

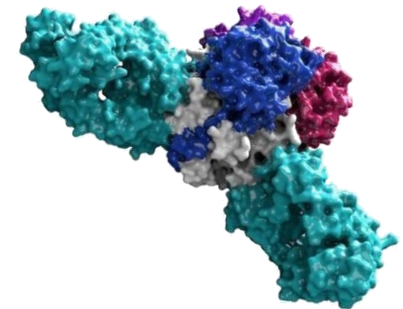
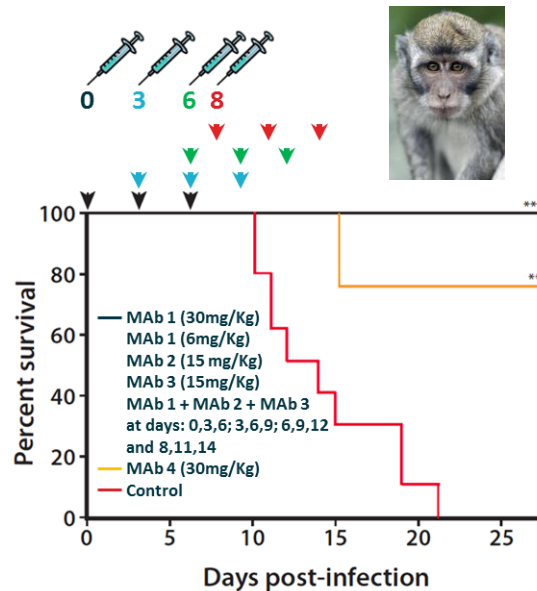
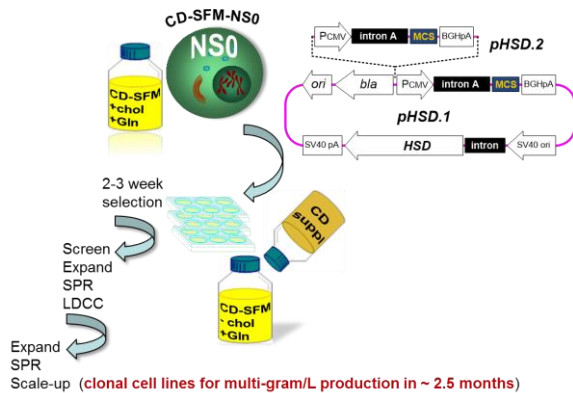
Zalgen Labs LLC

Business Introduction
August 2017



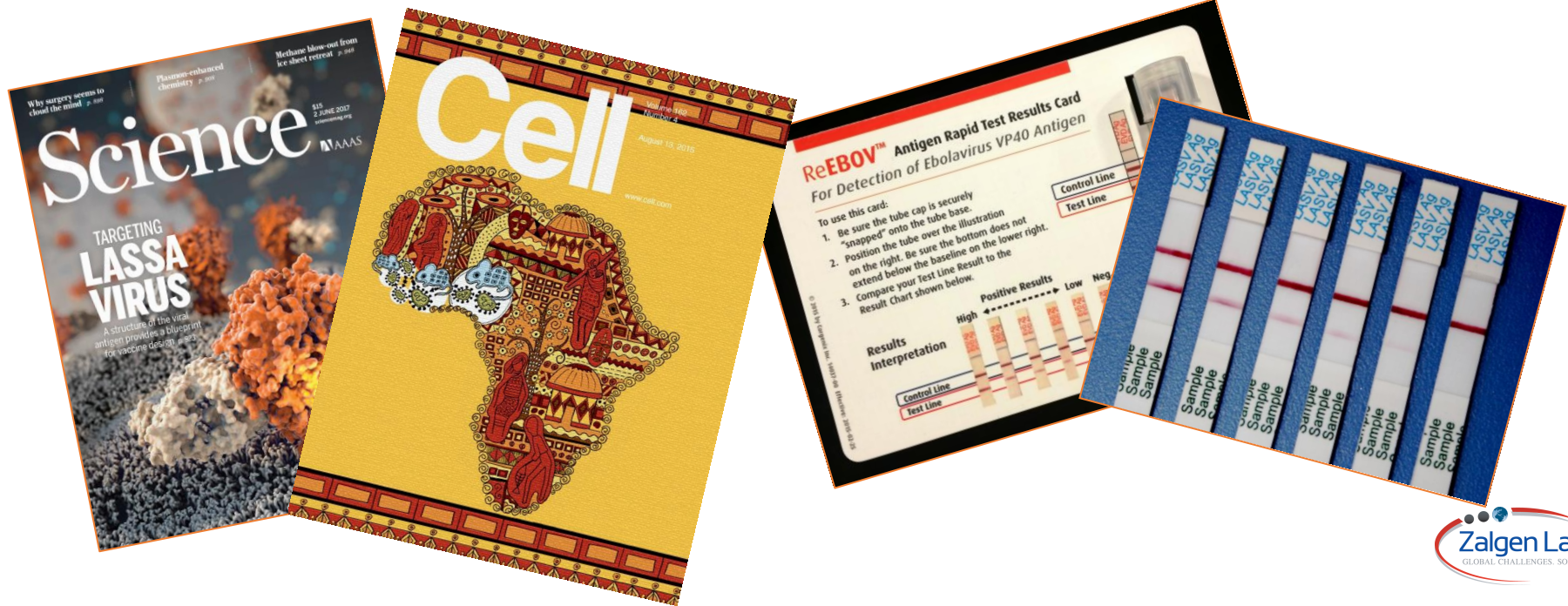
Introduction

Zalgen Labs is a biotechnology company specializing in the design and production of superior biological molecules. These biological molecules are critical in the development and commercialization of highly effective immunotherapeutics, novel vaccines, reliable rapid and affordable diagnostic platforms, that target neglected and underrepresented human infectious diseases. The company makes use of its proprietary expression platforms, including its patented mammalian cell-based biomanufacturing system, *CHOLCelect*, to deliver the next generation of biologicals to global health and biodefense settings.



Key Accomplishments

- First-in-class immunotherapeutic specifically designed to treat acute Lassa infections
- First (and only) rapid diagnostic test for Ebola to receive both FDA Emergency Use Authorization (EUA) and WHO Emergency Listing Approval
- First (and only) rapid diagnostic test for Lassa to be CE Marked
- Extensive unique line of immunodiagnosics for detection of acute Pan-Lassa infections and for characterization of the post acute humoral immune response
- E-commerce platform for commercialization of VHF reagents and diagnostic kits
- Peer reviewed publications in high impact scientific journals



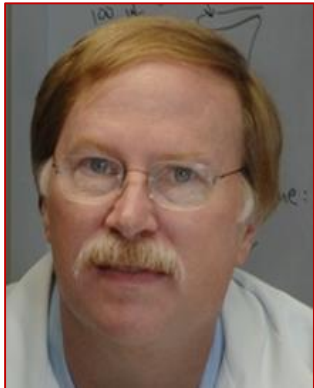
Senior Management



Luis M. Branco

Managing Director and Co-Founder

PhD (Tulane University), BS (University of Massachusetts at Amherst)



Robert F. Garry, Jr

Co-Founder and Chairman, Scientific Advisory Board

Tulane University Professor of Microbiology & Immunology

PhD (University of Texas), BS (Indiana State University)

Facilities

Headquarters and Biotechnology Operations
Germantown MD



Diagnostic Product Development Center
Aurora CO

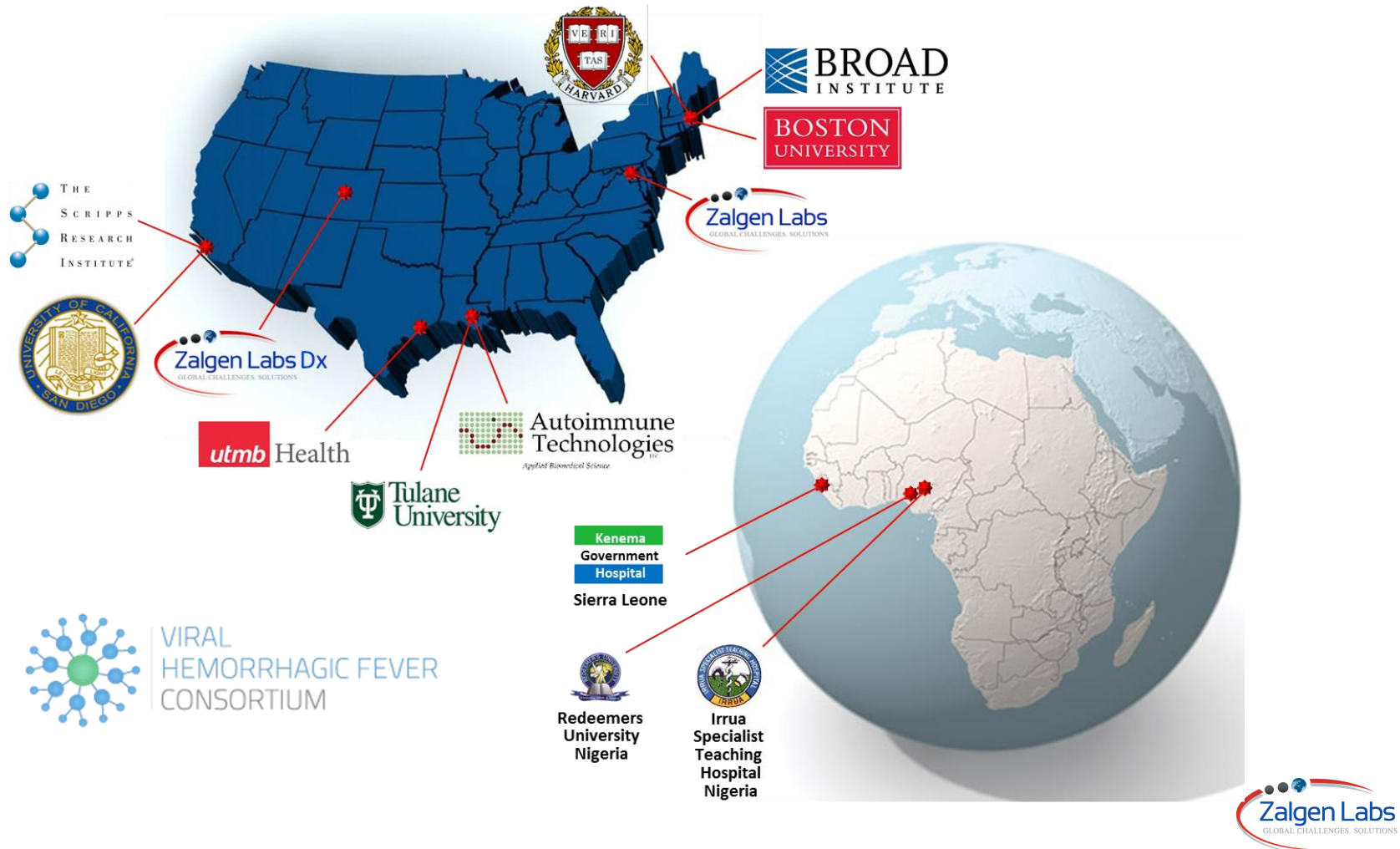


Clinical and Research Testing Site
Kenema, Sierra Leone



Viral Hemorrhagic Fever Consortium

Zalgen is a member of the VHFC, an international public-private partnership of highly respected academic, clinical, and medical, organizations.



Strategic Focus and Priorities

Immunotherapeutics Program

- File an IND and initiate Phase I studies of Arevirumab-3, our first-in-class fully human monoclonal antibody cocktail specifically designed for the prevention and treatment of acute Lassa fever infections
- Advance to pre-clinical testing additional human monoclonal antibodies in our existing portfolio directed against Lassa and Ebola viruses

Vaccine Program

- Advance selected LASV GPC constructs from our proprietary library through validation and scale-up to assess immunogenicity and vaccine efficacy in two animal models; down-select prime vaccine candidates for pre-clinical evaluation as a first-in-class multivalent vaccine for all circulating lineages of Lassa and Ebola viruses

Diagnostics Program

- Enhance our position as global leader for hemorrhagic fever immunodiagnostic tests by securing additional regulatory approvals and building market presence
- Expand our diagnostic product portfolio with additional products for detection of acute viremias (circulating antigens) and human convalescent immune responses (IgM/IgG) to support immunotherapeutic and vaccine research

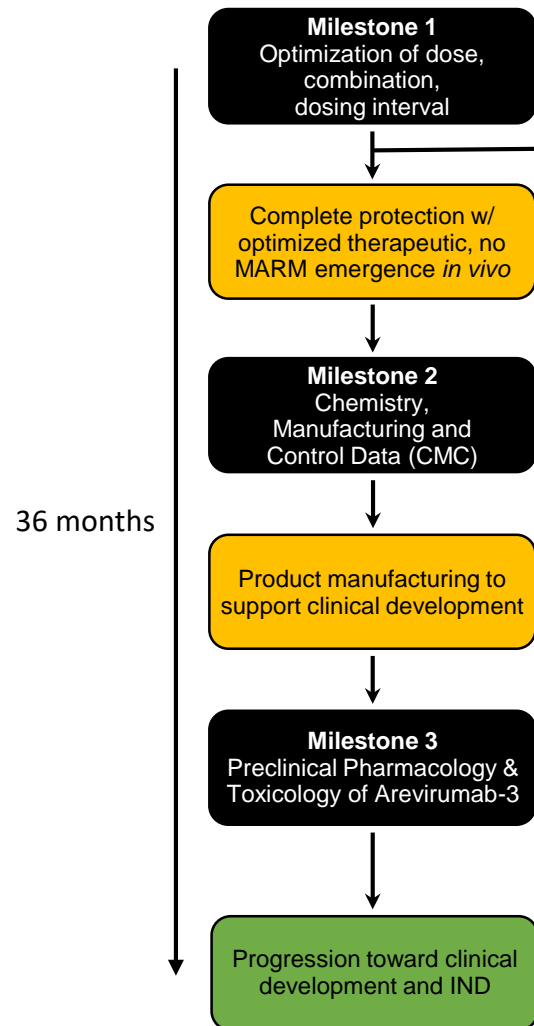
Immunotherapeutics Program



Zalgen has core competency in the development of multiple platforms for generation of high quality recombinant proteins from difficult-to-express genes. Our proven approaches are supported by the successful development of first-in-class immunotherapeutics for prophylaxis and treatment of Lassa Hemorrhagic Fever. The first three fully human monoclonal antibodies, administered in single or cocktail formats have demonstrated remarkable efficacy in relevant animal models in Biosafety Level-4 (BSL-4) settings.

Our efforts are revolutionizing the understanding of epidemiological, immunological, and basic research notions in hemorrhagic viruses, thus contributing to dramatic improvements in the management and successful outcome of these viral diseases.

Example: The Arevirumab-3 Project



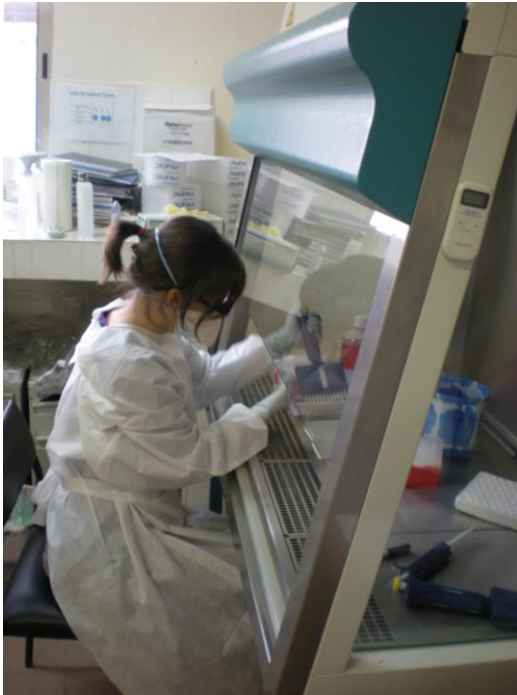
Reformulation of BNhMAb cocktail with alternative hMAbs with better clinical profile if any are identified through ongoing structural and mechanistic studies

Project Goal: To advance Arevirumab-3 through IND and into Phase 1 testing.



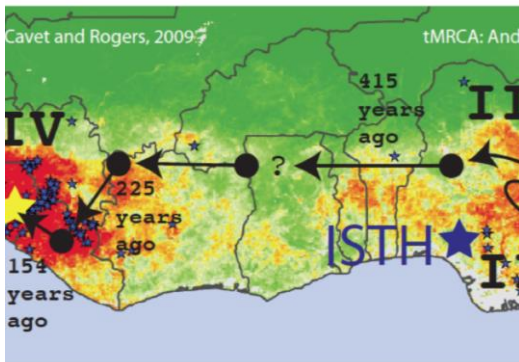
Proposed issue cover art –
Courtesy of Dr. Robert F Garry

Vaccine Program



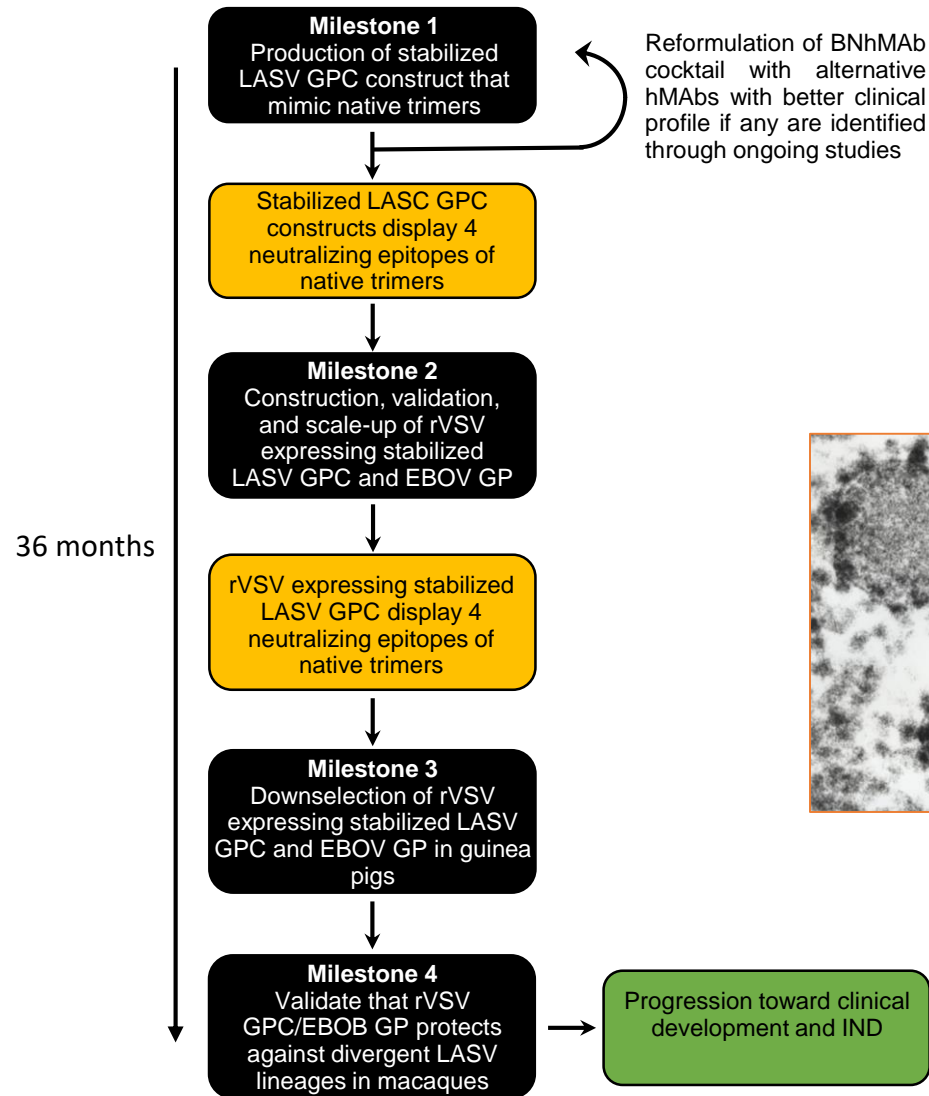
Zalgen has an active, milestone-driven research program utilizing structure-based vaccine design approaches to generate candidate vaccine immunogens against LASV.

We have demonstrated that the prefusion virion configuration (native) is the structure to which the most important humoral immune responses (antibody-mediated) are directed. Our antigens faithfully mimic the native, functional trimers that are present on the LASV surface. We employ structure-based design to stabilize this structure, limiting conversion to post fusion states that fail to elicit protective immune responses, while minimizing generation of non-protective antibodies.

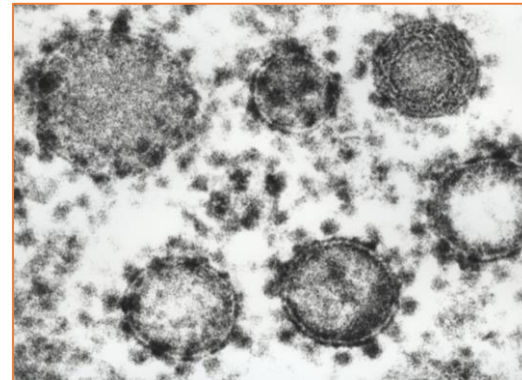


There are no approved vaccines or therapeutics for human use, and the potential for geographic expansion, ease of procurement and weaponization of the virus necessitate development of broadly reactive fast-acting protective vaccines.

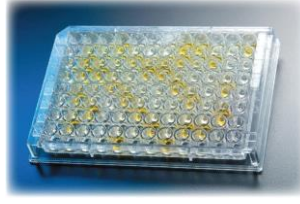
Example: LASV Vaccine Development



Project Goal: To develop and test an effective dual vaccine platform to LASV and EBOV, and perform critical pre-clinical studies



Diagnostic Products



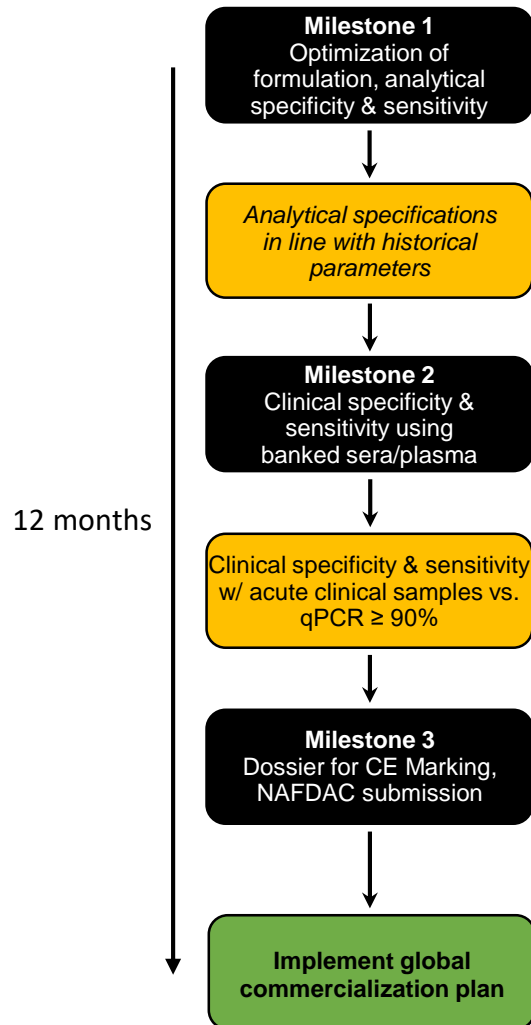
Zalgen is the global leader in immunodiagnostic products for hemorrhagic fever viruses, not only for use in clinical settings but to support immunotherapeutic and vaccine research along with development.

Our assays include antigen detection as well as IgG/IgM antibody detection of viral agents including Lassa (LASV), Junin (JUNV), Ebola (EBOV), Marburg (MARV) and Dengue (DENV).

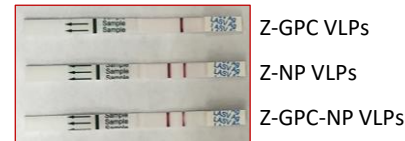
Our ReEBOV[®] Antigen Rapid Test, a 15 minute test for Ebola virus VP40 antigen, is the first and only rapid Ebola test to receive both FDA Emergency Use Authorization and WHO Emergency Listing. Our ReLASV[®] Lassa Rapid Test is a 15 minute test for Lassa virus NP, is the first and only Lassa virus rapid test to be CE marked.

We are continuing to expand our diagnostic product offerings using both lateral flow immunoassay (LFI) and ELISA microplate delivery platforms to meet the global market needs.

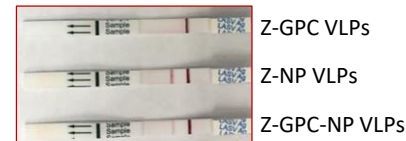
Example: Pan LASV Rapid Diagnostic Test



Project Goal: To expand Lassa diagnostic product portfolio by completing development and advancing to global commercialization a highly sensitive and specific rapid diagnostic test (RDT) detecting all circulating lineages of Lassa virus.



**LASV-Nig08-A18-Nigeria 2008H
(Lineage III) VLPs analyzed on
Pan LASV RDTs (detects
Lineages II, III, IV, Mali, Togo)**



**LASV237-Nigeria 2010H
(Lineage II) VLPs analyzed on
Pan LASV RDTs (detects
Lineages II, III, IV, Mali, Togo)**

Active Pipeline

Monoclonal antibody-based therapeutics development programs

Target	Discovery	Lead Selection <i>in vivo</i>	Pre-Clinical	Collaborators	Funding
Lassa virus				Tulane [*] , UTMB	NIH/NIAID
Pan Arenavirus				TSRI [*] , Tulane, UTMB, VIC	NIH/NIAID
LCMV ^{**}				TSRI, Tulane, UROCH	NIH/NIAID
Ebola virus				Tulane [*] , UTMB	NIH/NIAID

Diagnostics development programs

Target	Development	Field Validation	CE	Approved WHO ¹ /FDA ¹	Collaborators	Funding
ReLASV RDT ^{**}					Tulane, NOWDx, AIT	NIH/NIAID
Pan Lassa virus ^{**}					Tulane, NOWDx, AIT	NIH/NIAID
ReEBOV RDT ^{**}					Tulane, NOWDx, AIT, UTMB, TSRI	NIH/NIAID/ BMGF

Vaccine development programs

Target	Discovery	Lead Selection <i>in vivo</i>	Pre-Clinical	Collaborators	Funding
Lassa/ Ebola virus				Tulane [*] , UTMB, TSRI, Burnham	NIH/NIAID

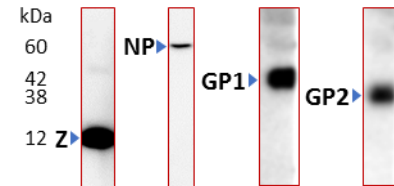
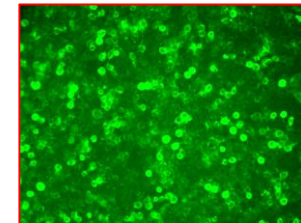
* Prime awardee

** Zalgen prime awardee

¹ Emergency Use Authorization (EUA)

Commercialization Program

- 4 Ebola testing platforms (Antigen RDT [Emergency Use Authorization and Research Use Only], Antigen ELISA (Research Use Only), IgM/IgG (Research Use Only))
- 6 Lassa testing platforms (Lineage IV Antigen RDT [IVD - CE and Research Use Only], Pan LASV RDT (Research Use Only, 2 sizes), Pan Lassa Antigen ELISA (Research Use Only), Pan Lassa IgM/IgG (Research Use Only))
- 18 human monoclonal antibodies specific to LASV GPC or subunits (GP1 and GP2), with defined research applications
- 3 virus-like particles (VLP), from lineages II, III (Nigeria), IV (SLE, GIN, LBR)



LAS Josiah Z-GPC-NP VLPs

Market Potential

Humanitarian impact:

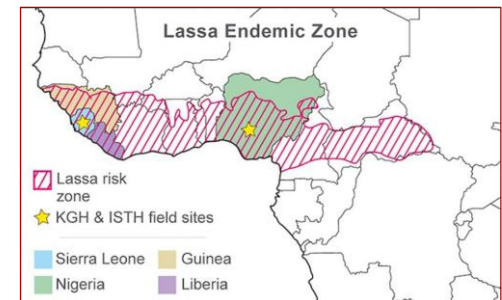
- At risk Lassa fever population in West Africa, from Senegal to Nigeria, as high as 200 million
- Annual regional incidence of Lassa fever as high as 3 million, with as many as 67,000 deaths/year

Biodefense and pandemic preparedness impact:

- Preparedness and USN Stockpiling of rapid diagnostics; therapeutics for effective and rapid response; novel vaccines for public health, pandemic and biodefense use

Market Potential:

- Direct sales of rapid LASV and EBOV diagnostics to West African nations
- Sales of diagnostics to private entities with business interests in West African nations
- Only rapid diagnostic platforms specifically developed for austere environments, with regulatory compliance and path to approval
- First-in-class therapeutic specifically designed to target multiple lineages of LASV
- Structure-based derivation of native human monoclonal antibodies from Lassa fever survivors
- Markets include USN Stockpile of new therapeutic options for Biodefense; use in accidental laboratory exposures; distribution to endemic areas with foundational or economic development-based international aid



Lassa Fever Map - Credit: Sigrid Knemeyer, Kristian Andersen, Pardis Sabeti (Broad Institute) via NIAID

This is Why we do What we do



Acute Lassa fever survivor
KGH LF Ward
Sierra Leone, 2010

Acute Lassa fever survivor
KGH LF Ward
Sierra Leone, 2011



Impactful publications in the VHF field

- CE Mire, et al. Human monoclonal antibody therapy protects nonhuman primates against advanced Lassa fever. 2017. *Nature Medicine*. *In Press*
- KM Hastie, et al. Structural basis for antibody-mediated neutralization of Lassa virus. 2017. *Science*. 02 JUN 2017 : 923-928
- Cross RW, et al. Treatment of Lassa virus infection in outbred guinea pigs with first-in-class human monoclonal antibodies. *Antiviral Res*. 2016 Aug 13;133:218-222
- Robinson JE, et al. Most neutralizing human monoclonal antibodies target novel epitopes requiring both Lassa virus glycoprotein subunits. 2016. *Nature Communications* 7, Article #11544
- Boisen ML, et al. Development of Prototype Filovirus Recombinant Antigen Immunoassays. *J Infect Dis*. 2015 Oct 1;212 Suppl 2:S359-67
- Andersen KG, et al. Clinical Sequencing Uncovers Origins and Evolution of Lassa Virus. *Cell*. 2015 Aug 13;162(4):738-50
- Hartnett JN, et al. Current and emerging strategies for the diagnosis, prevention and treatment of Lassa fever. *Future Virology*. 2015. Review. Vol. 10, No. 5, Pages 559-584
- Shaffer JG, et al. Lassa Fever in Post-Conflict Sierra Leone. 2014. *PLoS Negl Trop Dis* 8(3): e2748
- LM Branco, et al. Lassa Hemorrhagic Fever in a Late Term Pregnancy from Northern Sierra Leone with a Positive Maternal Outcome: Case Report. *Virology J*. 2011, 8:404
- LM Branco, et al. Emerging trends in Lassa fever: redefining the role of immunoglobulin M and inflammation in diagnosing acute infection. *Virology J*. 2011, 8:478
- JN Grove, et al. Capacity building permitting comprehensive monitoring of a severe case of Lassa hemorrhagic fever in Sierra Leone with a positive outcome: Case Report. *Virology J*. 2011, 8:314

Contacts

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