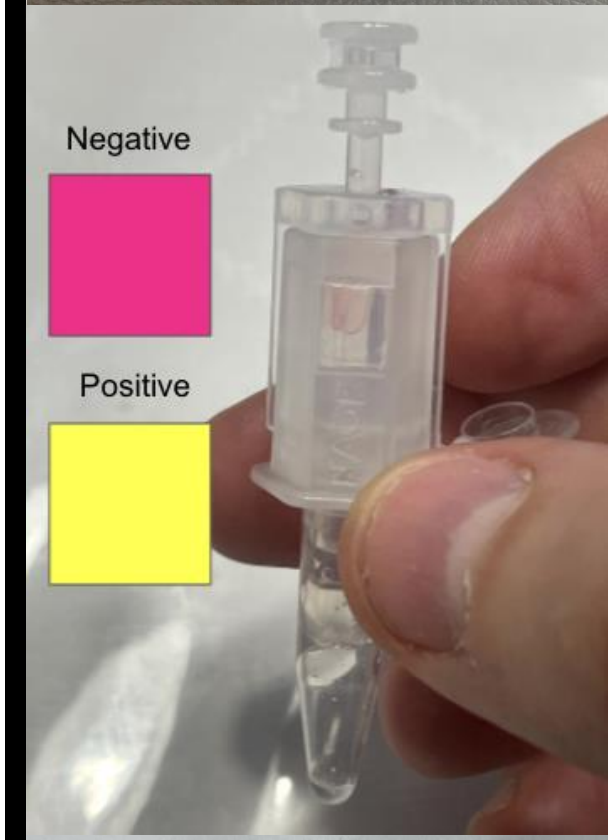
1 minute

Report results to Med. Files of all subjects **for each primer pair**

- Positive samples for each and every TB strain are detected in a single round of testing
- Pipeline like above can process 4000-5000 samples per day/instrument
- Reduction in reagent costs by a factor of 8-10

IsoThermal SINGLE TEST

- ✓ Rapid, Easy to use, Saliva-based molecular diagnostic platform for a variety of indications.
- ✓ Disruptive, modular and scalable process for a variety of non-lab settings.
- ✓ Based on a highly enhanced version of RT-LAMP, a well-recognized simplified, RNA extraction-free PCR process.
- ✓ Obtained CE for the COVID-19 indication, with high sensitivity (>90%) at the infectious range, >99% specificity. Easily adapted to new indications and targets.
- ✓ 40 minutes to obtain results of multi-samples, using self-collected samples, plain heaters and low skilled personnel. Color change reflects results, which can be easily viewed by a naked eye or by smartphone.
- ✓ Changing target indications by rapidly altering the primers and the buffer.
- ✓ TB diagnostic using RT-Lamp was already shown to be scientifically sound.
- ✓ Can be ready for large scale deployment within 12-18 months.



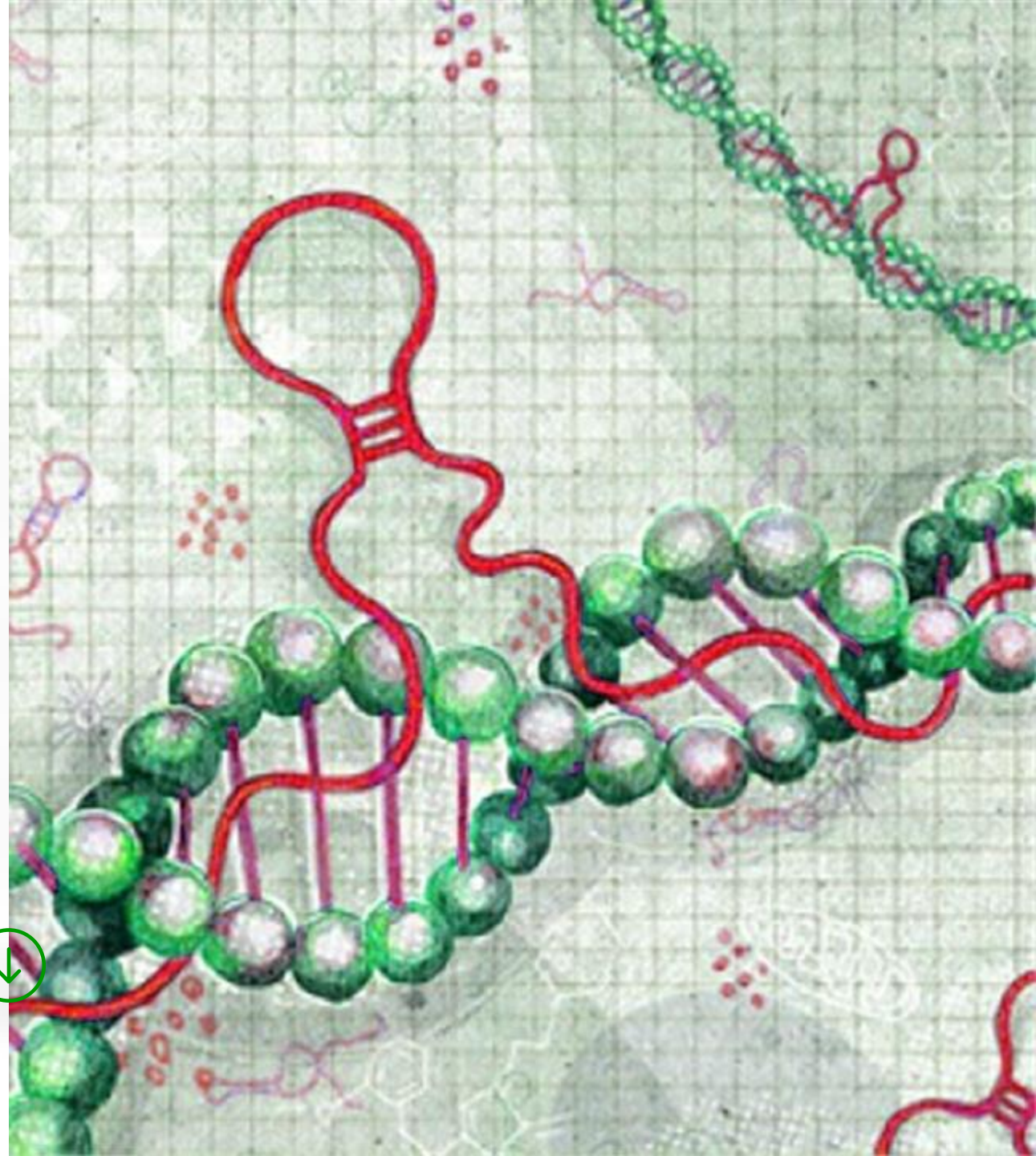
Team lead by: Dr. Oren Fuerst

NATlab

MDx
Innovative
Rapid &
Compact
Solution

Confidential

RCA VS PCR



Team lead by:

Dr. Vladimir Hurgin

Dr. Ari Tadmor

Dr. Aya Khwaja

ADAR DIAGNOSTICS

NATlab

PCR vs RCA

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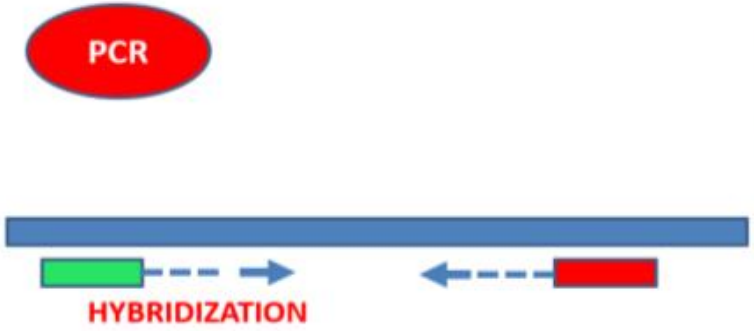
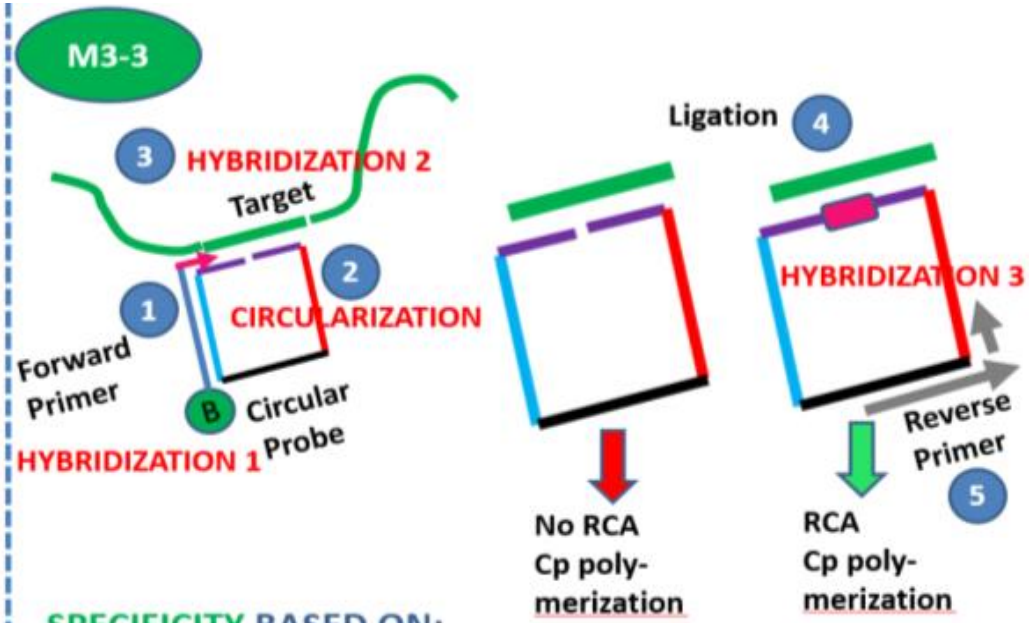


SPECIFICITY BASED ON:

1. HYBRIDIZATION OF PRIMERS (15 -20 bp)



SPECIFICITY BASED ON:

1. HYBRIDIZATION OF FORWARD PRIMERS (~22 bp)
2. CIRCULARIZATION OF CP PROBE
3. HYBRIDIZATION TO TARGET (30-40 bp)
4. LIGATION
5. HYBRIDIZATION OF REVERSE PRIMER (~20 bp)

ADSR DIAGNOSTICS

NATlab

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Sample to answer system

15-90 min to result

Hands-on time < 2 min

Up to 100 pathogenic targets

NATlab is a diagnostic (MDx) platform

NATlab is unique:

- ✓ Rapid, fully automated, sample-to-answer, multiplexed analysis of individual samples.
- ✓ No need for preparation.
- ✓ No nucleic acid extraction for the PCR process.
- ✓ Up to 100 targets in one run.
- ✓ Performs on board data analysis and sends the results to the clinician with optional data sharing with public health services.
- ✓ Combines patented* electronic carbon array technology, innovative chemistry and state of the art micro fluidics, guaranteeing sensitivity and specificity.
- ✓ Ultra short time for panel development.
- ✓ The NATlab can be rapidly upgraded in case of a new pathogen appearance.

*** Patented: Several patents:**
US, Europe, Japan, Canada.

ADSR DIAGNOSTICS

NATlab

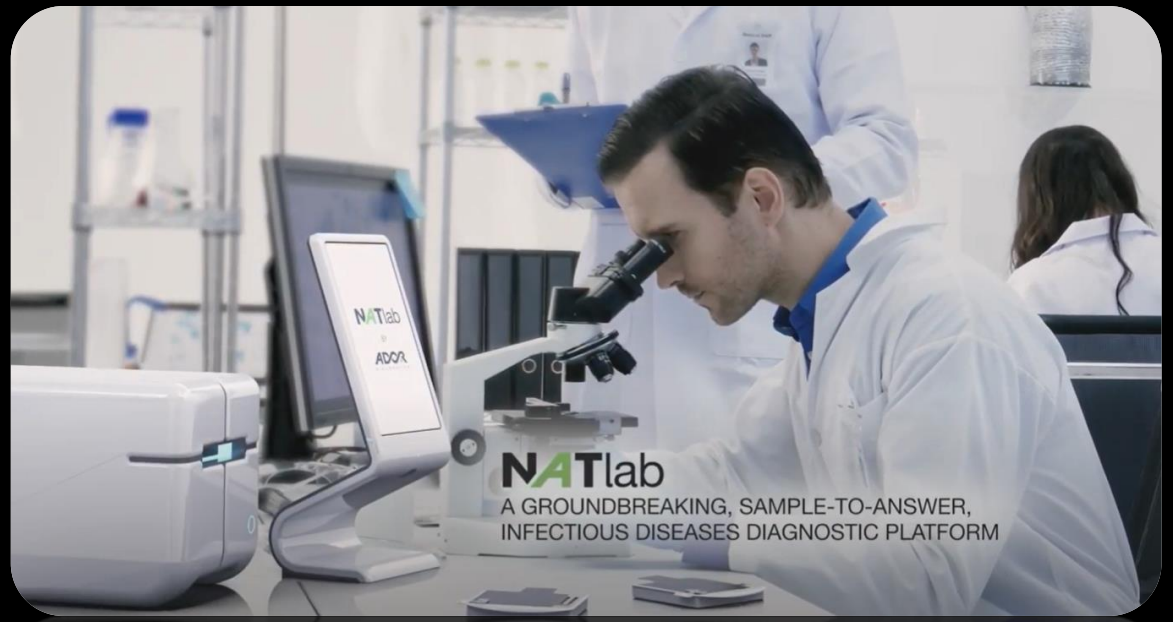
Scalable Throughput

Horizontal Combination

ADOR DIAGNOSTICS

NATlab Introduction Movie

https://youtu.be/hywM-8x7uXM



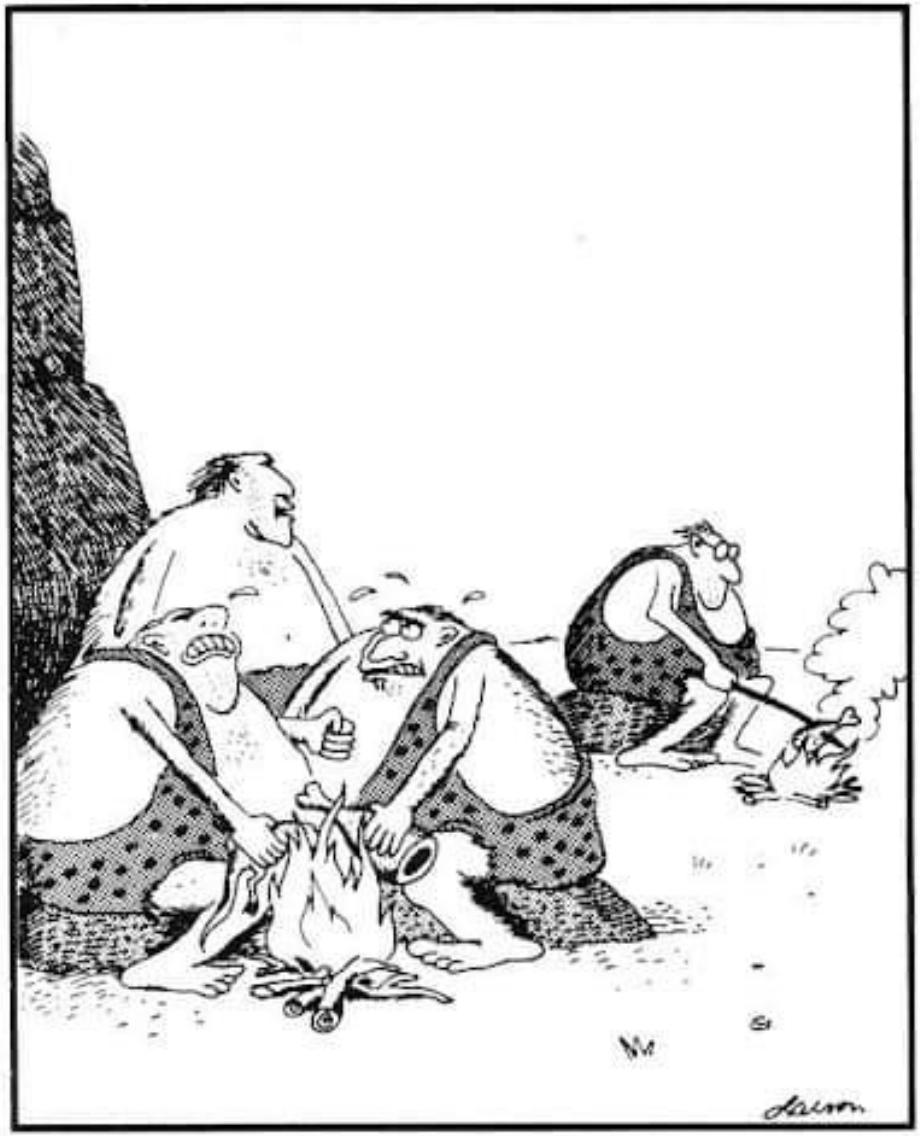
Rambam Hospital Clinical Testing

https://youtu.be/RcEfgbpcTr4

MOVIES

SUMMARY

1. Approach TB from Innovation and not disease point of view.
2. Use PCR / IsoThermal + Algorithmic approach to scan populations and enable immediate start of suitable antibiotic treatment.
3. Lower cost in order of magnitude by taking that new approach.
4. Possibly “ride” on other respiratory illness, for example, COVID-19.
5. Use either standard of the shelf lab equipment or enable rigorous POC’s with NATlab sample to answer solution.



"Hey! Look what Zog do!"

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