Transformative Biotech

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Transforming PCR Testing for Infectious Diseases @ANYWHERE™

LEADERSHIP TEAM

EXTENSIVE DIAGNOSTIC EXPERIENCE

Kevin Kraus, MBA
Chief Executive Officer

Mark Kelleher, PhD
EVP, Research & Development

Jay Foust, MBA
EVP, Business Development

Shelle Pourmanafzadehardabili
VP, Business Operations

BOARD OF DIRECTORS

Barbara Handelin, PhD
Board Member, pioneer in PCR

Russ Hullet
Co-Founder, Board Director

Bob Blomquist
Co-Inventor, Board Chair

KEY ADVISORS

Chuck Henry, PhD
Professor Engineering, CSU

Tony Shuber
Diagnostics Advisor & Sr. Executive

Mickey Urdea, PhD
Diagnostics Advisor & pioneer

INTELLECTUAL PROPERTY

- Landmark US Patent 12,344,889 issued July 2025
- US Patent 12,680,130 issued July 2026
- Broad patent estate with 5 additional patents pending

PARTNERSHIP OPPORTUNITIES

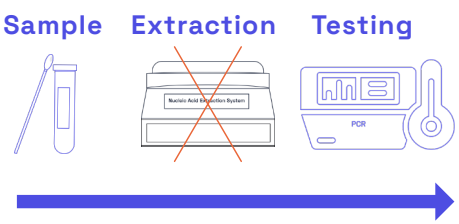
- Evaluate DirectAmp™ in existing PCR workflows
- Collaborate on assay development & clinical validation
- Explore OEM, licensing, and distribution opportunities
- Support @ANYWHERE™ device proof-of-concept development

PROBLEM

- 14M people die annually from infectious diseases like tuberculosis, respiratory infections, and sexually transmitted infections (STIs).
- People lack access to rapid, accurate & affordable PCR testing.
- PCR is the gold-standard for infectious disease testing but it is complex, expensive, and still stuck in the lab.

OUR SOLUTIONS

- Direct-to-PCR platform technologies that deliver rapid, accurate, and affordable testing for infectious disease @ANYWHERE.



Simplify conventional PCR

Moving PCR out of the lab with @ANYWHERE device

CLINICALLY VALIDATED

- >590,000 patients tested for SARS-CoV-2 using technologies developed by predecessor company, Summit Biolabs.
- 5-14x faster turnaround time, 7x lower cost and with the same high accuracy compared to conventional PCR.
- Non-toxic chemistries with ≥7-day sample stability at 40°C.
- Proof-of-concept: viruses (Flu+COVID), and bacteria (STIs chlamydia, gonorrhea) with further studies planned on challenging pathogens (e.g., tuberculosis).

TARGET MARKET OPPORTUNITY

- $17B global molecular diagnostics target market (labs and manufacturers), spanning reagents, sample collection, and lab and point-of-care PCR.
- Establish partnerships for platform technologies, including @ANYWHERE device, for sales & licensing opportunities.
- Drive DirectAmp™ reagent sales beginning with RUO, then IVD (ISO 13485) through partners & distributors.

IMPACT

- Change the future of PCR diagnostics for infectious disease to expand access, accelerate treatment, reduce the spread of disease, and ultimately save lives.

Problem/Need:

PCR is the gold standard, but today extraction creates a trade-off between speed and performance.

PCR's current workflows for infectious disease testing depend on complex, time-consuming nucleic acid extraction and transport media (UTM/VTM) that add cost and time. Existing direct-to-PCR methods try to bypass extraction but often sacrifice sensitivity, stability, or reproducibility. A solution is needed that delivers rapid, extraction-free workflows without loss of performance.

Technical Approach/Solution:

Extraction-free PCR without loss of performance.

Transformative Biotech's DirectAmp™ buffer enables extraction-free RT-qPCR by stabilizing biological samples and mitigating PCR inhibitors. This approach maintains sensitivity and specificity comparable to conventional extraction-based workflows while simplifying sample preparation and enabling compatibility with existing PCR systems.

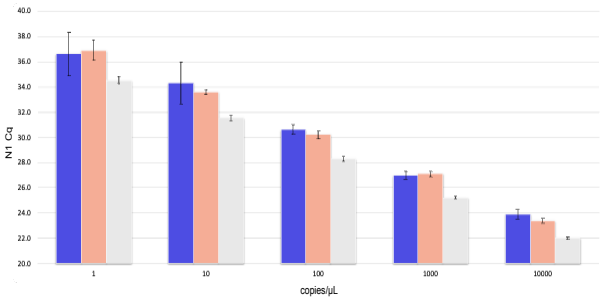


Figure 1: Heat-inactivated SARS-CoV-2 (copies/µl, x-axis) in saliva samples. DirectAmp™ no-extraction (blue) vs Cryovial samples: extraction-based (orange). Commercial device: extraction-based (grey). (Qiu et al., J Biotechnol Biomed, 2024).

Impact/Payoff:

Enabling scalable surveillance across centralized and point-of-need settings.

Centralized Testing (Sample → Laboratory)	Point-of-Need Decentralized Testing
• Stabilizes samples at ambient temperature (≥8-10 days) • Eliminates extraction → ~30% cost reduction • Maintains RT-qPCR sensitivity and specificity • Simplifies high-throughput laboratory workflows	• Stabilizes samples at ambient temperature (≥8-10 days) • Enables delayed testing, retesting and confirmatory sequencing • Preserves sample integrity beyond initial test event • Supports deployment of molecular testing outside traditional laboratory settings

One platform that supports both centralized and point-of-need diagnostics

Execution Plan/Metrics:

Funding will enable:

- Validation of extraction-free RT-qPCR workflows across relevant sample matrices
- Expansion of assay panel to include additional viral and non-viral pathogens
- Stability-enabled workflows supporting reflex testing and sequencing
- Scaleup of buffer production and readiness for pilot deployment
- Feasibility assessment of integration into point-of-need molecular testing platforms

6 Month Deliverables

- Validated extraction-free duplex RT-qPCR assay
- Multiplex panel with ≥2 additional targets
- ≥8-to-10-day ambient sample stability demonstrated
- Performance benchmarked vs extraction-based workflow
- Defined pathway to pilot deployment and POC integration

Outcome: A validated, scalable extraction-free PCR workflow ready for pilot deployment and decentralized testing.