

High-Throughput IgY Antibody Manufacturing for Military Diagnostics, Prophylaxis, and Therapeutics

High-throughput production of avian polyclonal antibodies enables
scalable biologics for military diagnostics, infectious disease
prevention, and biodefense

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Disclosures

Julius Goepp, MD is an owner of Evimero, LLC

Presentation Overview

- Current problems – persistent ID, limited therapeutic antibody responses, limited immunoassay performance and range
- A different approach – introducing avian pAbs: IgY
- AI-enabled antigen design, IgY development
- Case study: EV-26-01, a passive norovirus prophylactic/therapeutic
- IgY Manufacturing, Regulatory, Cost Considerations
- Military applications of IgY platform
- Key Takeaways

Military Infectious Disease Burden and Unmet Need

Disease remains a major operational threat

- Acute infectious diseases reduce force readiness: training, deployment, humanitarian operations.

Disease causes more lost duty days than combat

- Enteric and respiratory infections remain leading causes of Disease and Non-Battle Injury (DNBI).

Deployed environments increase risk

- Crowding, austere environments, contaminated food/water, emerging pathogens increase exposure.

Current countermeasures have limitations

- Vaccines unavailable for many pathogens.
- Monoclonal antibodies: expensive, difficult to deploy.
- Rapid diagnostics remain limited.



Disease and non-battle injuries continue to reduce operational readiness despite advances in vaccines and therapeutics.

Limitations of Current Antibody Technologies

Cold Chain & Logistics

- Most require 2–8°C
- Cold-chain logistics (field biosensors) alone ~\$10M/year
- Limited shelf life

Safety, Constraints

- Human efficacy inferred
- Informed consent, mandate challenges
- Forward deployment legally complex

Manufacturing, Logistics

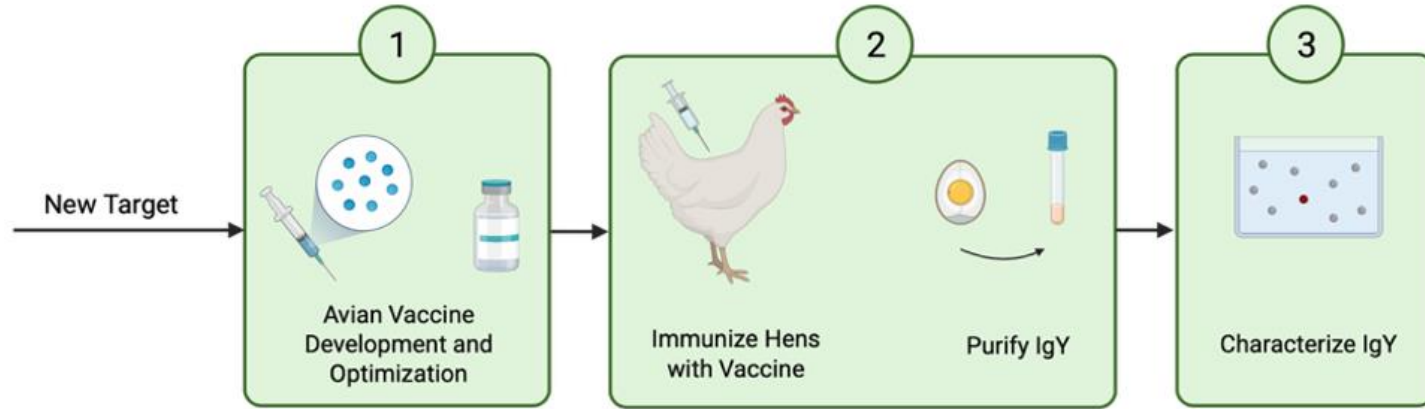
- mAb production slow, expensive, can't surge
- Critical dependencies: foreign, single-source manufacturers

Performance, Flexibility

- LFAs: Low sensitivity
- Multiplex threat detection incomplete
- Antibodies unstable in heat, humidity

Antibody technology is underutilized because of current limits

A Different Approach: Avian Polyclonal Abs (IgY)



- 1) Leverage non-mammalian antibody maternal-egg transfer to produce abundant polyclonal IgY against selected targets; proprietary novel Ag design.
- 2) Immunize, non-invasive IgY harvest, purification to multiple purity levels (100 mg/egg)
- 3) Characterize, pursue novel Dx, Px, Tx uses.

IgY combines rapid production, broad immune recognition, and scalable manufacturing to meet emerging military health needs.

IgY Advantages



Thermostability

- Heat Stable
- No Cold Chain
- Austere Deployment



Low cost

- Lower COGS
- Affordable Scale
- Existing Infrastructure



Broad Epitope Coverage

- Variant Resistant
- Multi-Epitope Binding
- Broad Neutralization



Rapid Manufacturing

- Weeks, Not Years
- Surge Capacity
- High Throughput



Mucosal Delivery

- Oral Delivery
- Intranasal Delivery
- Self-Administration



Diagnostics

- Higher Sensitivity
- Lower Background
- Better Specificity

IgY is a scalable antibody platform capable of transforming military diagnostics, prophylaxis, and therapeutics.

AI-Enabled Antigen Design and IgY Platform



Functional Protein Discovery → Rapid Antibody Production

Problem

Slow
Development

High Cost,

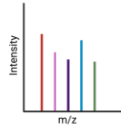
Fragile Supply
Chains

***No Surge
Capacity***



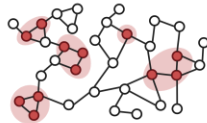
Evimero Platform

Metaproteomic
Analysis



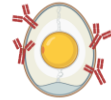
***Function
not
Taxonomy***

AI-Driven
Discovery



***Causal
Pathway***

IgY Antibody
Development



***Weeks
not
Years***

Processing/
Purification



***Multi-
Product
Capacity***

Integrated Ag design and IgY platform: rapid,
scalable next-generation military medical
countermeasures.

Capability Leap

Functional Protein
Targeting

Rapid Discovery -
***Biologics in
Weeks***

Distributed,
Scalable,
Domestic
Production

Surge Capacity



Case Study EV-26-01:

A Dx-Tx Platform against Norovirus

Problem:

- Acute Gastroenteritis (AGE)
- 2-4 Days incapacitated
- Major cause of lost duty days
- Multiple active genotypes, strains
- No vaccine
- No rapid diagnostic
- No therapeutic
- Only prophylaxis is hygiene

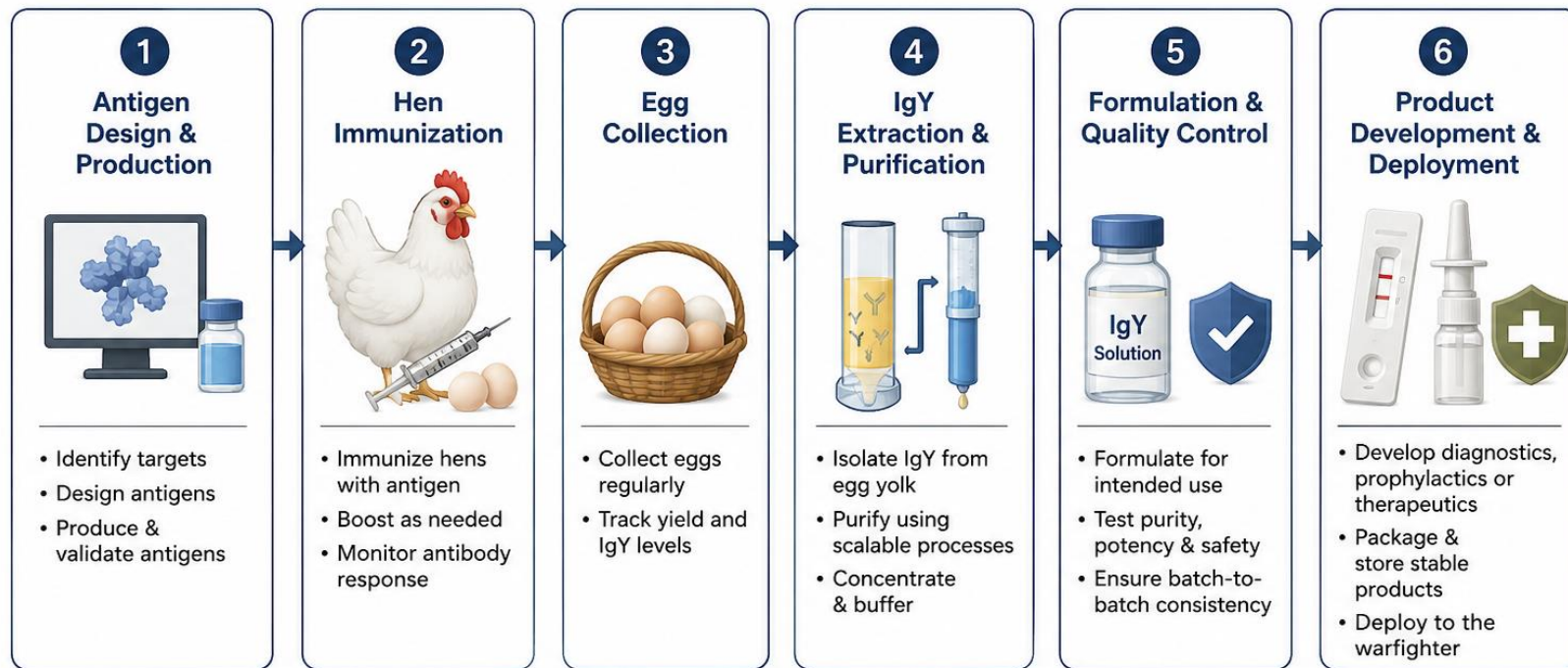
Solution:

- EV-26-01 – trivalent plgY
 - Raised against “P-domain”
 - Targets GII.4 cin3/Sydney, GII.6
 - Titers >1:900,000 combined
 - Neutralizes all tested strains at achievable concentrations
- Proprietary Ag development:
 - “Pan-HuNoV” drug targets “S” moiety of virus
- Companion LFIAD Dx in development

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EV-26-01 against Norovirus validates the IgY platform as a rapid, scalable approach for developing next-generation military medical countermeasures.

IgY Manufacturing Workflow



Rapid

Weeks from antigen to IgY product



Scalable & Cost-Effective

High yield from low-cost inputs



Stable

Heat-stable IgY suitable for austere environments



Versatile

Enables diagnostics, prophylaxis and therapeutics

Scalable. Affordable. Versatile. Built for Military Readiness.

Regulatory Feasibility Established (12/2025)

INTERACT Meeting Outcomes

- IgY-based therapeutics are biological drugs (CBER)
- Proposed lot release criteria appropriate (attained)
- CMC appropriate; No affinity purification
- Organoid testing acceptable
- Antigen cocktails appropriate
- Raw material: Commercial food-stream egg production OK

Meeting Implications

- Rx pathway for biologicals
- CMC as outlined commercially feasible
- Economies of scale from Ag cocktails
- SPF hens not required
- ***Advances other pcdIgY drug substance development***
- ***Multiple Pharma, non-Pharma applications open up***

Early FDA engagement validates a clear, scalable regulatory pathway for the development of IgY-based medical countermeasures.

Cost and Production Advantages of IgY

More Antibody. Lower Cost. Greater Impact.

Mammalian Monoclonal Antibodies (IgG)



Production Time

6–12 months



Cost of Goods

High
(\$100s–\$1000s per gram)



Yield

Low
(mg–grams per batch)



Infrastructure

Complex, capital intensive facilities



Antibody Type

Monoclonal (single epitope)

VS.

Avian Polyclonal Antibodies (IgY)



High
Yield



Production Time

2–4 weeks



Cost of Goods

Low
(\$1s–\$10s per gram)



Yield

High
(grams–kilograms per hen/year)



Infrastructure

Simple, scalable, uses existing agricultural facilities



Antibody Type

Polyclonal (multiple epitopes)



Lower Cost
Up to 10–100x
lower cost
per gram



Faster to Produce
Weeks, not
months



Higher Yield
Grams to kilograms
per hen annually



Scalable
Leverages existing
poultry infrastructure



Heat Stable
Greater stability
reduces storage
and shipping costs



Sustainable
Renewable source,
animal welfare
friendly



IgY delivers a scalable, cost-effective solution for diagnostics, prophylactics, and therapeutics to strengthen military readiness.

Military Applications of the IgY Platform

PREVENT (Prophylactic)

- Norovirus
- ETEC
- Influenza
- SARS-CoV-2
- Biothreats

DETECT (Diagnostic)

- Rapid LFIA
- Companion Dx
- Biosensors
- Microbiome Dx
- Treat ID

TREAT (Therapeutic)

- Therapeutics
- Wound Care
- Respiratory Disease
- Antitoxins
- AMR Infections

One IgY platform supports prevention, rapid diagnosis, and treatment across the military infectious disease lifecycle.

Key Takeaways

- Platform technology - not a single product.
- Rapid, scalable, and affordable antibody manufacturing.
- Broad protection against evolving infectious threats.
- Regulatory and commercial pathways are established.
- Supports military readiness through diagnostics, prevention, and treatment.
- A new generation of deployable biologics for defense and civilian healthcare.

Norovirus (EV-26-01) validates the IgY platform as a rapid, scalable approach for developing next-generation military medical countermeasures.

Acknowledgements

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