



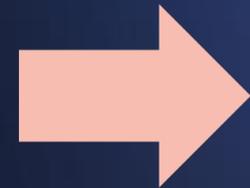
Transformative
Biotech

Simplified PCR testing for infectious diseases @ANYWHERE™

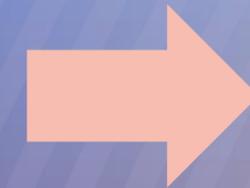
Kevin Kraus
CEO

THE PROBLEM

People
lack
access



Delayed
or missed
diagnosis



14M
deaths

affordable,
accurate,
rapid testing

annually from
infectious
diseases

Pandemic scaled testing, not PCR-level confidence



Antigen
(SARS-Cov-2)



Molecular (NAAT)
(SARS-Cov-2, Influenza)



PCR
Gold standard test for
infectious diseases

Fast & Cheap



Accurate & Sensitive

Note: PCR (Polymerase Chain Reaction) is a highly accurate molecular diagnostic technique that is fundamental to all analysis of DNA/RNA. NAAT = nucleic acid amplification test

PCR adoption hasn't reached its full potential

Sample purification steps required before testing



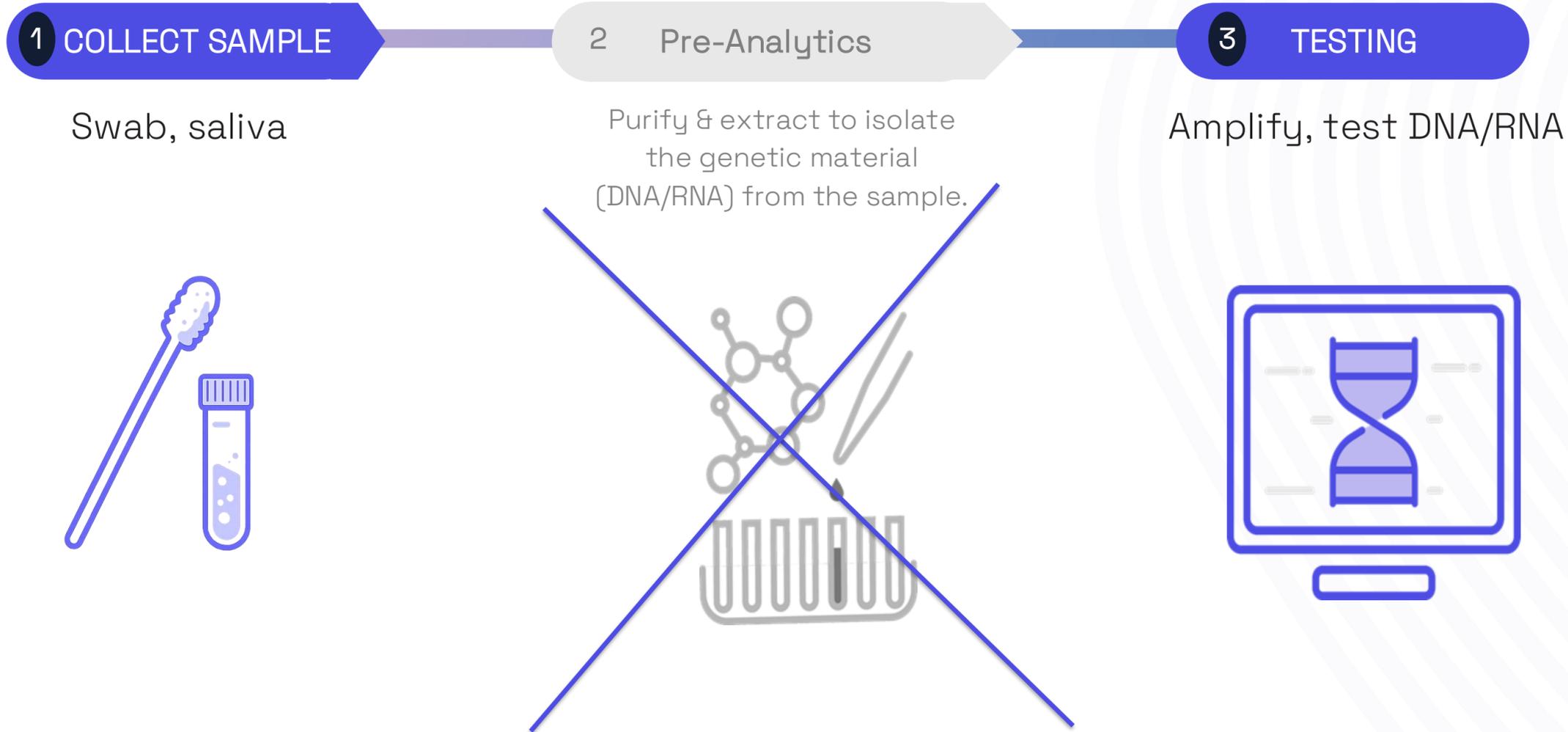
Toxic inhibitors in sample collection



Skilled technicians, costly equipment / reagents needed



Breakthrough direct-to-PCR testing



Compared to conventional PCR

5-10x faster
turnaround time

Lower cost
average across test types

Highly accurate

Reduce PCR instrument complexity and costs



Compared to conventional PCR

Simpler hardware design / workflow

Eliminates toxic reagents

~33% lower system cost

CLINICALLY PROVEN

Built on a validated, real-world clinical foundation



- >590,000 patient samples tested for SARS-CoV-2
- 100% concordance with conventional PCR (swab)

*87% of samples were nasal swabs; 13% were saliva. All used the extraction-free buffer and direct-to-PCR workflow developed at Summit Biolabs. Data is from 2020–2023 under CLIA certification #06D2213521.

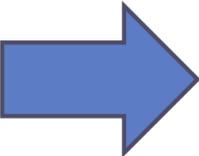
INTELLECTUAL PROPERTY

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

Type: Composition of matter and methods
(covers chemistry and testing workflow)

Exclusive license with  Anschutz
with freedom to operate and full commercialization rights

Patent estate: 1 patent issued
5 patents pending



including the @ANYWHERE™ portable PCR device platform, leveraging proprietary approaches (proof of concept underway)

(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		
WO	WO-2022192440	A1	*	9/2022	C12Q	1/6806
WO	WO-2022198086	A1	*	9/2022		
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

PCR for infectious disease testing @ANYWHERE™

PROVEN "DIRECT-TO-PCR"



ADVANCED MICROFLUIDICS



@ANYWHERE™ PCR



1 COLLECT SAMPLE

Swab, saliva



2 TESTING

Visualize results



Lab-on-a-chip heating technologies



PCR testing device



MARKET SEGMENTATION

\$20B+ Total Available Market (TAM)



RESEARCH MEDIA
(Non-Clinical)



SAMPLE COLLECTION
MEDIA (Clinical)



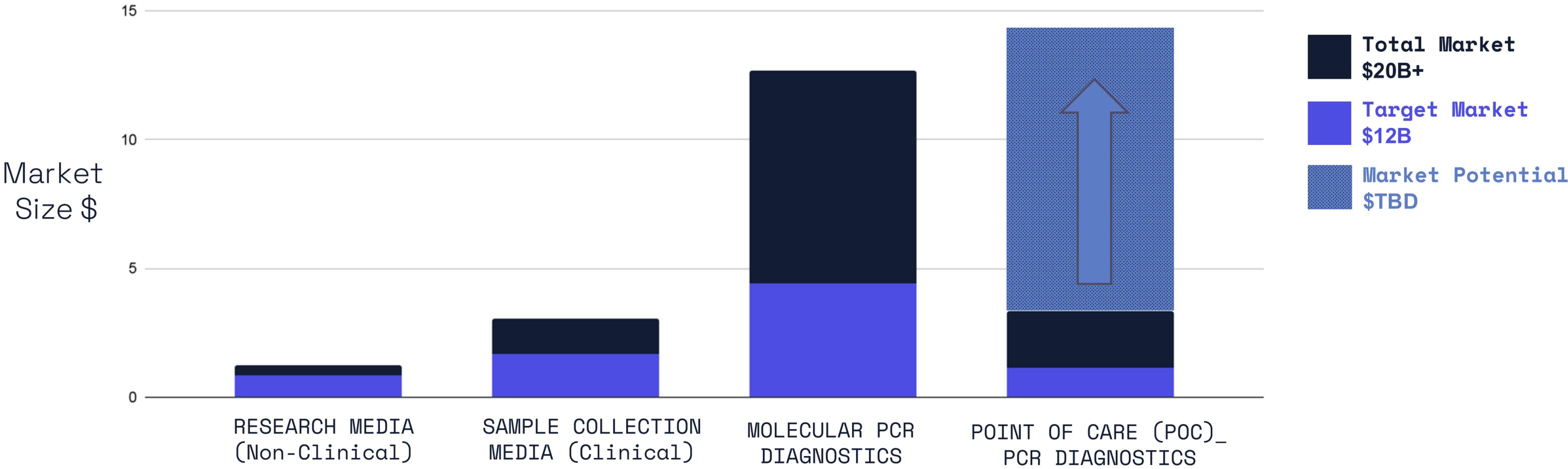
MOLECULAR PCR
DIAGNOSTICS



POINT OF CARE (POC)
PCR DIAGNOSTICS

THE OPPORTUNITY

\$12B TARGET MARKET



\$6M raise

\$2.75M (1st tranche)

Use of Funds

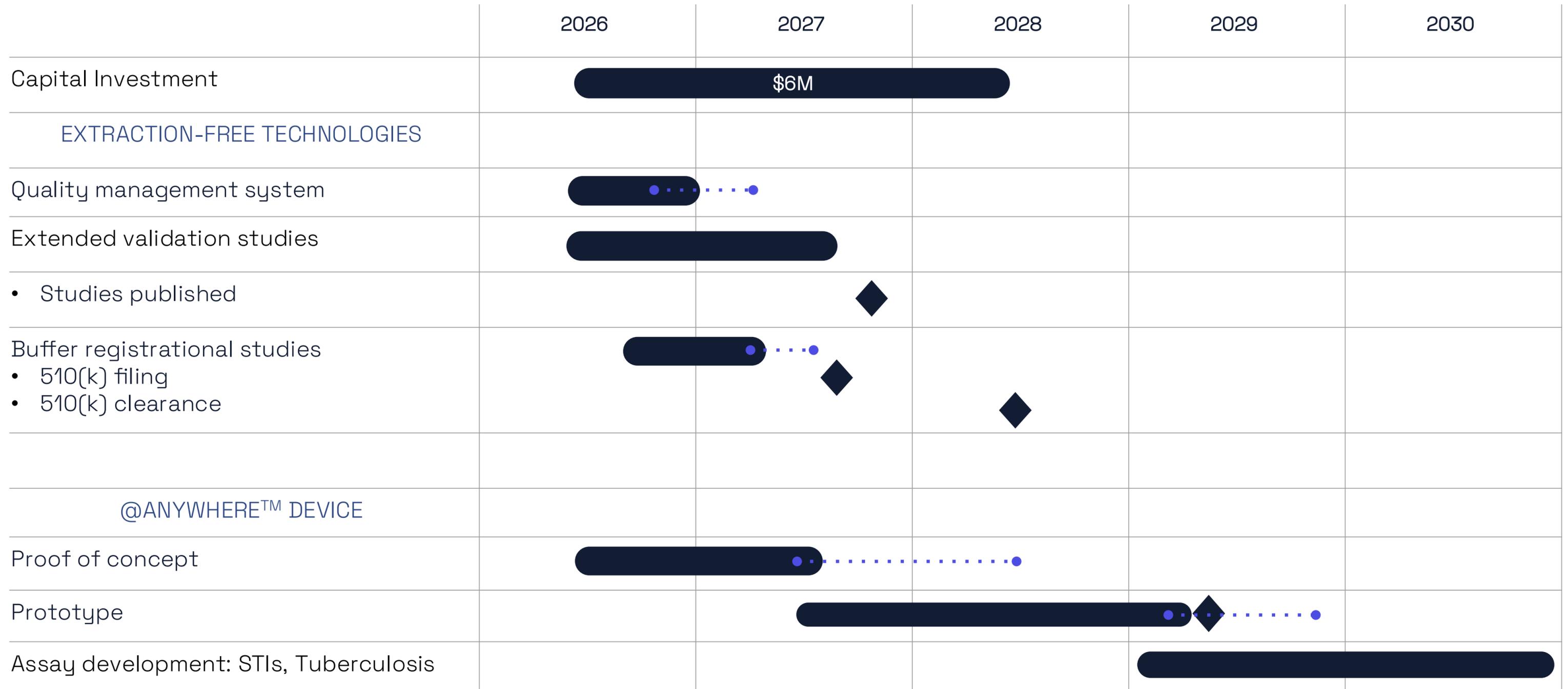
- Expand evidence and utility
- Quality and regulatory filings
- Patent prosecution
- Third-party manufacturing
- Handheld device development
- Generate sales and partnerships

Milestones

- ✓ More data published
- ✓ 510(k) buffer clearance
- ✓ Expanded claims / filings
- ✓ Customer, licensing and OEM revenue initiated
- ✓ New hires and advisors strengthening execution

KEY PLANS

Product development and milestones



GO-TO-MARKET & LICENSING ROADMAP

2026

2027

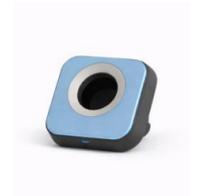
2028

2029

2030

Product
Examples

MOLECULAR DIAGNOSTIC SALES
(Licensing @ANYWHERE™)



CLINICAL LAB SALES
(Direct Amp™ IVD** reagents, sample collection kit)



POINT-OF-CARE SALES
(Licensing of IP for @ANYWHERE™ device)



NON-CLINICAL SALES (Direct Amp™ RUO* extraction-free reagents for use on open PCR systems)



*RUO = Research Use Only. **IVD = In Vitro Diagnostic.

Clear path to break-even and profitable growth

(USD '000)

	2026	2027	2028	2029	2030
<i>Sales: extraction-free reagents</i>	65	312	1,655	4,891	7,687
<i>Sales: Licensing of extraction-free reagents and @ANYWHERE™ device</i>		1,000	5,000	16,500	67,500
Total Revenue	65	1,312	6,655	21,391	75,187
Net Income	(1,770)	(3,427)	(1,288)	3,756	34,204

THE CORE TEAM

EXPERIENCED IN DIAGNOSTICS & PRODUCT LAUNCH



KEVIN KRAUS
CEO



MARK KELLEHER, PHD
EVP, Research & Development



JAY FOUST
EVP, Business Development



SHELLE POURMANAFZADEHARDABILI
VP, Business Operations



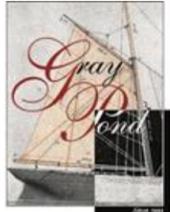
BOB BLOMQUIST
Co-Inventor,
Board Chair



BARBARA HANDELIN, PHD
Board Member

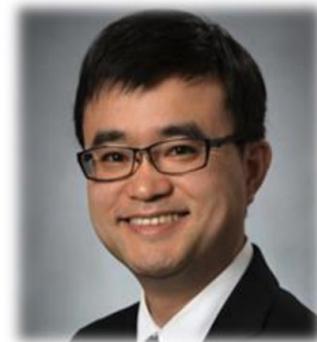
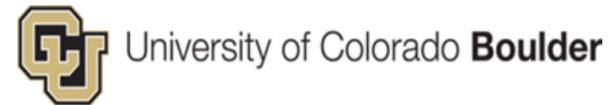


RUSS HULLET
Co-Founder,
Board Member



ADVISORS & COLLABORATORS

EXPERTISE IN DIAGNOSTICS & PRODUCT DEVELOPMENT



CHARLES HENRY, PHD
Professor, Chemical & Biological Engineering; Chemistry, Advisor

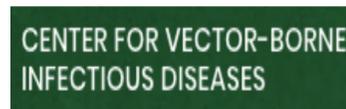
BRIAN GEISS, PHD
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XIAOYUN DING, PHD
Associate Professor, Mechanical Engineering, Co-Inventor @ANYWHERE™

MICKEY URDEA, PHD
Diagnostics Advisor & Technology Pioneer

DUSH RAMACHANDRAN
Strategic & Information Technology Advisor



Affordable, accurate and rapid PCR testing for infectious diseases

TEAM & ADVISORS



Proven in diagnostics

IP

- ✓ Landmark US patent
- 5 patents pending

EVIDENCE & POTENTIAL

- ✓ >590,000 clinical tests
- ✓ Licensing interest with clear monetization path

ASK

\$6M

IMPACT

- Sustainable growth and multiple exit pathways
- ~4M fewer deaths globally from infectious diseases

FUTURE

@ANYWHERE™ PCR





Transformative
Biotech

THANK YOU

GET IN TOUCH!

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Extraction-free 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%	—

EXIT HISTORY: POINT-OF-CARE DIAGNOSTICS

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

Company (Exit Value)	Curiosity (\$137M)	Iquum (LIAT) (\$275M)	Mesa (\$407M)	BioFire (\$450M)	Alere (\$6B)
Acquiror (Year)	 (2022)	 (2014)	 (2021)	 (2014)	 (2017)

COMPETITION

Direct-to-PCR companies lack our breakthrough technologies



Transformative
Biotech

BREAKTHROUGHS

- Direct-to-PCR testing from swab & saliva
- Rapid, robust and highly accurate
- High-volume workflow, reduces cost

COMPETITIVE ADVANTAGE

Leading the extraction-free PCR buffer market

Company	Raw Saliva	Saliva (in solution)	STI (CT/NG)	Patent (extraction-free)
 SALIVADIRECT™	1 st	N/A	N/A	N/A
Others (e.g., Zymo, Takara)	Yes (RUO only)	N/A	N/A	N/A
 Transformative Biotech	2 nd	1 st	1 st	1 st Patent '889 issued

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*)

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

COMPETITION

Incumbent molecular systems embed complex pre-analytics



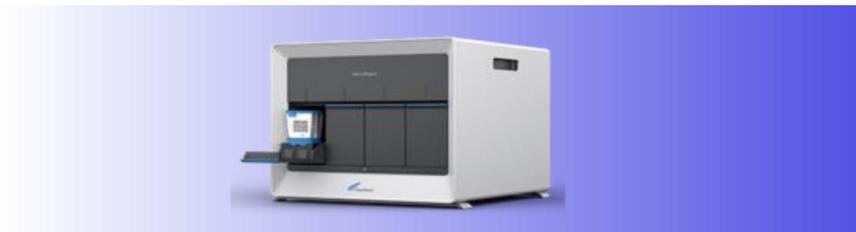
Transformative
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ENABLING ALL COMPANIES TO IMPROVE THEIR DEVICES

- 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

OUR SOLUTION

Enable simpler PCR testing for all manufacturers & labs

PCR Platform Type	Primary Customers	 Value
Open PCR instruments	Clinical and research labs running LDTs or open PCR workflows	Eliminate extraction using Direct AMP™ reagents to reduce operating costs, save labor time, and accelerate workflows.
Closed PCR instruments	Clinical labs running large walk-away RT-PCR analyzers (IVD, cartridge-based)	Remove embedded extraction to simplify instruments, lower hardware and operating costs, and shorten time to result.
Point of Care devices	Decentralized testing environments: <ul style="list-style-type: none">- ER and urgent care- Physician offices / clinics- At-home testing using self-collection	Eliminate extraction to reduce device complexity, COGS, and power requirements, enabling true low-cost, instrument-light PCR at the point of care (via @ANYWHERE™ technologies)

TARGET CUSTOMERS: Research and Clinical Labs

Open PCR workflows burdened by standalone extraction

Research /
Clinical labs
running high
volume DNA
extraction
(i.e. LDTs)

ThermoFisher
SCIENTIFIC



KingFisher
Standalone extraction
instrument.
Required before PCR.

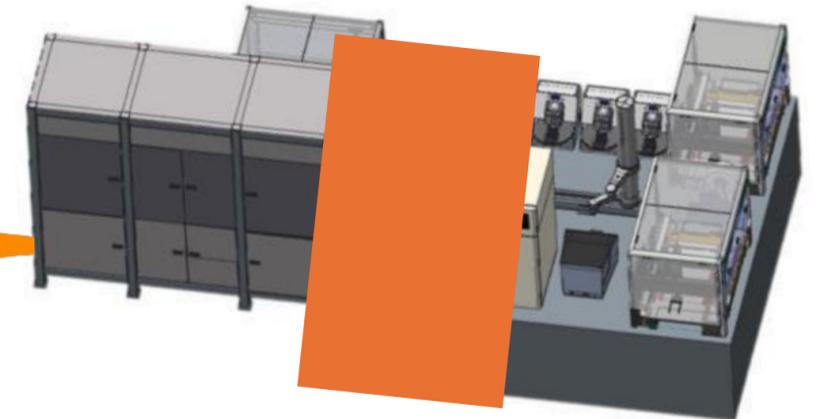
QIAGEN



Qiagen Symphony
Integrated extraction platform
Required before PCR.

Representative extraction
subsystem that
could be removed

Estimated 33%
savings possible



Custom automation
High-throughput extraction
workflow
Required before PCR.

TARGET CUSTOMERS: Closed PCR platform manufacturers

Eliminate sample preparation to reduce PCR time, cost, and complexity by an estimated ~33%

Clinical labs
running closed
RT-PCR
systems



Abbott Alinity m
*Integrated extraction + RT-PCR
(high cost, complex workflow)*

Representative extraction
subsystem that
could be removed



Roche cobas 5800
*Centralized PCR with
embedded sample prep*

*LDT (Laboratory Developed Test) which are regulated by CMS not the FDA and for which performance characteristics are confirmed by the lab.

TARGET CUSTOMERS: POINT-OF-CARE Manufacturers

POC devices trade accuracy, cost, and/or complexity to manage sample prep

Decentralized care settings



Abbott ID now

- Limited sensitivity (non-PCR)
- Higher instrument, per-test cost



Binx io:

- Extraction embedded
- High cartridge cost and design complexity for STIs*



Visby Medical

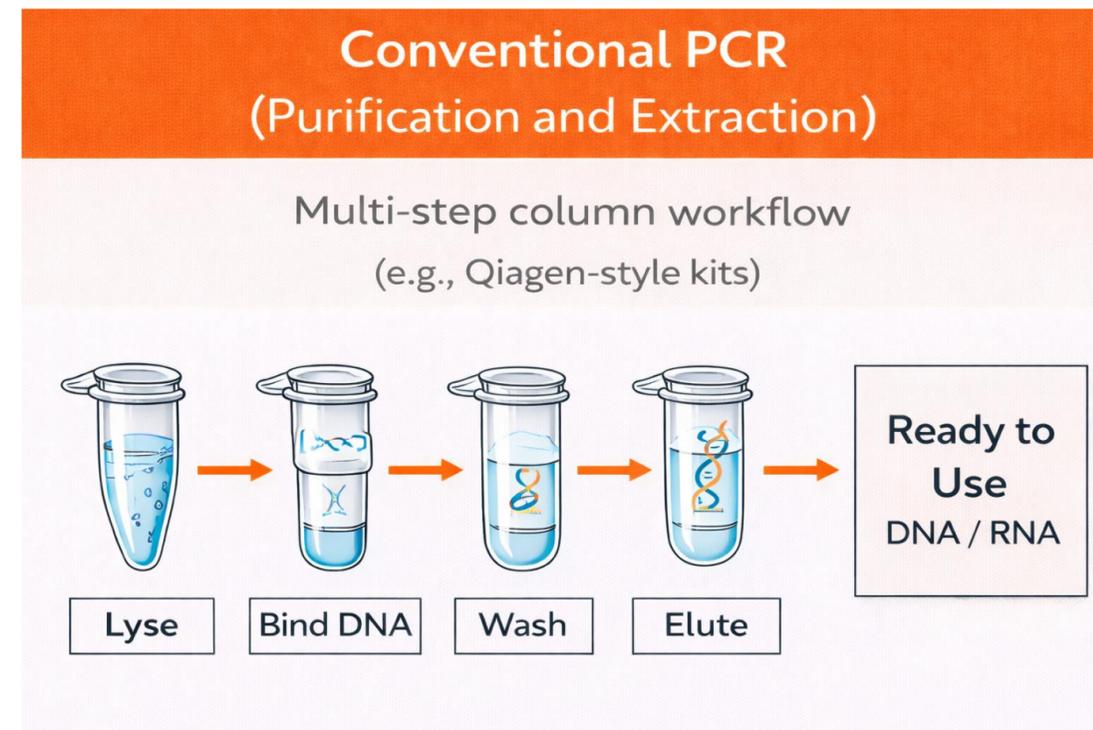
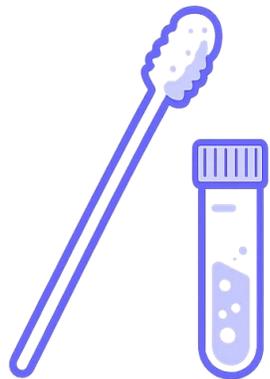
- Extraction pushed upstream
- Added user steps before test
- Lateral flow readout for STIs

*STI = Sexually Transmitted Infections such as Chlamydia, Gonorrhea.

Today's PCR requires multiple prep steps



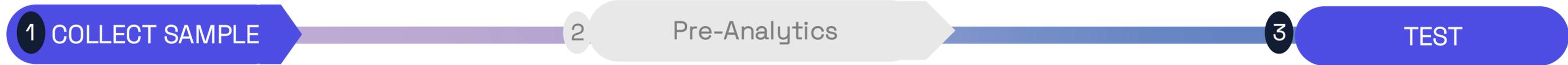
Swab, saliva



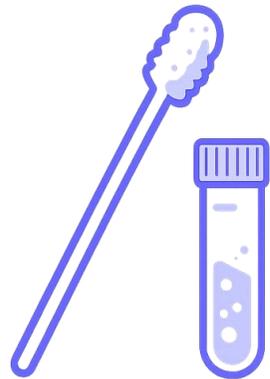
Visualize results



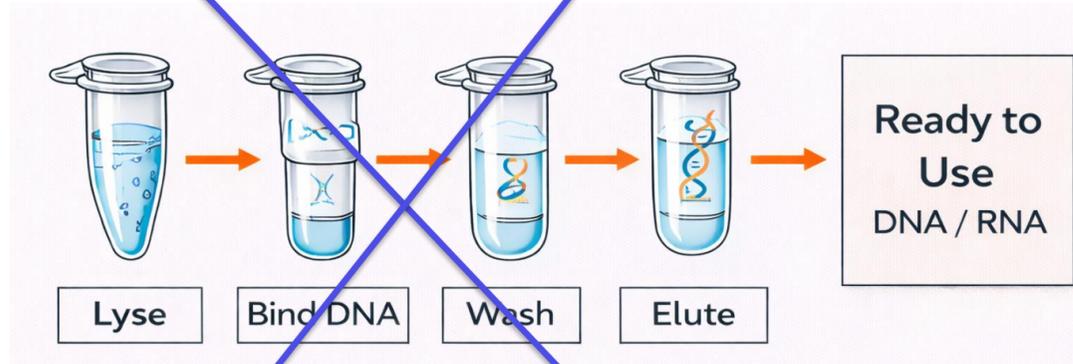
Technologies that allow a simplified PCR workflow



Swab, saliva



DirectAmp™
reagents



Visualize results

