



..... it's a long story

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**Saga Bio, Inc.**

# We're a Translational Immunology and Immunodiagnostics Company

## Kawasaki Disease



- Febrile vasculitis (inflamed blood vessels) with a predisposition for the coronary arteries → untreated coronary artery aneurysm rate of 20%
- Typically seen in children 0.5 to 6 years of age
- Diagnosed based on prolonged fever (5 days) plus 4 of 5 possible findings on physical exam.
- Looks like a viral illness and easily missed by pediatricians. 2/3rds of cases in the U.S. go undiagnosed. Causes significant acute and delayed cardiac morbidity and mortality. ~6000 diagnosed cases per year in the US.
- Treatment: Hospitalize and give pooled human gamma globulin (antibodies), \$\$\$
- **NEED:** Rapid diagnostic test for a dangerous illness to guide an expensive therapeutic decision

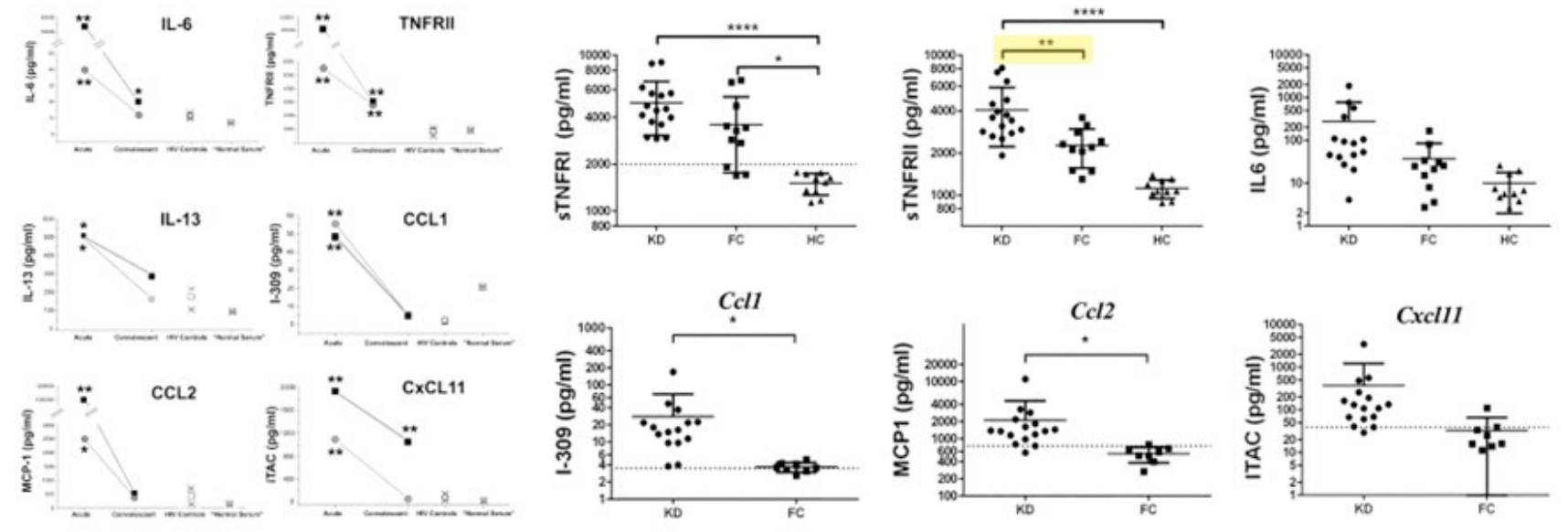


Kawasaki-like syndromes associated with human immunodeficiency virus infection. **Johnson RM**, Little JR, Storch GA. Clin Infect Dis. 2001 Jun 1;32(11):1628-34.

# Pediatric Kawasaki Disease and Adult Human Immunodeficiency Virus Kawasaki-Like Syndrome Are Likely the Same Malady

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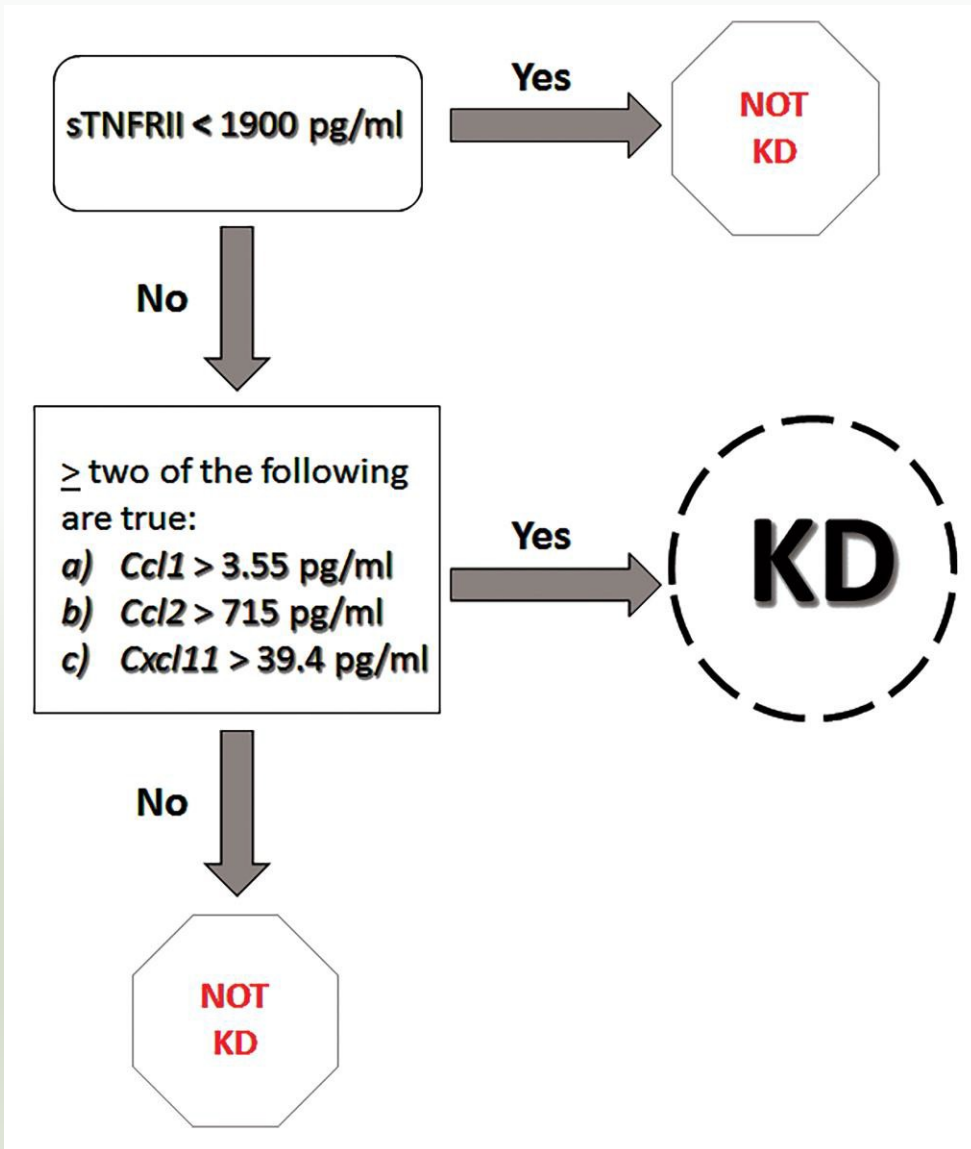


Adults/HIV

KIDS

**SAME (WEIRD) INFLAMMATORY SIGNATURE!!!**

# POC Screening test for Kawasaki Disease (KD):



- **sTNFR II < 1900 pg/ml = Not KD**

“This is likely a viral infection that will go away on its own. Ok to go home and follow up with your pediatrician or family practice doctor.”

- **sTNFR II > 1900 pg/ml – serious medical event - admit to hospital and finish fever evaluation, consider Kawasaki Disease.**

**Viral infections are about interferons**

**Bacterial infections and KD are about TNF $\alpha$**

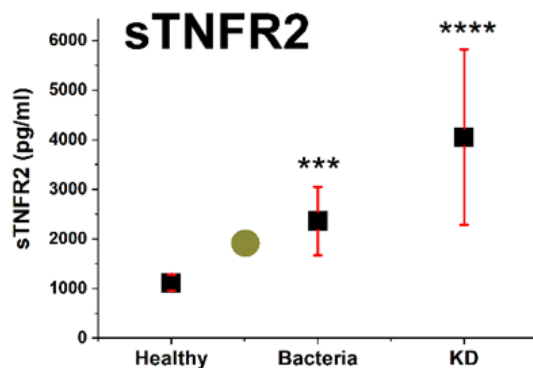
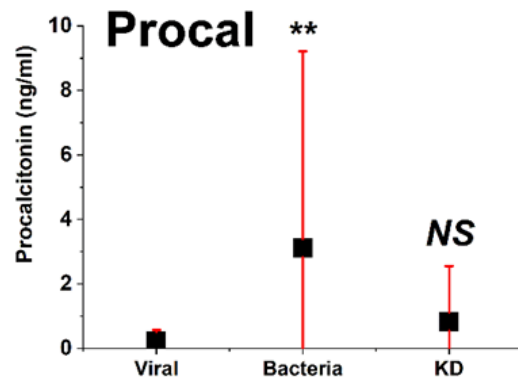
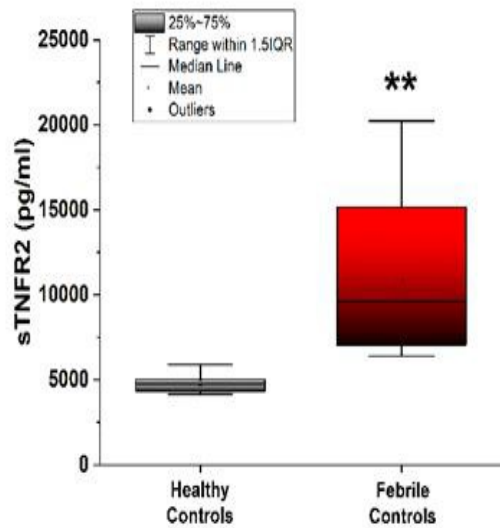
**KD includes blood vessel inflammation (vascular chemokines).**



# Febrile Child sTNFR2 POC Test

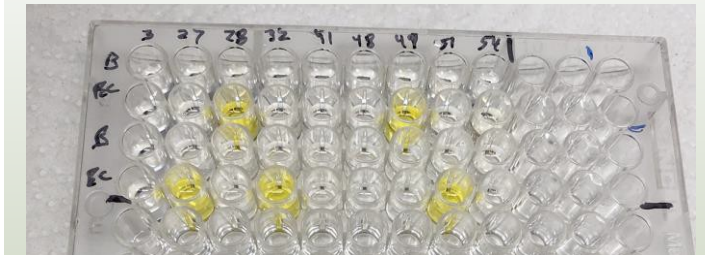
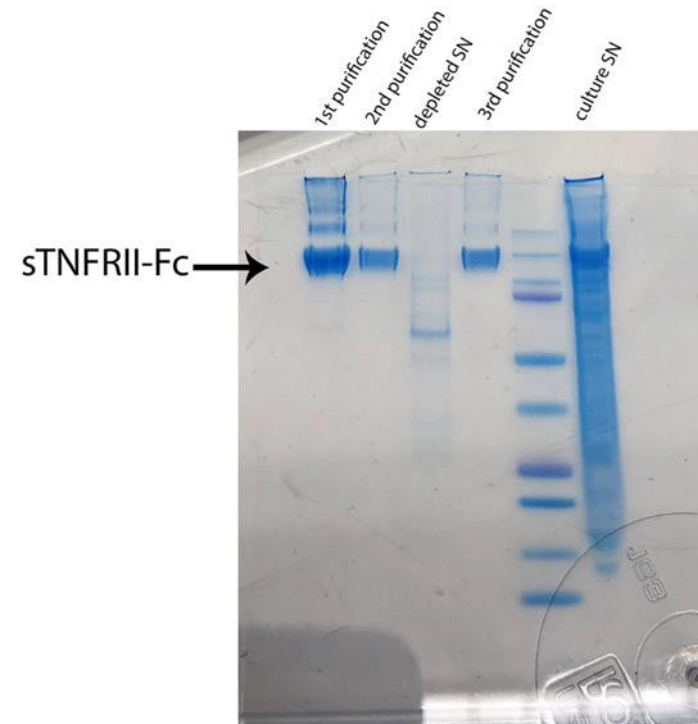
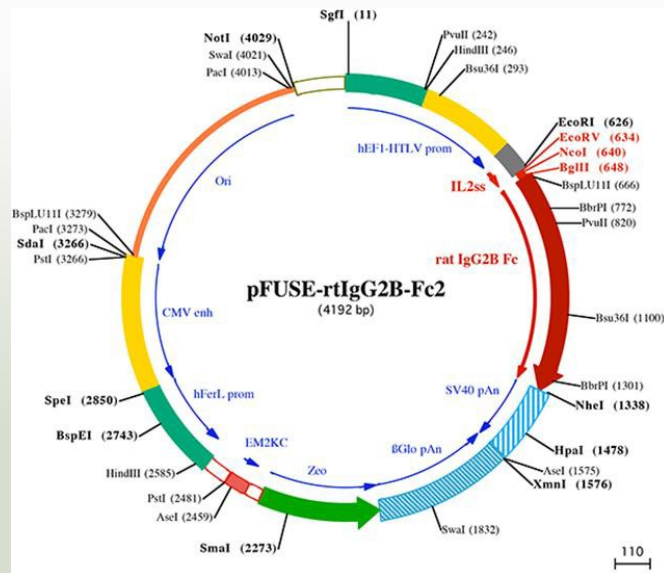
more than a Kawasaki Disease Screening Test

- Rapidly rules out serious inflammatory events (**need for admission**) to simplify febrile child ER workflows
- Identifies children who may have KD for additional evaluation
- **The market is febrile children in emergency rooms and primary care clinics:**
  - Fever is the #1 complaint in pediatric emergency rooms representing **5 million visits annually** in the relevant age group.
  - “Fever” accounts for 30% of outpatient pediatric clinic visits, **70 million visits annually.**



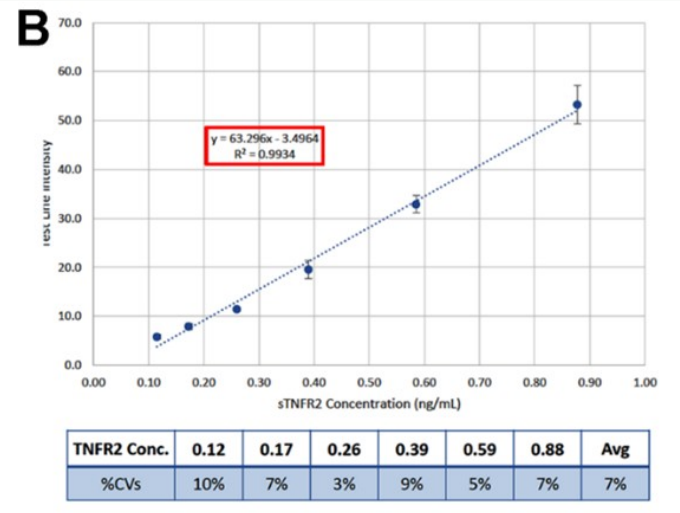
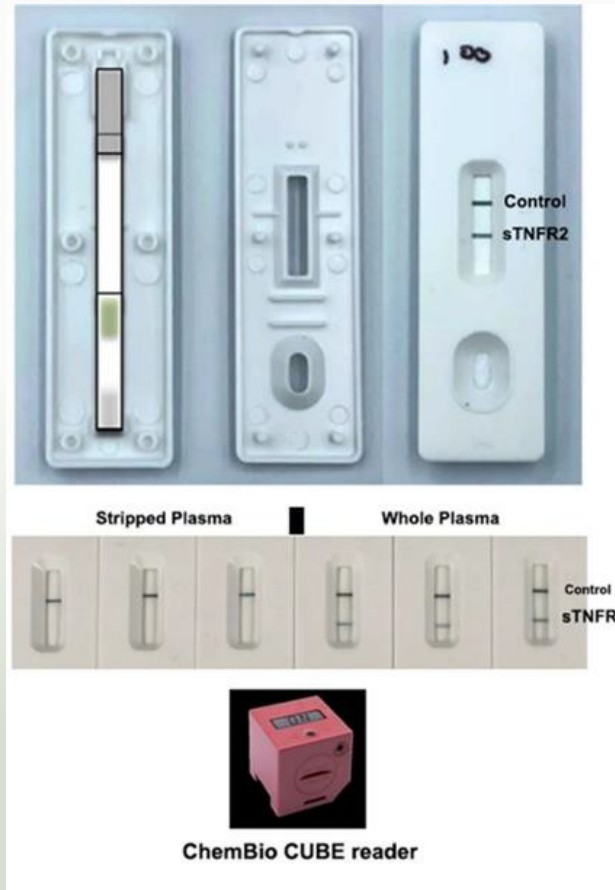
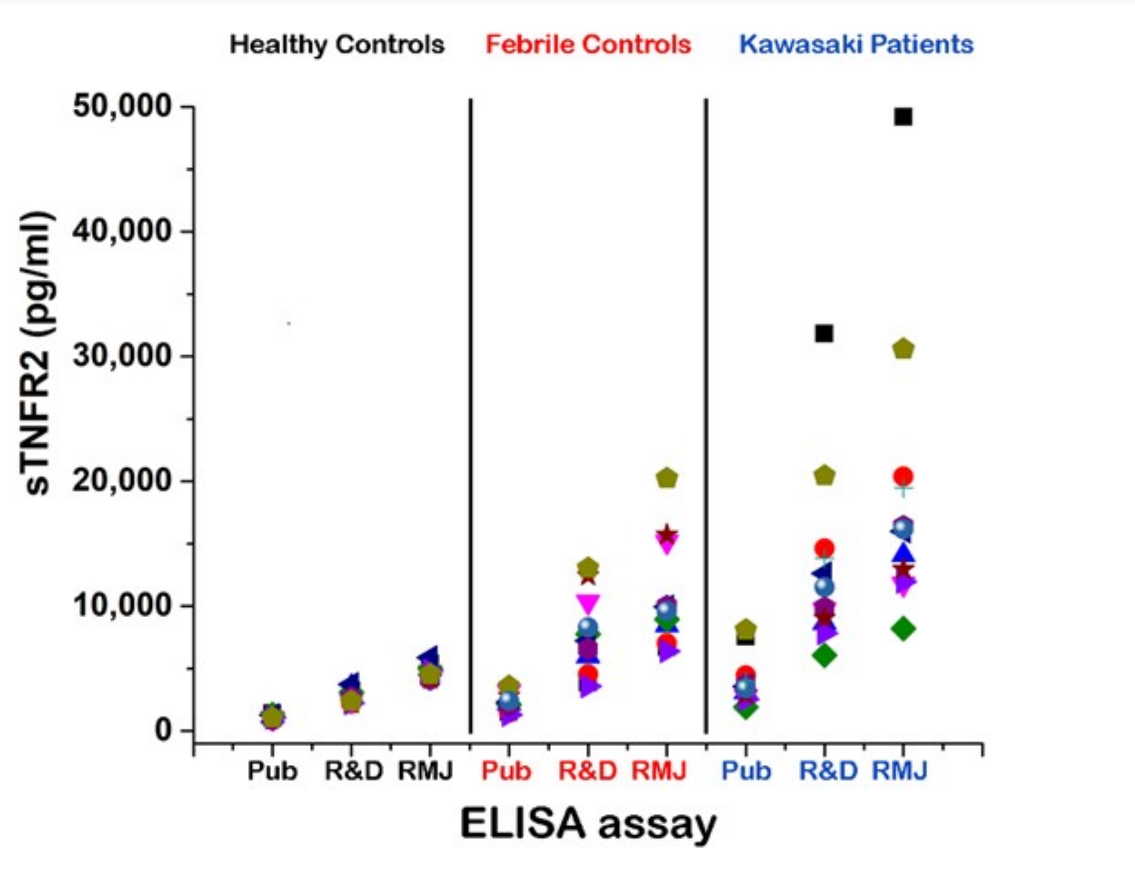
# Technology barrier = lack of antibody pairs for capture-detection for a POC test

Phase I STTR: Developing a point-of-care test to Diagnose Kawasaki Disease R41HD093473



**Result: New noncompeting rat anti-human monoclonal antibodies to sTNFRII**

# Phase I STTR: Developing a point-of-care test to Diagnose Kawasaki Disease



**Product #1** CLIA-certifiable sTNFR2 ELISA

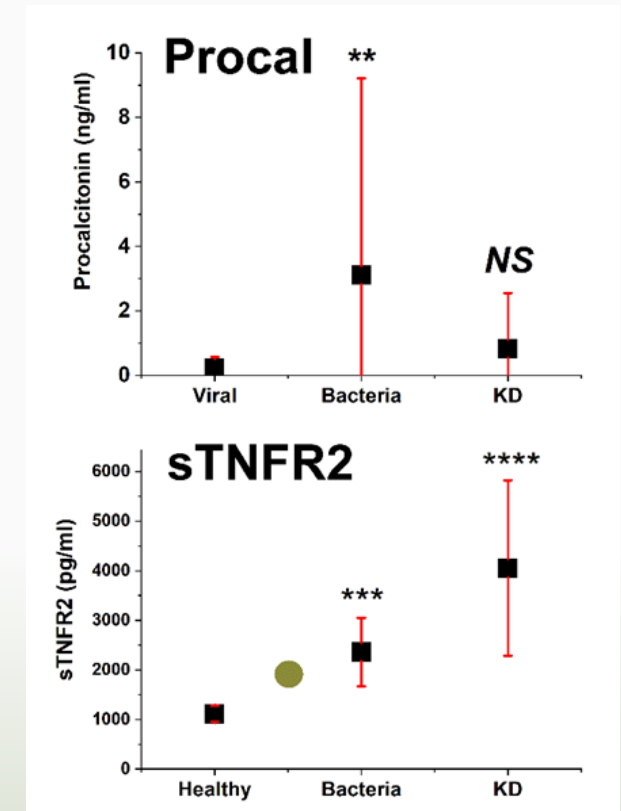
**Product #2** sTNFR2 POC test- prototype device

**No known competitors in the public domain** for either the sTNFR2 ELISA or POC test. Monoclonal antibody barrier to new entrants who otherwise have the technologic skillset.

**Relevant comparator/competitor is the procalcitonin test (Procal).** FDA indication to initiate or discontinue IV antibiotics for lower respiratory tract infections and discontinue antibiotics in sepsis. Poor performer for KD. \$70 per test \$700 million in annual revenue combining children and adults.

### Revenue stream:

- 1) *sTNFR2 POC test*: 20% adoption rate by Emergency Rooms would be 1 million tests annually x \$70 = 70 million. Anticipate 20% per year growth as testing migrates into the outpatient clinic setting.
- 2) *Vascular chemokine POC test* to complete KD diagnostic algorithm
- 3) *sTNFR2 ELISA*: Distribute through 3<sup>rd</sup> party vendor or run as a laboratory developed test (LDT).



**Pipeline:** Therapeutic anti-inflammatory monoclonal antibodies (humanized ) in preclinical development. Vascular chemokine ELISAs.

**Intellectual property:** Johnson, Yale; U.S. Application No. 63/423,223, filed 7 November 2022; TNFR2 Antibodies and Methods of Using the Same

**Investors:** Raymond Johnson, senior executive at Johnson & Johnson (therapeutic development leader), a nephrologist, and a business consultant. Yale owns 10% of common stock.



## The Team:

- Acting CEO: **Raymond M. Johnson**, M.D., Ph.D., Associate Professor Medicine, Infectious Diseases, Microbial Pathogenesis at Yale University.
- CEO in waiting (01/01/2024): **Sigmond G. Johnson**, Ph.D., M.B.A. currently senior executive at Johnson & Johnson (therapeutic development leader). Managed development and FDA approval of Xarelto.
- Lead Academic Investigator: **Kelly Bergmann, D.O.**, M.S. Director of Emergency Medicine Research at Children's Minnesota Hospitals in Minneapolis, MN (University of Minnesota)
- GMP manufacturing and lateral flow development partner: **nanoComposix**, San Diego, CA

## Immunodiagnosics milestones:

**Phase II R42 STTR grant renewal submitted April 5<sup>th</sup> - \$2 million over 2.5 years**

FDA-approval of sTNFR2 ELISA..... within 2 years

Phase III trial and FDA approval of the sTNFR2 POC device..... within 4 years

Phase III trial and FDA approval of the vascular chemokine POC device within 6 years

**Laboratory:** Laboratory space in Biolabs New Haven beginning June 1<sup>st</sup> (today).

