A Rapid Discovery and US-Based Manufacturing Platform for Diagnostic and Prophylactic Antibody Countermeasures

An Accelerated, End-to-End Monoclonal Antibody Development Pipeline Case Study

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Tactical Need vs. Platform Capabilities

THE TACTICAL NEED

The Threat Matrix

- Emerging biological pathogens
- Engineered agents
- Mutating variants

Tactical Defense

- Rapid testing
- Scalable: Low cost, lightweight
- Robust field operability: No-electricity, low skill requirement

PLATFORM CAPABILITIES

- **10 Weeks: Sequence to Antibodies**

  Shortened discovery cycle — threat-agnostic response to "Disease X"

- **Picomolar High Affinity Antibodies**

  Natural affinity and specificity of rabbit monoclonal antibodies

- **LFA Rapid Test Ready Pairs**

  Optimized matching pairs, ready for lateral flow assay (LFA) development

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Core Platform Technology

The Rapid Antibody Engineering Platform

Accelerated Single B-Cell Rabbit Monoclonal Antibody Cloning

1

Pathogen Sequence

- AI-aided antigen and epitope design

2

Rapid Antibody Selection

- Proven technology
- High affinity binders
- 8 weeks

A **LFA Diagnostics**

Highly sensitive zero-power field rapid tests

B **Prophylaxis & Therapeutics**

In-silico + wet-lab antibody humanization

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Filovirus Antibodies for Rapid LFA Diagnostics

The Epidemiological Threat

- *O. ebolavirus* & *O. marburgvirus*
- High-lethality pathogens
- Sporadic, unpredictable outbreaks
- Acute biodefense liabilities

2026 Ebola Outbreak

- 915 confirmed cases
- 234 fatalities

CDC Update: June 20, 2026

Project Objective

Develop a multiplexed, point-of-Care Lateral Flow Assay (LFA) rapid test

- ✓ Simultaneous & differential detection of EBOV and MARV
- ✓ POC fingerstick blood
- ✓ Single-use digital readout

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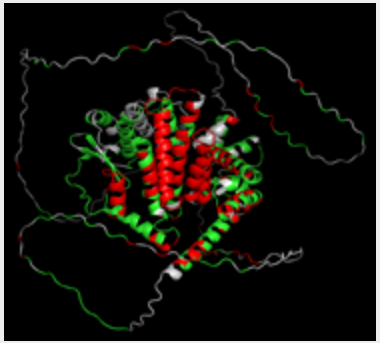
Strategic Antibody Portfolio

Pan **Pan-Filovirus**
EBOV + MARV

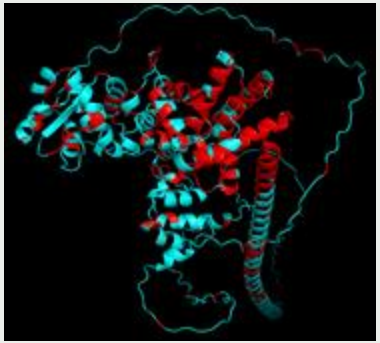
EBOV **Pan-Ebola**
EBOV Only

MARV **Pan-Marburg**
MARV Only

Structural Mapping of Conserved Filovirus NP Epitopes



EBOV-NP



MARV-NP

Sequence Analysis Scope

Genus	Species / Strain	Sequences
EBOV	Zaire, Sudan, Bundibugyo, Reston, Tai Forest	3,214
MARV	Marburg German Voege, Ravn, Musoke, Angola	147

Sequences retrieved from NCBI GenBank (Sayers et al., 2026); Structure predicted via OpenFold3 (OpenFold Consortium); Visualized using PyMOL v3.0.0 (Schrödinger, LLC)

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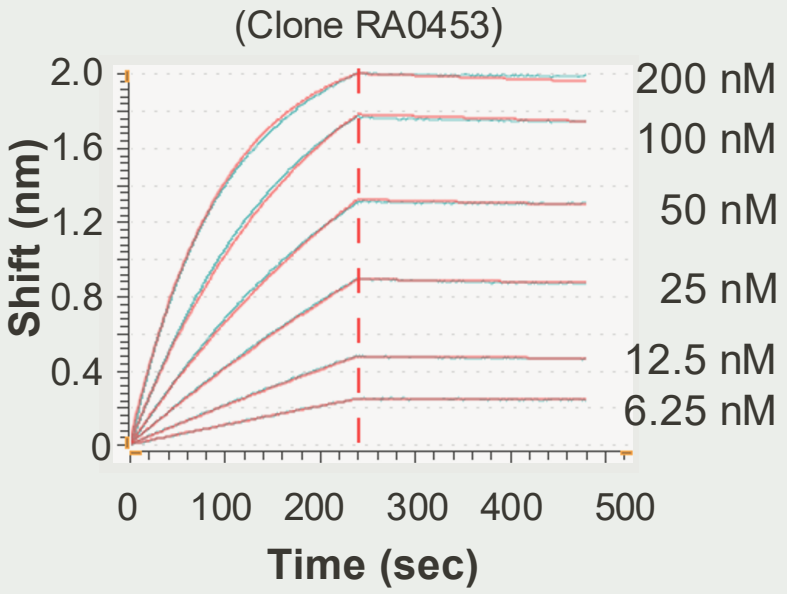
Kinetic Characterization of Target Antibodies

Representative BLI Kinetics



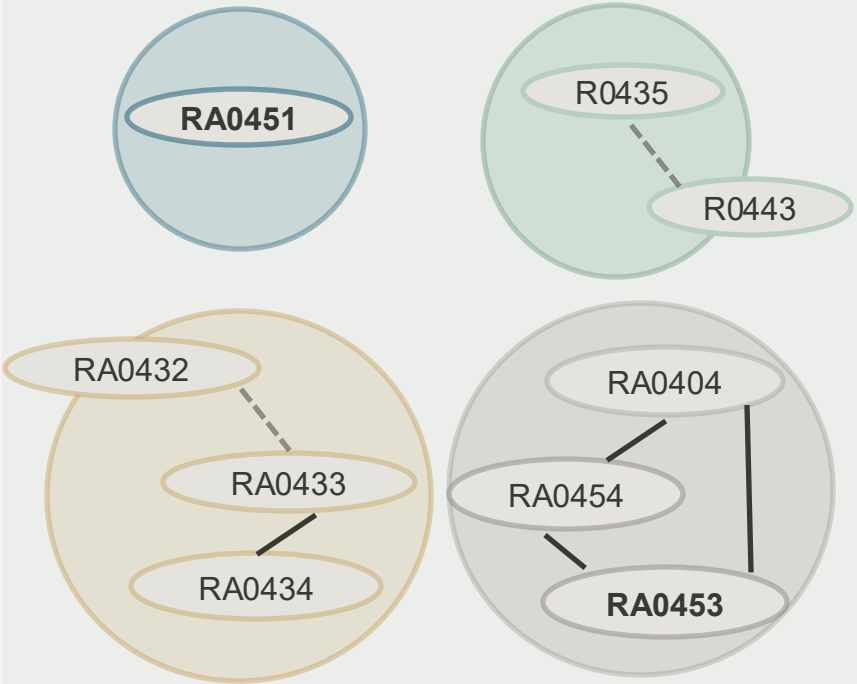
Ab Portfolio Kinetics Summary

Epitope Group	High Affinity Clones (N)	Affinity Range (K_D)
EBOV & MARV	9	61 pM – 8 nM
EBOV	15	54 pM – 2 nM
MARV	7	59 pM – 0.4 nM

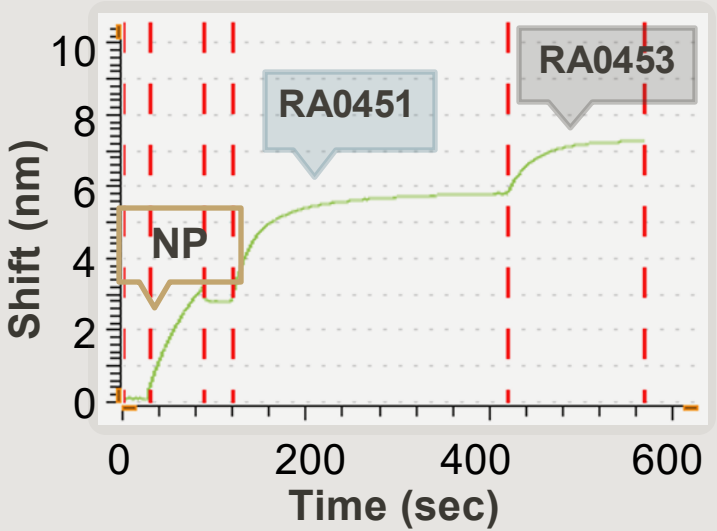
- Method: Biolayer Interferometry (BLI)
- Kinetic Profile: Picomolar affinity (K_D)
- Assay Integration: Sensitive LFAs

Strategic Sandwich Pair Selection for LFA

Epitope Network Map



Non-Competing Antibody Pairs



- Tandem BLI assay
- Steric compatibility

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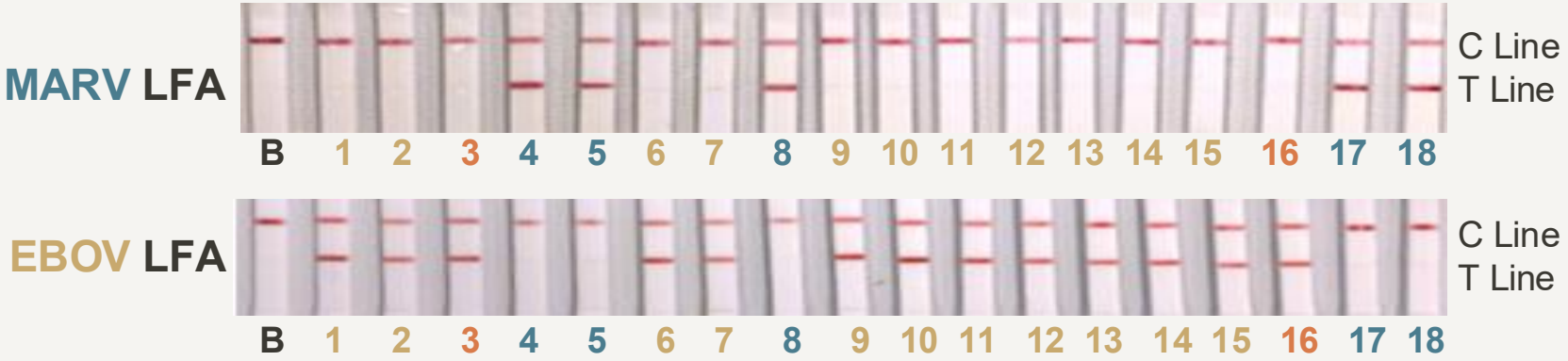
LFA: Specific Detection of MARV and EBOV



EBOLA (n = 13) (~$8x10^4$ pfu/ml)

Zaïre • Sudan • Bundibugyo • Reston • Taï Forest

MARV (n = 5) (~10^5 pfu/ml)

Angola • Musoke • Ravn • Voege

- **Pan-Genus Coverage**

  100% Coverage

  All tested EBOV & MARV Strains

- **Species Specificity**

  No Inter-Species Cross-Reactivity

Inactivated virus samples provided by BEI Resources, NIAID, NIH.

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Automated Humanization Pipeline

1 Humanization by Design

One-Click Pipeline

- Automated CDR grafting
- ML back mutations
- Generative Biophi engine
- Sapiens generative language model
- OASis humanness score

2 *In Silico* Screening

Developability

- Stability & foldability
- Biophysical solubility
- Proteome-wide off-target screening

3 Rapid Wet-Lab Validation

< 2 WKS

- ✓ Humanized sequence
- ✓ Mammalian expressed full IgG
- ✓ Binding kinetics profile

BioPhi: Prihoda D, et al. mAbs. 2022;14(1):2020203.

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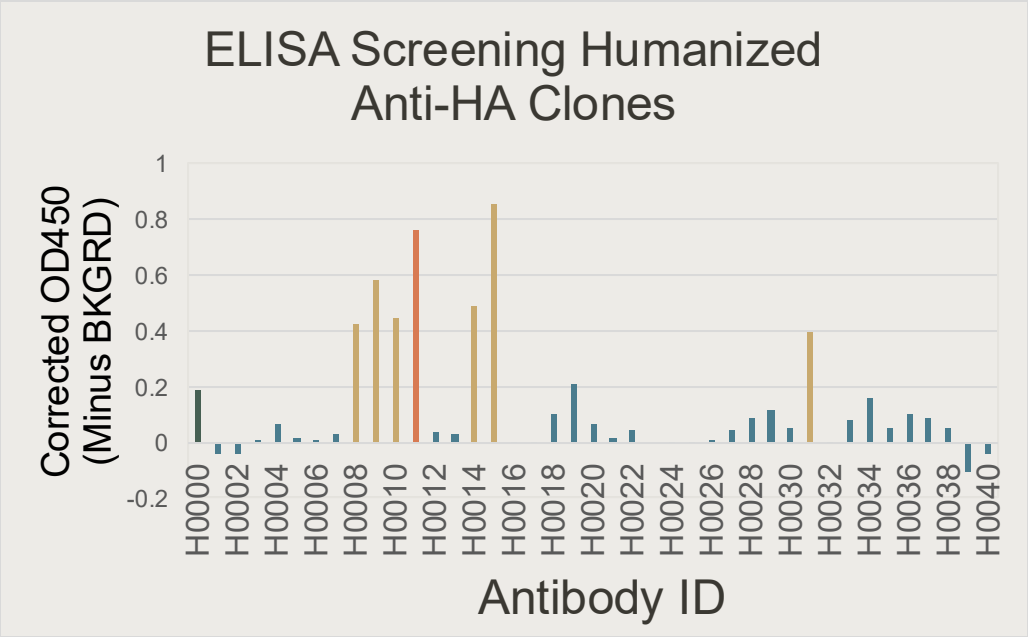
Broad Spectrum Anti-HA of Influenza A

Binding and Humanness Profile



Humanization Outcomes

Germline Content

Before: 64% → **After: 74%**

OASis Identity

Before: 49% → **After: 70%**

OASis Percentile

Before: 4% → **After: 19%**

BioPhi: Prihoda D, et al. mAbs. 2022;14(1):2020203.

US-Based Development & Manufacturing

Located in Carlsbad, California

Qoolabs End-to-End Platform

- ISO 17025 accredited labs
- Advanced antibody development
- Pilot LFA rapid test development
- Multi-gram scale antibody production

TrueDiagnostics LFA Manufacture

- FDA-registered, ISO 13485-certified
- Portfolio of 510(k) cleared devices
- 50M Tests/year capacity

100-Day Mission: Day-Zero Readiness

Proven Capabilities:

- **Diagnostics:** Delivered high-affinity antibodies for EBOV/MARV under the BARDA RRPV program
- **Therapeutics:** Integrated AI *in silico* humanization design with rapid wet-lab validation

Diagnostic Development Paradigm Shift

Reactive Response

- Slow
- Delay

➡

Proactive Threat Interception

- Preemptive assay expansion
- Pre-built countermeasure portfolios
- Immediate outbreak response

Partnerships

Seeking collaborative development

- CPE-CBRND
- DTRA
- DoW

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