



Transforming PCR testing for infectious diseases @ANYWHERE™

Kevin Kraus
CEO

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THE PROBLEM

**14M
deaths**

annually from
infectious
diseases

**Lack of
access**

to diagnostic
tests
& treatment

**Unmet
need**

rapid, accurate,
affordable
PCR tests
@ANYWHERE™

WHY PCR TESTING MATTERS?

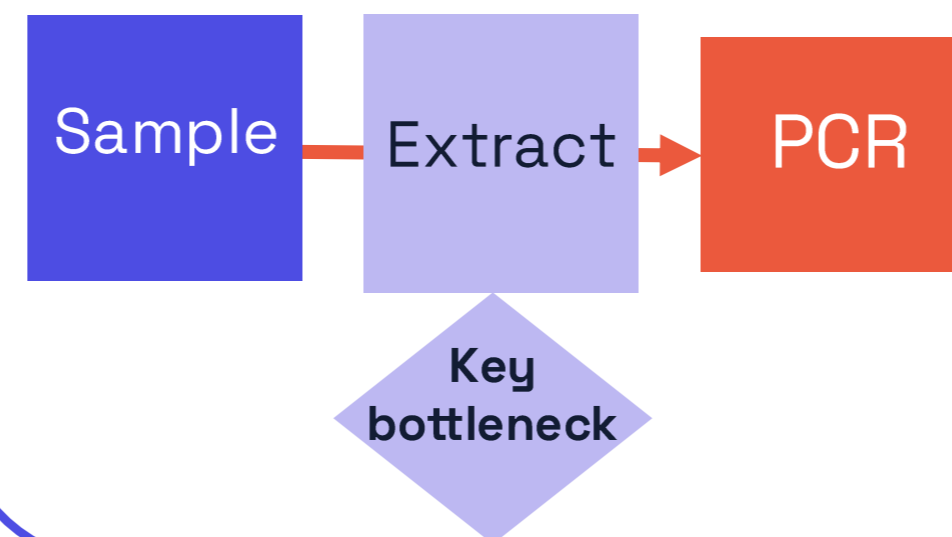
PCR is the gold-standard
for infectious diseases testing

But it's complex, expensive and still stuck in the lab

Sample collection
has toxins



Complicated
tests & equipment



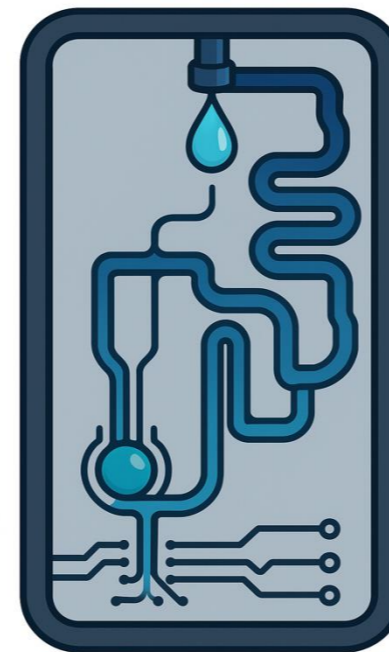
High cost & skilled
staff required



Transforming PCR testing for infectious diseases @ANYWHERE™



Direct-to-PCR chemistries
& Sample collection



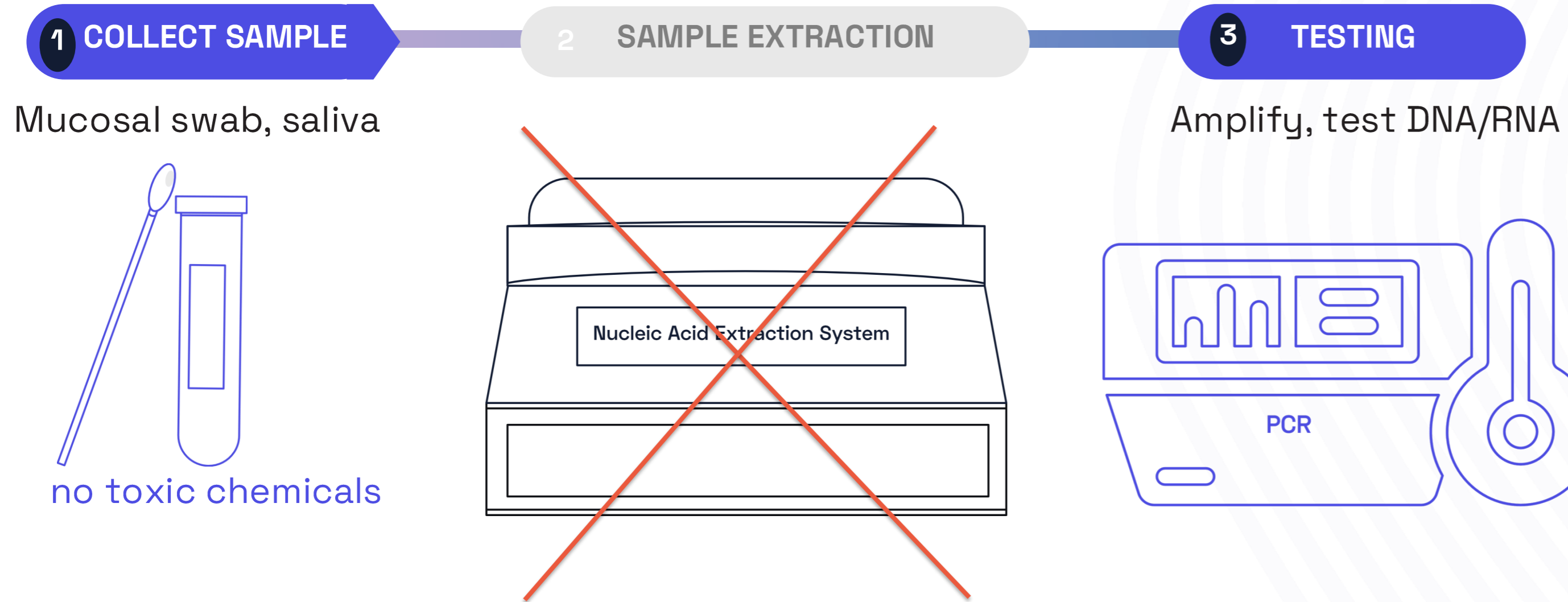
Microfluidics
& Acoustic mixing



Handheld, smartphone
powered testing device

Combining proven platform technologies
to deliver rapid, accurate and affordable tests anywhere

Simplified PCR testing enables rapid, accurate and robust infectious disease testing



Dramatic improvement vs. conventional PCR

- 5 - 14x faster
- Highly accurate
- Lower cost

Direct-to-PCR: 1st in nasal swabs & saliva

590,000+

patients tested
for SARS-CoV-2

100%

diagnostic accuracy
(swab)


**Proof of
Concept**

- Flu + COVID
- STIs (CT/NG)

Landmark US patent #12,344,889 Extraction-Free Pathogen Testing

Patent Estate:

- 1 patent issued
- 1 notice of allowance
- 4 patents pending



US012344889B2

(12) **United States Patent**
Blomquist et al.

(10) **Patent No.:** **US 12,344,889 B2**
(45) **Date of Patent:** ***Jul. 1, 2025**

(54) **EXTRACTION-FREE PATHOGEN TESTING METHODS**

(71) Applicants: **Transformative Biotech, LLC**,
Boulder, CO (US); **The Regents of The University of Colorado**, Aurora, CO (US)

(72) Inventors: **Robert E. Blomquist**, Boulder, CO (US); **Shi-Long Lu**, Englewood, CO (US); **Brian L. Harry**, Denver, CO (US); **Jose P. Zevallos**, St. Louis, MO (US); **Xin Yao**, Boulder, CO (US)

(73) Assignees: **Transformative Biotech, LLC**,
Boulder, CO (US); **The Regents of the University of Colorado**, Aurora, CO (US)

FOREIGN PATENT DOCUMENTS

EP	3985129	A1	*	4/2022	C12Q 1/6876
WO	WO-2013006793	A3	*	5/2013	C12Q 1/68
WO	WO-2021133943	A1	*	7/2021	A61M 1/362
WO	WO-2021168478	A1	*	8/2021	C12Q 1/6844
WO	WO-2021202158	A1	*	10/2021	C12Q 1/6844
WO	WO-2022020886	A1	*	2/2022	C12Q 1/6806
WO	WO-2022192440	A1	*	9/2022	C12Q 1/6806
WO	WO-2022198086	A1	*	9/2022	C12Q 1/6806
WO	WO-2022236193	A2	*	11/2022	C12Q 1/701
WO	WO-2023287901	A1	*	1/2023	C12Q 1/6806
WO	WO-2023081029	A2	*	5/2023	C12Q 1/6806

OTHER PUBLICATIONS

Beltran-Pavez et al., 2020. SARS-COV-2 detection from nasopharyngeal swab samples without RNA extraction. Biorxiv, pp. 2020-03. (Year: 2020).*

Blow et al., 2004. Virus inactivation by nucleic acid extraction

Transforming PCR testing for infectious diseases

DIRECT-TO-PCR PLATFORM + **MICROFLUIDIC PLATFORM** → **@ANYWHERE™**

Platform technologies

1 COLLECT SAMPLE → **2 TESTING**

Swab, saliva Visualize results


no toxic chemicals

Lab-on-a-chip technologies

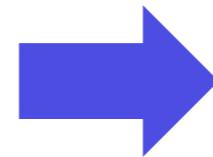
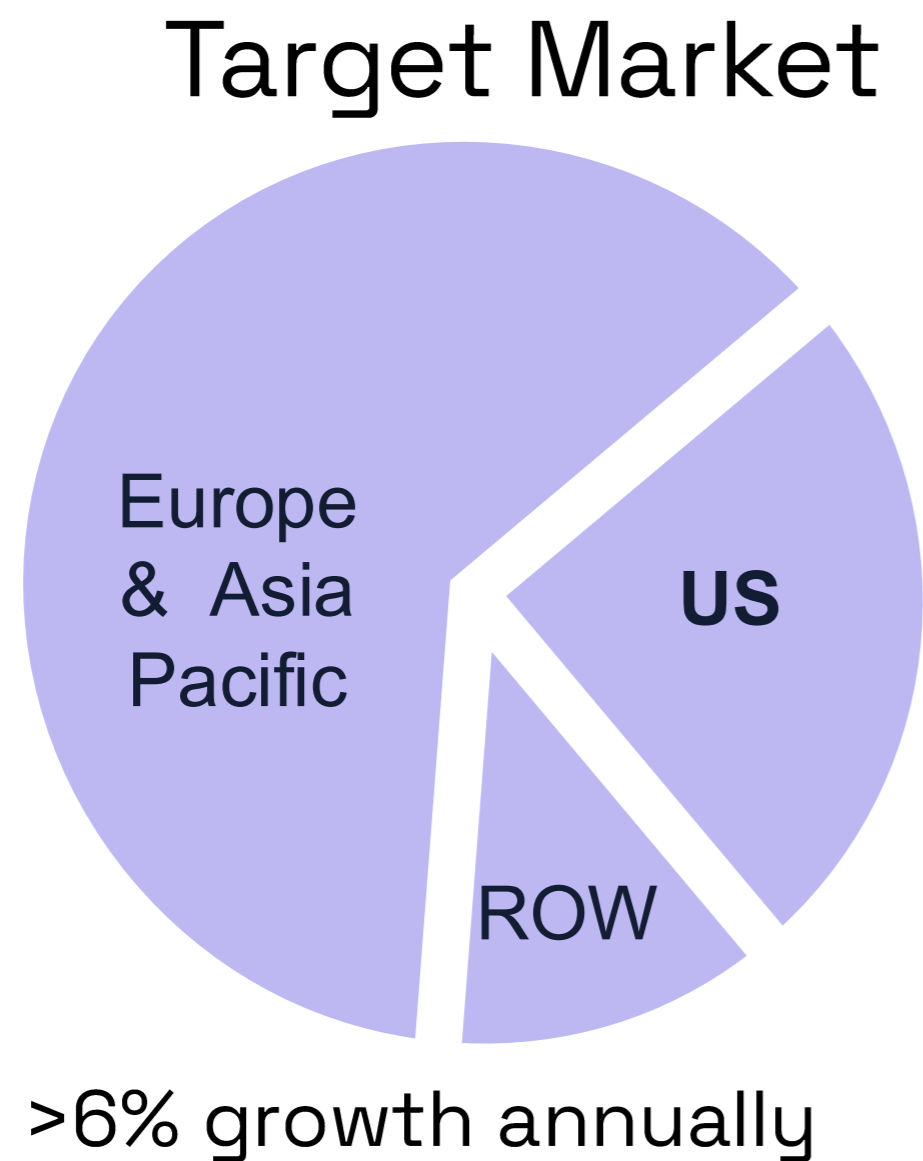
COLORADO STATE UNIVERSITY

University of Colorado **Boulder**

Smartphone powered, handheld device



\$17B PCR Target market: 2.5B tests

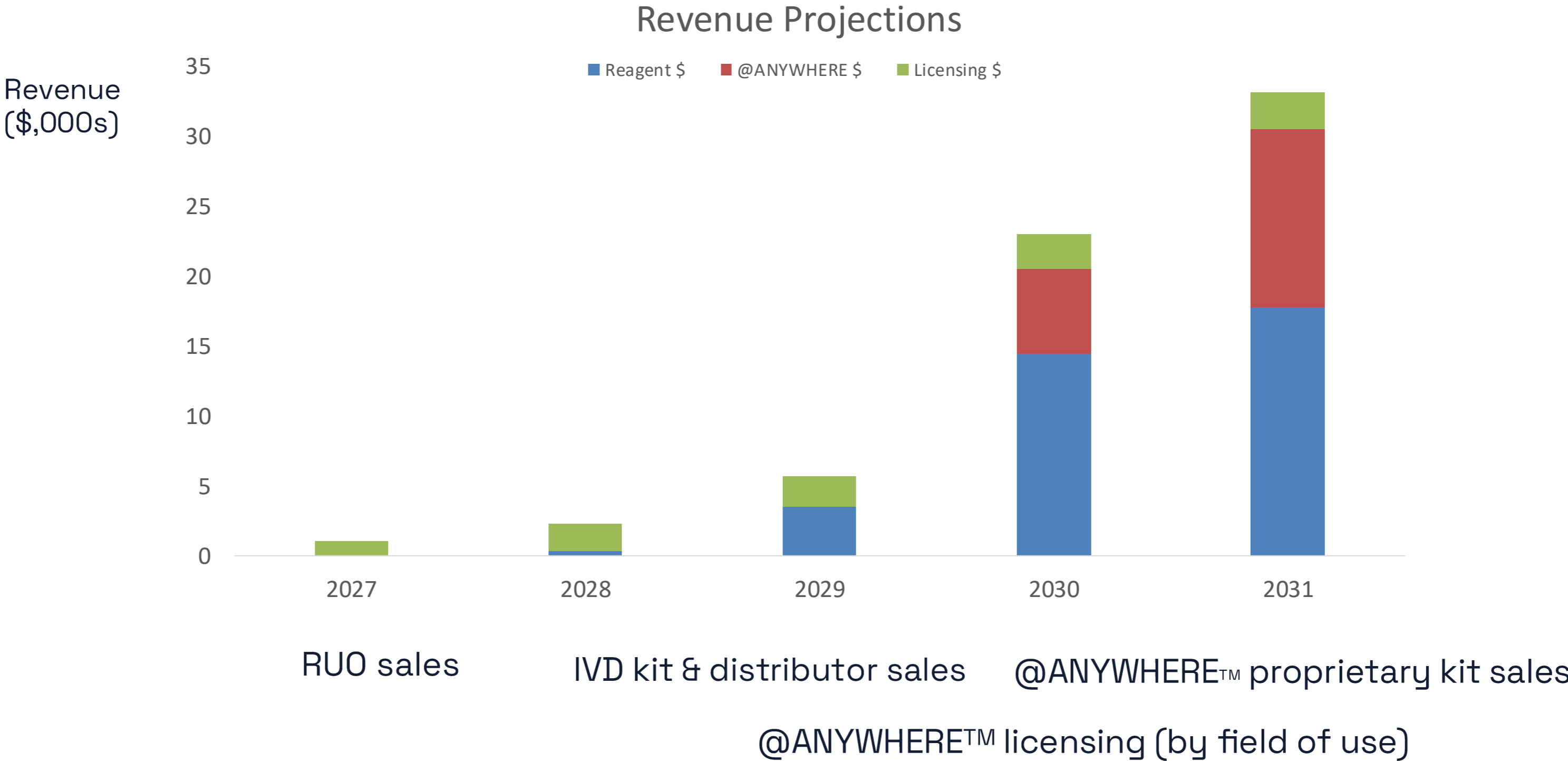


\$5B US Target Market

- 500M tests for infectious diseases (Respiratory, STIs)

REVENUE MODEL

Profitable revenue growth from reagents and licensing



GO-TO-MARKET



Product Examples

@ANYWHERE™ SALES
Proprietary kits and via partners



CLINICAL LAB IVD SALES & LICENSING
(reagents, sample collection kits via partners, distributors)



NON-CLINICAL RUO SALES (DirectAmp™ buffer reagents)



COMPETITION: PCR TESTING LANDSCAPE

Lab-based



Miniaturized



Handheld



- 1st STI handheld device
- Tethered to a powercord
- Unaffordable

Direct-to-PCR



SALIVADIRECT™

1st in raw saliva for SARS CoV-2

@ANYWHERE™



Smartphone powered handheld device



Transformative Biotech
(Summit Biolabs)

- 1st in swabs & saliva (SARS CoV-2)
- 1st in STIs (CT/NG) and Flu
- 1st in non-toxic sample stabilizing solution



Transformative Biotech

- 1st to combine proven platform technologies:
 - Direct-to-PCR
 - Advanced microfluidics
 - Acoustic mixing

WORLD CLASS EXPERIENCE IN DIAGNOSTICS, DISCOVERY & COMMERCIALIZATION

LEADERSHIP TEAM



KEVIN KRAUS
CEO



MARK KELLEHER, PHD
EVP, Research & Development



JAY FOUST
EVP, Business Development



SHELLE POURMANAFZADEH ARDABILI
VP, Business Operations

BOARD OF DIRECTORS



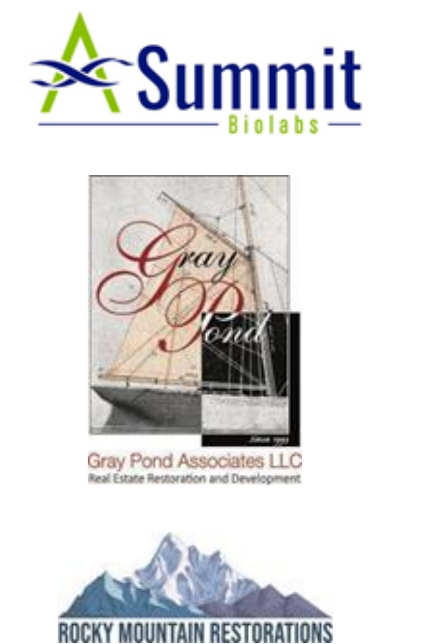
BOB BLOMQUIST
Co-Inventor,
Board Chair



BARBARA HANDELIN, PHD
Board Member



RUSS HULLET
Co-Founder,
Board Member



SCIENCE & BUSINESS ADVISORS

EXPERTS IN DIAGNOSTICS, DISCOVERY & DEVELOPMENT



CHARLES HENRY, PHD
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BRIAN GEISS, PHD
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TONY SHUBER
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DUSH RAMACHANDRAN
Strategic & Information Technology Advisor



University of Colorado
Boulder



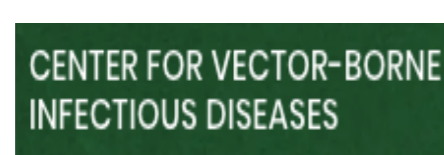
Halteres
Associates



Nabsys

UCLA

BROAD
INSTITUTE



Biomedical Microfluidics Lab
COLLEGE OF ENGINEERING AND APPLIED SCIENCE



EXACT
SCIENCES



OUR ASK & USE OF FUNDS

\$2.75M

1st tranche of \$6M raise

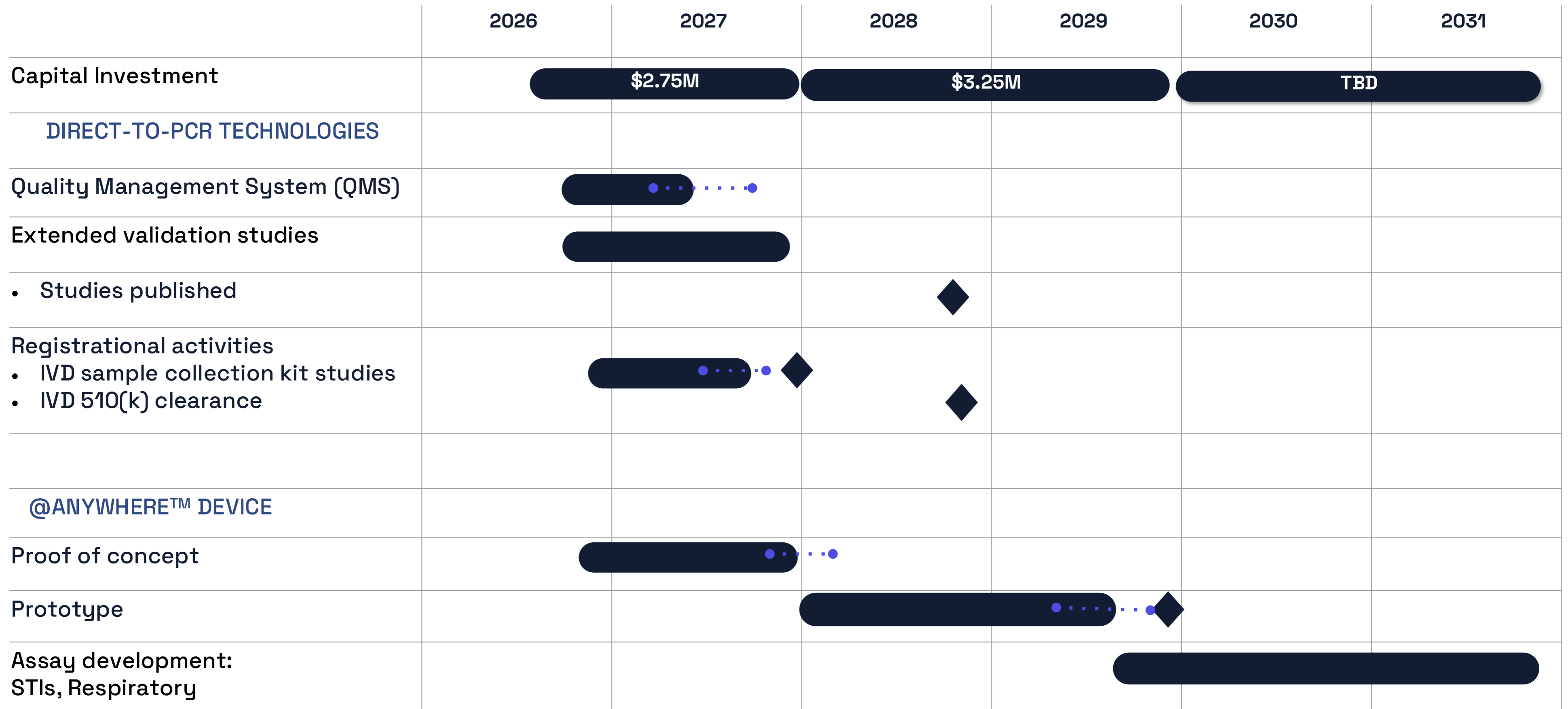
Actions

- Broaden data in direct-to-PCR for STIs
- Perform 510(k)-sample collection kit studies under quality management system
- Develop @ANYWHERE™ proof of concept
- Drive partnership discussions
- Prosecute patents and general operations

Milestones

- STI data package completed
- 510(k)-ready sample collection kit
- @ANYWHERE™ proof of concept
- Revenue from customers & OEMs
- Positioned for growth

USE OF FUNDS



PCR testing for infectious disease @ANYWHERE™

TEAM & ADVISORS

- ✓ Proven in diagnostics, discovery and commercialization

ASK

\$2.75M
1st tranche of
\$6M raise

CLINICALLY PROVEN

- ✓ 590,000+ clinical tests
- ✓ Licensing interest & clear path to monetize

IP

- ✓ Landmark US patent #12,344,889
- ✓ Notice of allowance
- 4 patents pending

MILESTONES

- 510(k)-ready sample collection kit
- @ANYWHERE™ proof of concept
- Customer / OEM sales

IMPACT

- ✓ Deliver @ANYWHERE™ infectious diseases testing and save lives





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Biotech

GET IN TOUCH!

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Direct-to-PCR: proven equivalent to conventional PCR

Summit Biolabs tests	DISEASE	SAMPLE TYPE	POSITIVE PERCENT AGREEMENT	NEGATIVE PERCENT AGREEMENT
CLINICAL STUDY				
COVIDFast	COVID-19	swab	100%	100%
COVIDFast	COVID-19	saliva	98.8%	99.4%
PROOF OF CONCEPT STUDY				
FLUVIDFast	COVID-19	swab	92.9%	99.2%
	COVID-19	saliva	92.0%	99.6%
	Flu	swab or saliva	100%	—

Equivalent PCR performance

Published* benchmarking vs. extraction-based PCR

What we tested

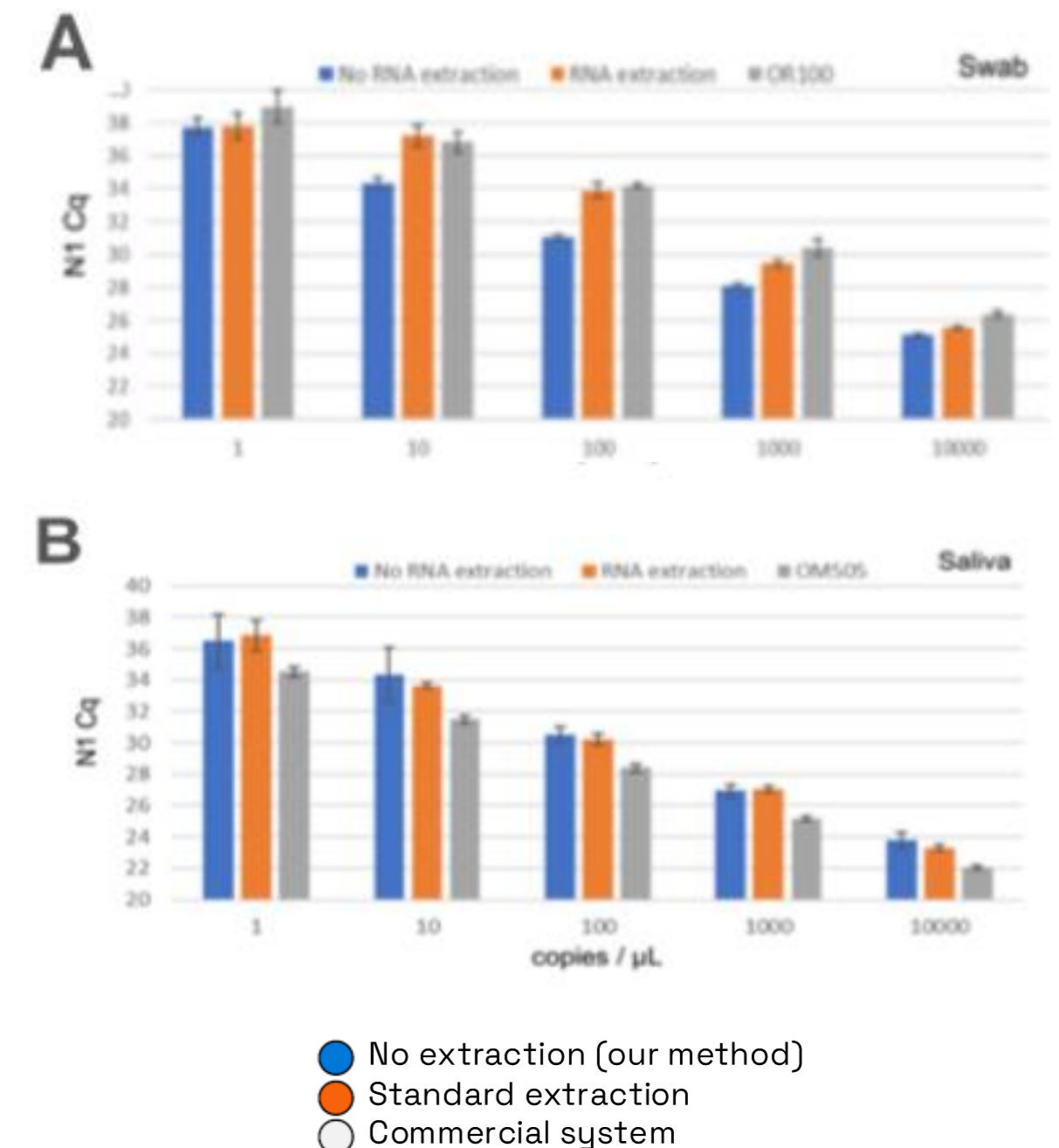
- SARS-CoV-2 in swab and saliva across viral loads

What we compared

- DirectAmp™ (no extraction) vs. standard extraction vs. commercial system

What we found

- Equivalent Ct values across sample types and viral loads
- Maintained sensitivity (LoD) at low copy levels
- Consistent, reproducible performance



Showing copies/ μ l (x-axis) of heat inactivated SARS-CoV-2 spiked into samples collected in cryovials or commercial collection device. Cryovials were extracted (orange) and not extracted (blue) commercial device was extracted grey) Panel A swabs, Panel B saliva. (from Qiu et al J biotechnol biomed 2024)

* Qiu Y, et al. *Journal of Biotechnology & Biomedicine*. 2024. Ct (cycle threshold): number of cycles needed to detect the virus, lower = more virus. LoD (limit of detection): the lowest amount of virus the test can detect.

COMPETITION

Sample collection media for PCR testing lack our breakthrough technologies

Copan



ThermoFisher
SCIENTIFIC



Transformative
Biotech



BREAKTHROUGHS

- No inhibitor chemicals to PCR
- Stabilizes mucousal swab and saliva samples
- Non-toxic for self-collection (no alcohol, GITC*) with >7 day stability @40 C)

*GITC (guanidinium isothiocyanate) is a toxic chaotropic agent used in many conventional nucleic-acid extraction buffers and sample media kits.

COMPETITION

Incumbent molecular systems are stuck in centralized labs due to their complexity



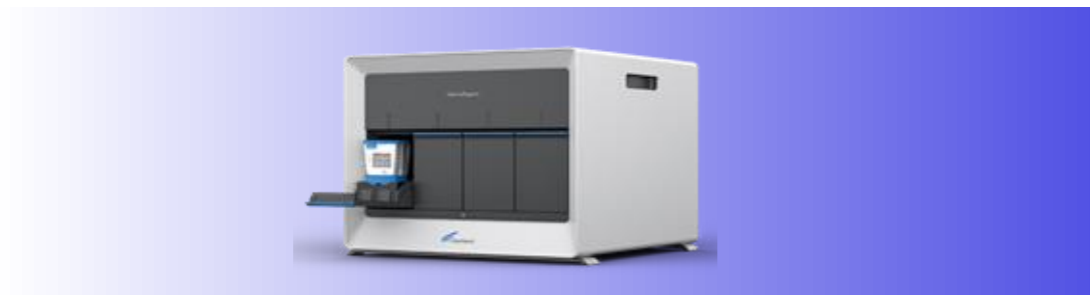
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ENABLING ALL COMPANIES TO IMPROVE THEIR DEVICES

- No sample purification required
- Reduces complexity and cost
- Shorten time to result
- Reduces overall device size

COMPETITION

POC manufacturers have “luggable” high-cost devices
... not @ANYWHERE™ testing









Transformative
Biotech

ENABLING ALL COMPANIES TO IMPROVE THEIR DEVICES

- No sample processing required
- Reduces complexity and cost
- Reduces test time
- Enables smaller device options

COMPARABLES: POINT-OF-CARE DIAGNOSTIC EXITS

Strategics acquire POC platforms that reduce complexity, time-to-result, or cost

Company	Lex Dx	Curiosity	Iquum	Mesa	BioFire	Alere
Revenue	Early Revenue	Pre-Revenue	~\$25M (LIAT)	\$45M	~\$70M	\$2.5B
Multiple	High	High	>10x	>10x	6 - 7x	2 - 3x*
Exit Value	~\$100M	\$130M	\$450M**	\$550M**	\$485M	\$5.3B
Acquiror						
Year	2026	2022	2014	2021	2014	2017

* Equity Value / Revenue multiple; ** = including milestone payments