

**V E T
TECH**

Empowering
Livestock Health



Empowering Livestock Economies
Through Health Innovation and Technology

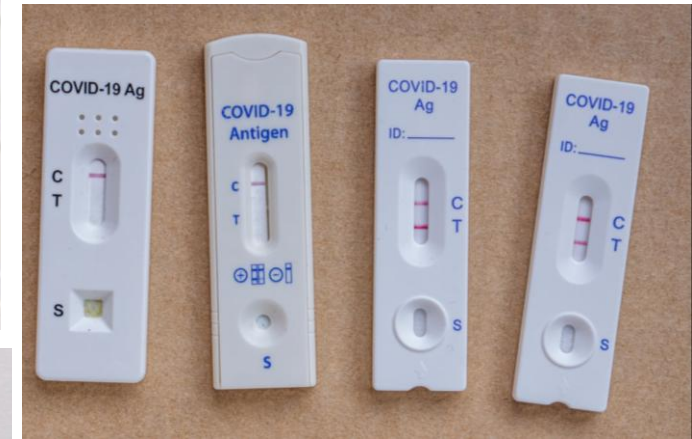
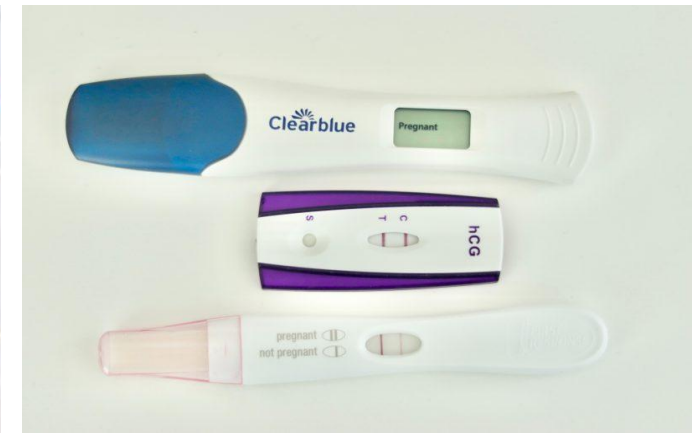
Breaking out the lab: lateral flow tests for one heath

- Caitlin Thompson, Liverpool School of Tropical Medicine
- 2-3 of December 2025, Riyadh



What is a lateral flow test?

- Rapid diagnostic test
- Easy to use
- Relatively cheap
- Lots of sample types – Blood, serum, Urine, nasal/throat swabs, Saliva etc...
- Point-of-care – No training needed
- 10-30 minutes to result



How they are used in Human and Animal health

Human Health

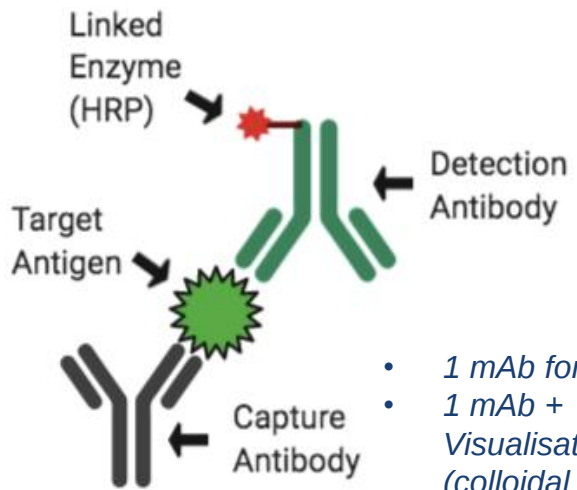
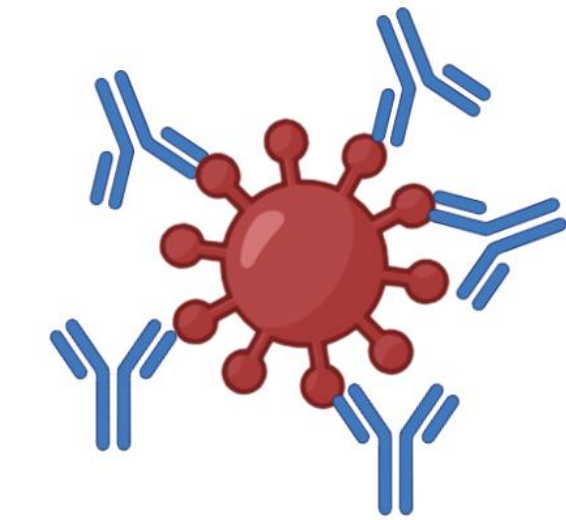
- **Infectious disease testing** - e.g., COVID-19, influenza, HIV screening.
- **Pregnancy testing** - one of the first and most common LFT applications.
- **Drug and toxin screening** - rapid urine or saliva tests.
- **Biomarker detection** - cardiac markers, allergies, and other point-of-care diagnostics.

Animal Health

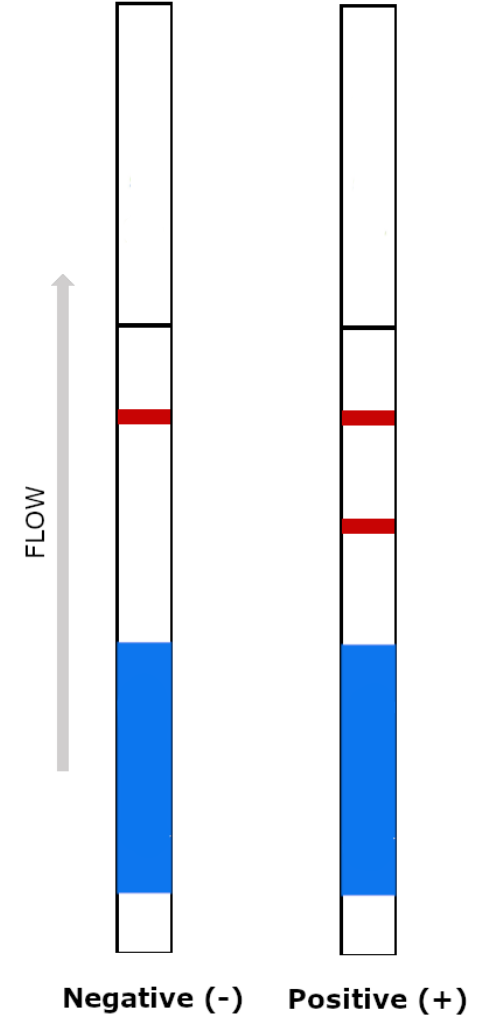
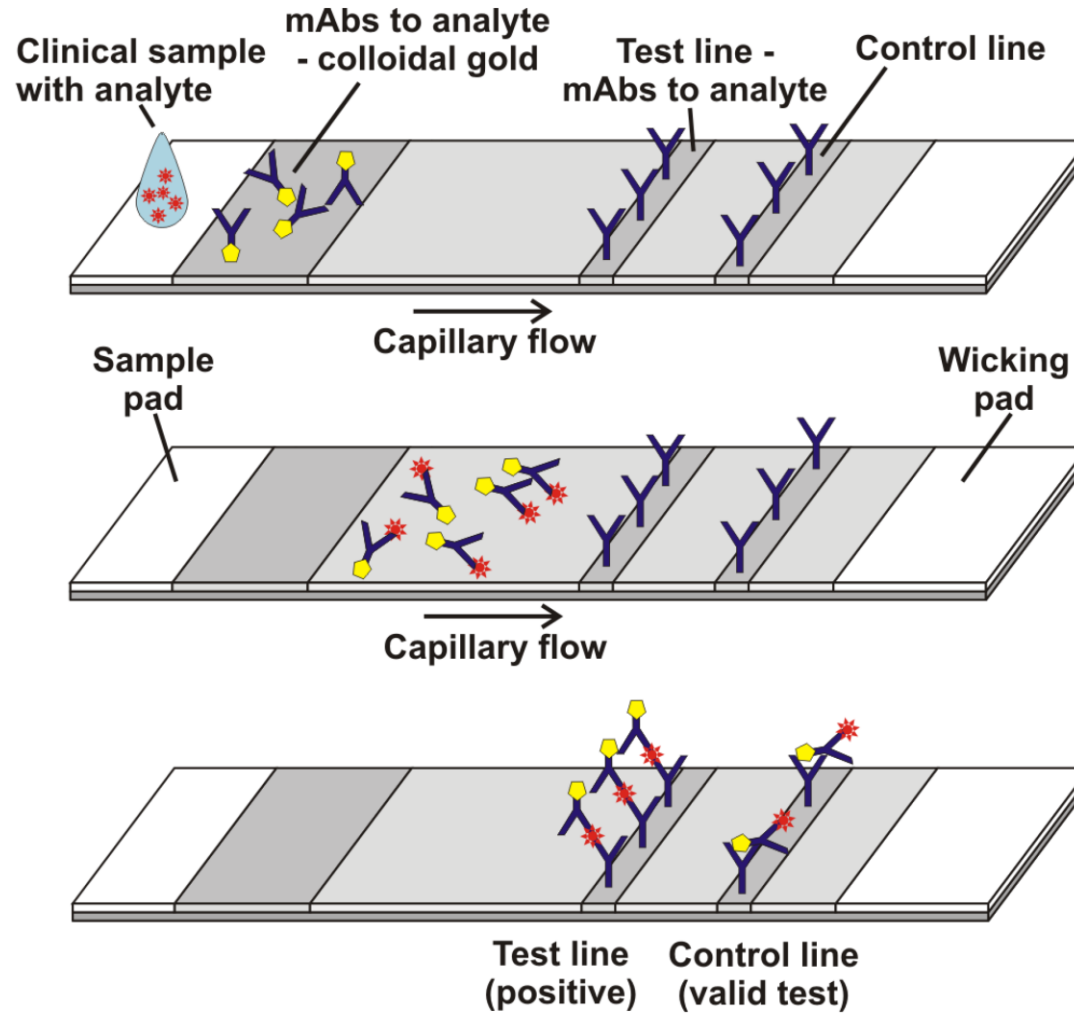
- **Veterinary infectious disease tests** - e.g., parvovirus, FeLV/FIV in cats, bovine diseases.
- **On-farm diagnostics** - rapid testing for livestock illnesses to prevent spread.
- **Food safety and zoonotic surveillance** - detecting pathogens in animals that could transmit to humans.
- **Wildlife disease monitoring** - quick field tests for conservation and disease control.



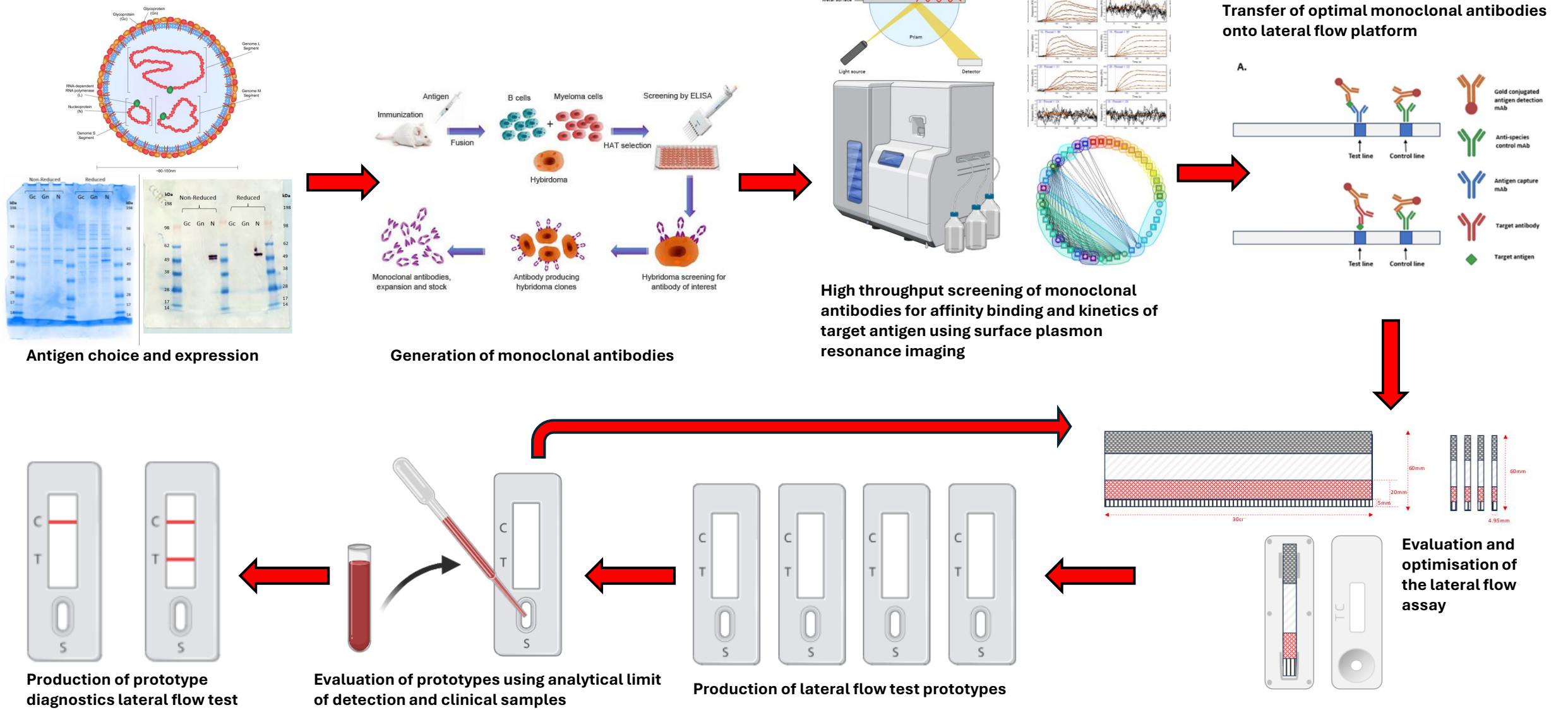
How does a lateral flow test work?



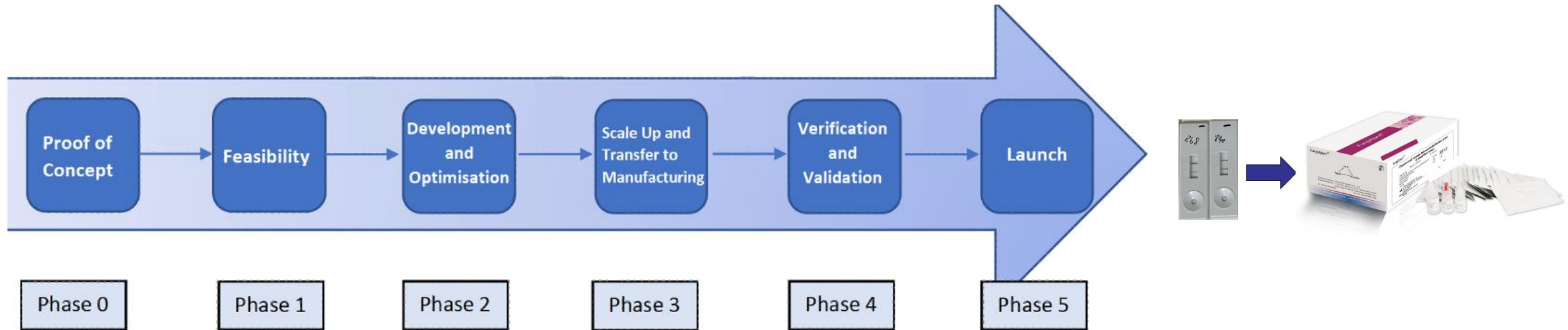
- 1 mAb for test line
- 1 mAb +
Visualisation tool
(colloidal gold)
= **Antibody 'Pair'**



Lateral flow development pipeline



Development pipeline to launch



Phase 0 – Development of assay materials (antigen/antibody)

Phase 1 – Transfer of material to lateral flow and initial proof of concept

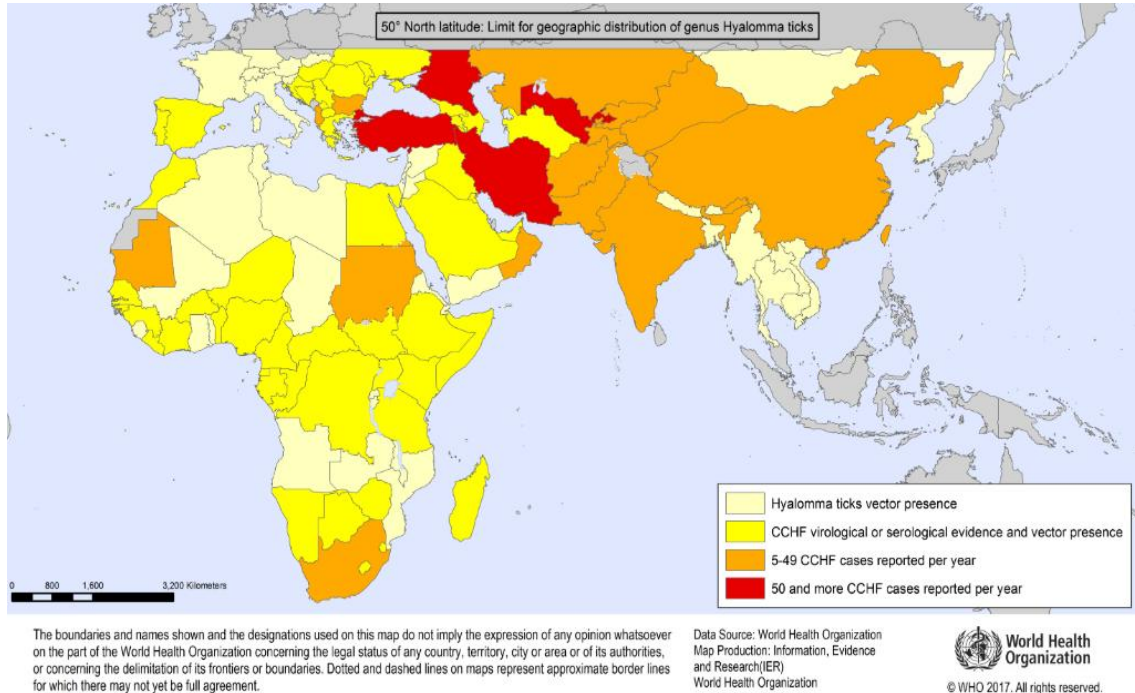
Phase 2 – Further developed, refined and fully optimized with reference samples

Phase 3 – Scale up to manufacturing quantity and quality

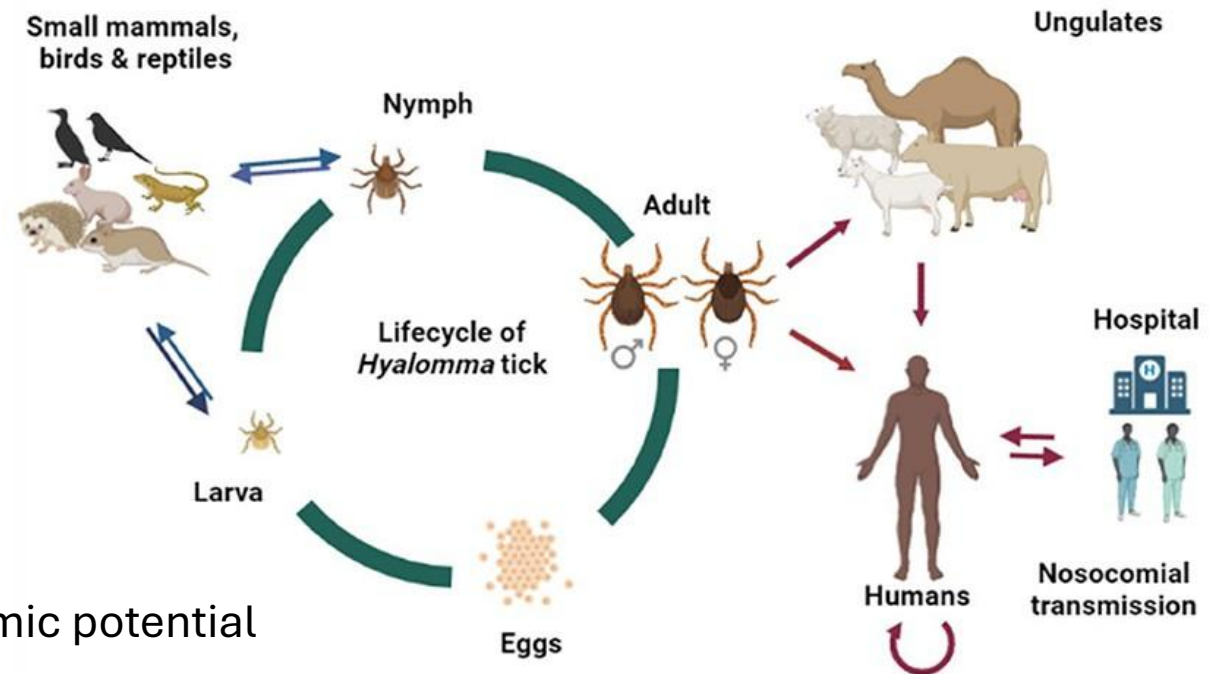
Phase 4 – Final design product verification with field validation

Phase 5 – Launch (+/- post market surveillance)

Case study: Crimean-Congo Haemorrhagic Fever

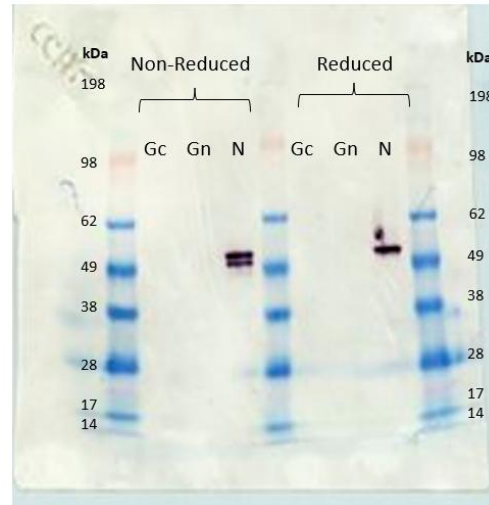
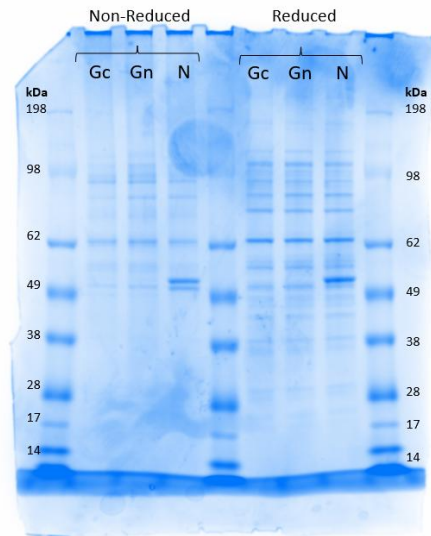
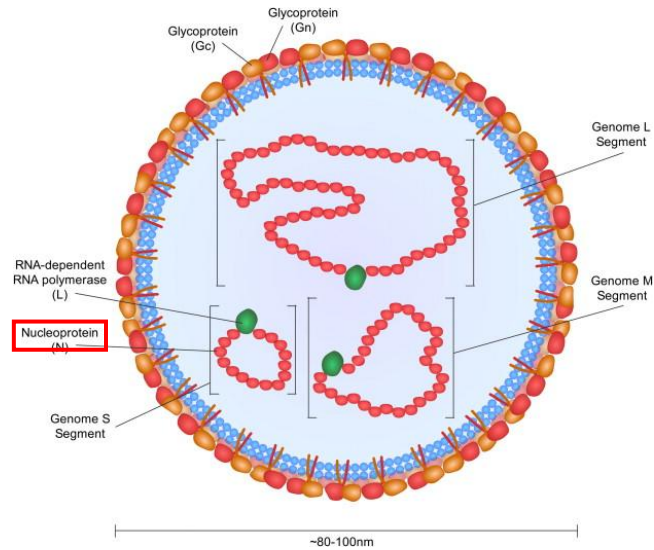


- First described in Crimea in 1944 & 1956 in The Congo – Recognised to be the same in 1966
- Found in Africa, the Middle East and Asia – increasing incidence in Europe



- Most widespread arbovirus worldwide
- Spread through ticks – livestock amplifying host
- World Health Organisation – Priority pathogen of pandemic potential

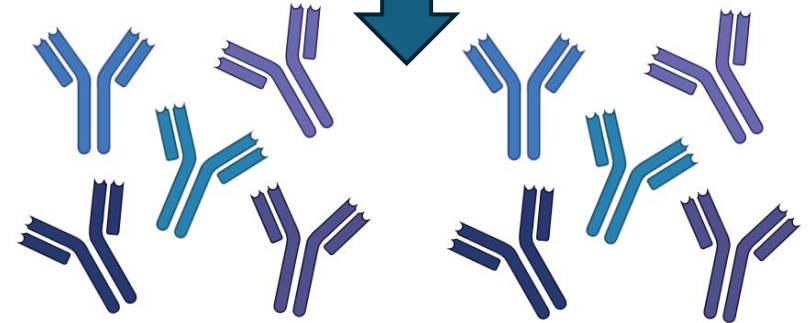
Identify target antigens



Produce mAbs using a mouse model



6 months

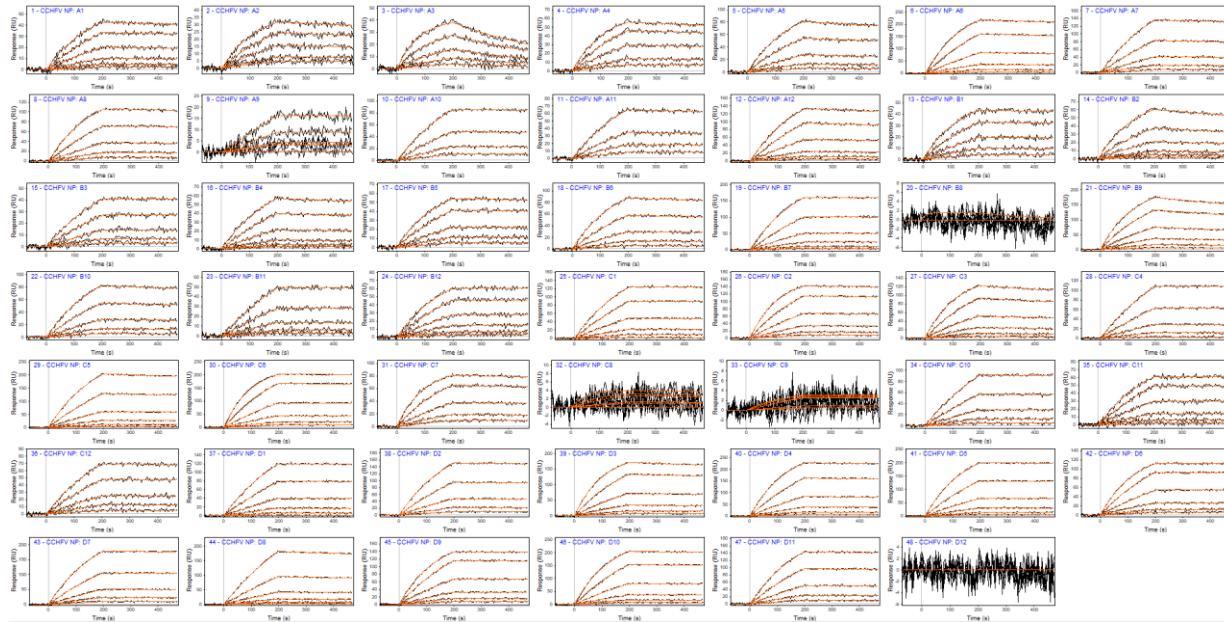


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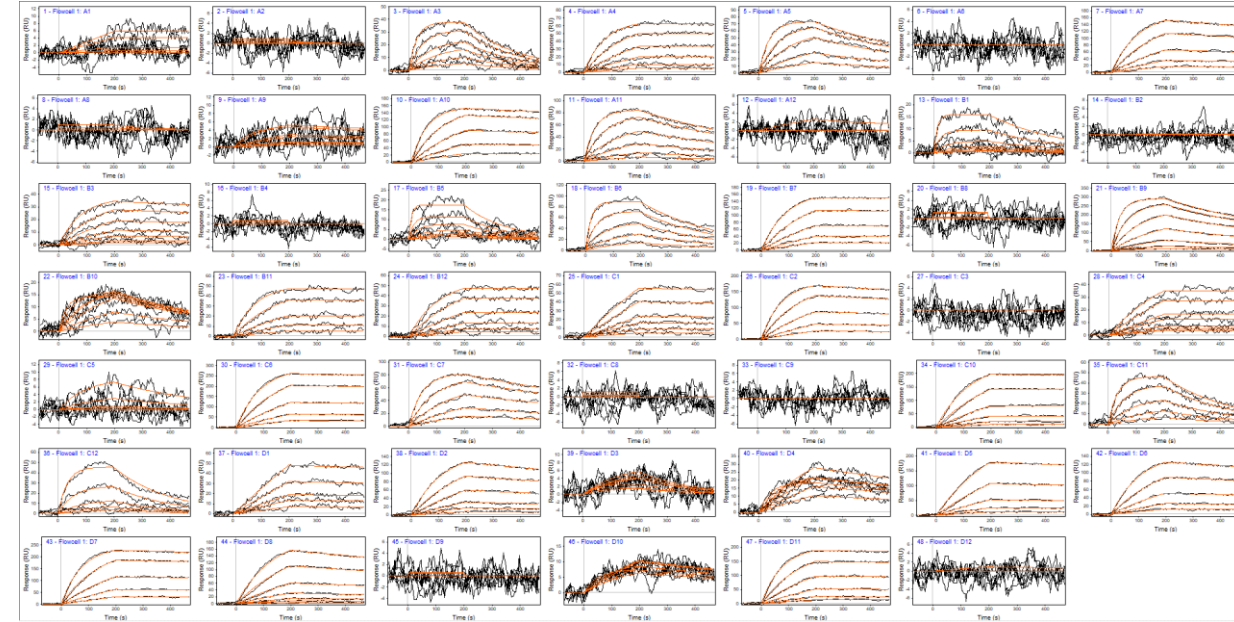
Anti-N CCHF monoclonal Antibodies

Monoclonal antibody binding evaluation

Kinetics - CCHF mAb binding **in-house** NP Ag



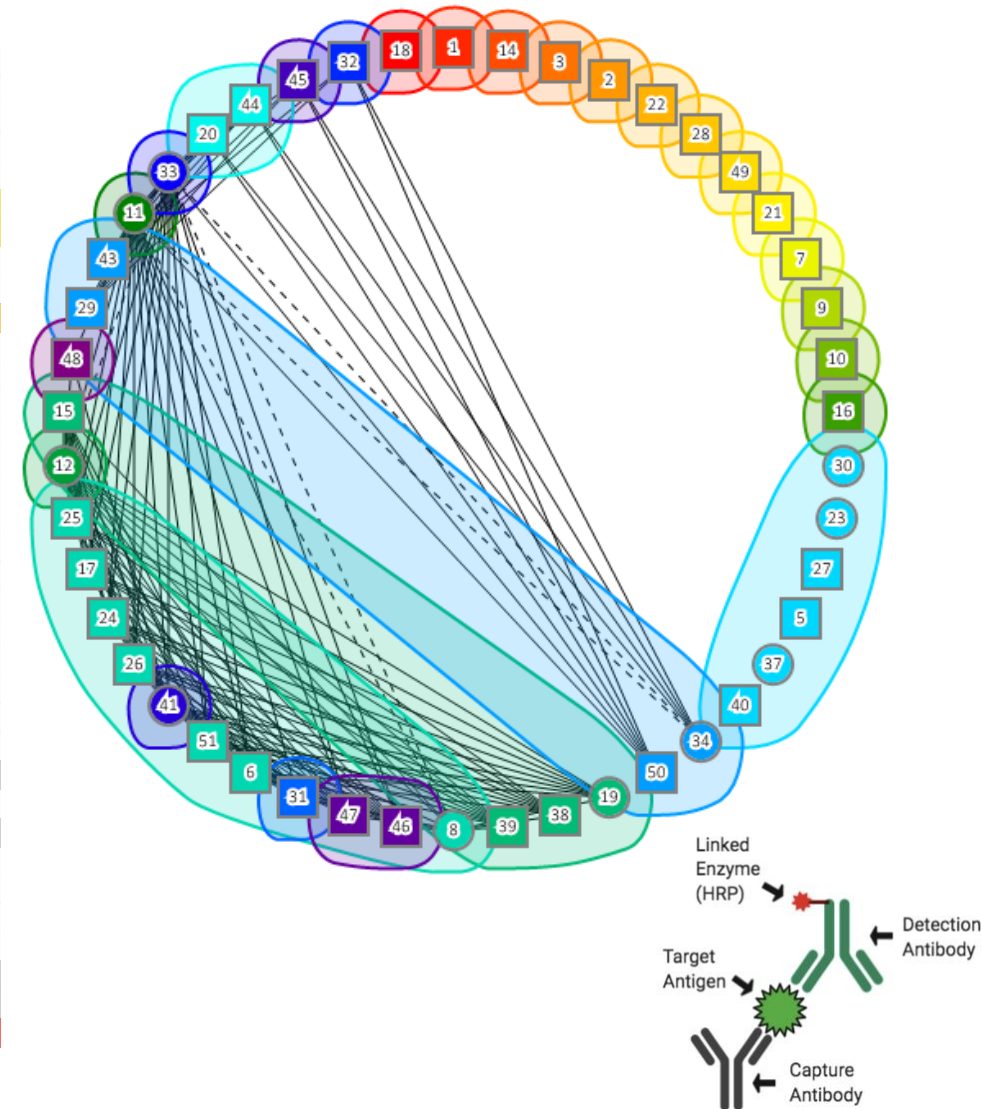
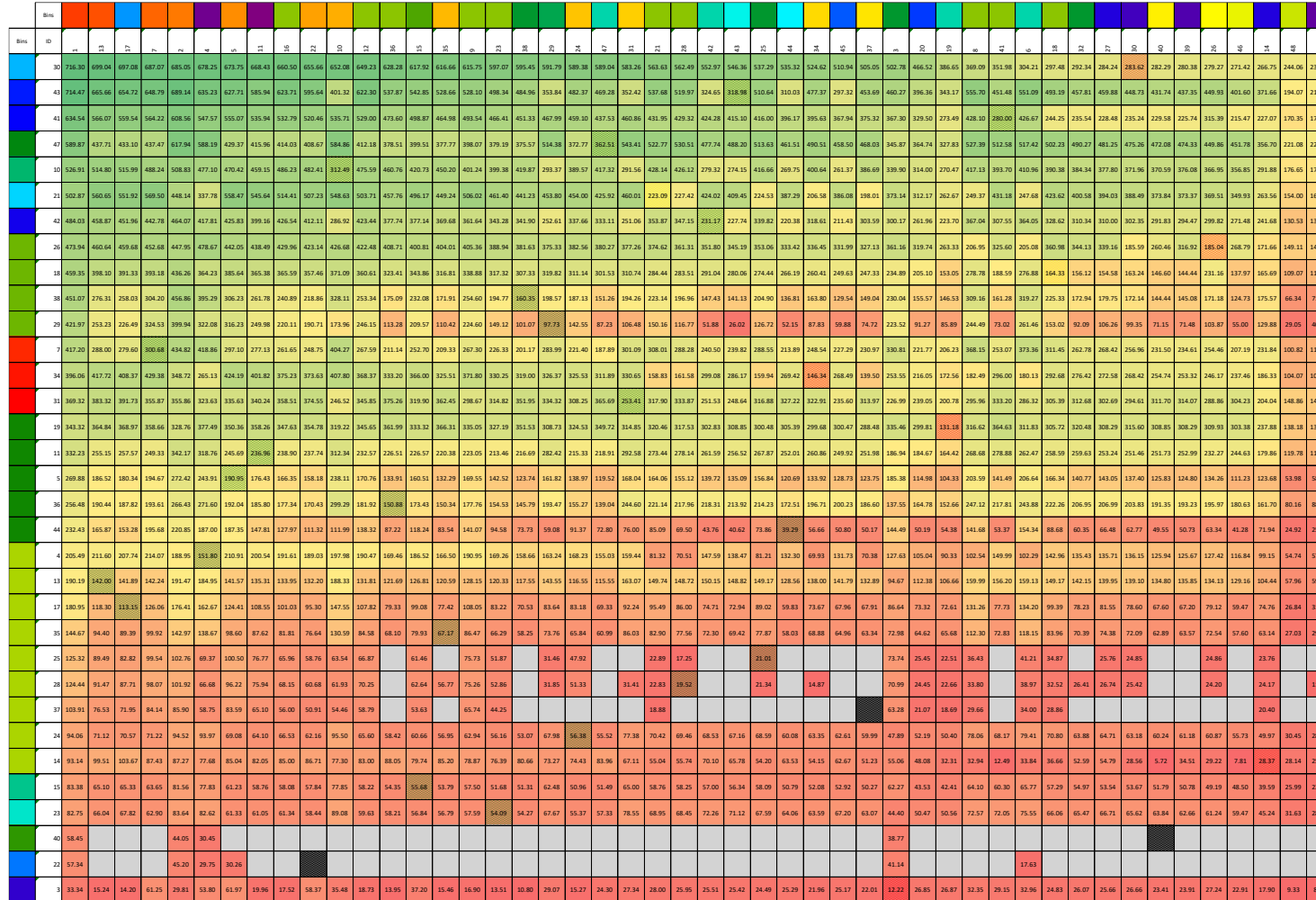
Kinetics - CCHF mAb binding **commercial** NP Ag



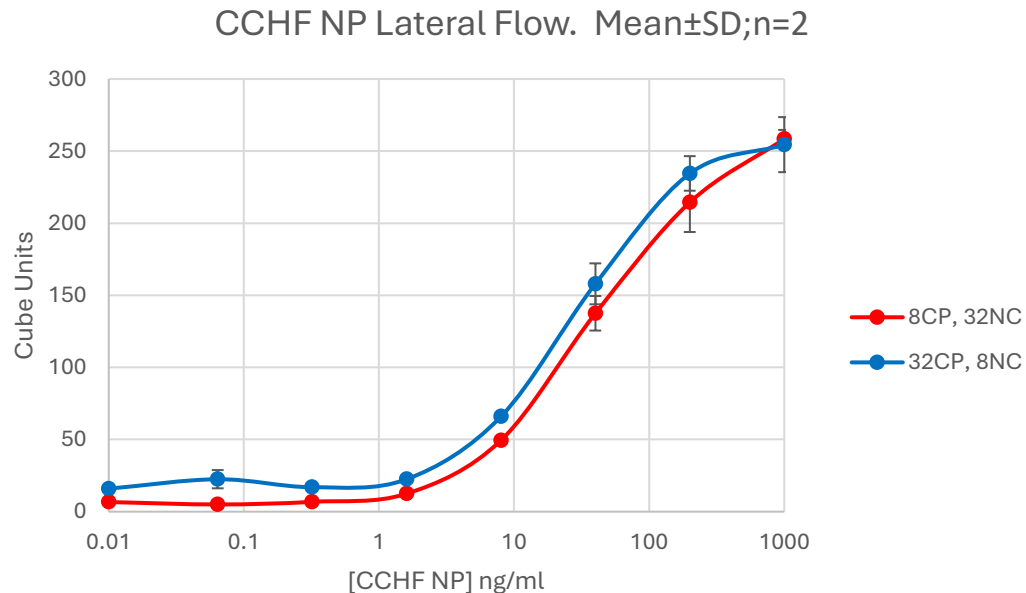
- Used IBIS - microarray-based surface plasmon resonance imager
- Obtained binding affinity and kinetics data

Identification of monoclonal antibody pairs

- A 'pair' is 2 mAbs that bind strongly to the Ag at different Ag epitopes



Prototype development



Limit of detection **1.6ng/mL**

54 Potential prototypes

Tested with N Ag, LOD, healthy WB/serum, inactivated CCHF samples



Prototype 1.
mAb 8 +
Colloidal Gold,
mAb 32 test line

Prototype 2.
mAb 32 +
Colloidal Gold,
mAb 8 test line



Test prototype in endemic country – Türkiye CCHF season (May – August)

Initial testing using ACTIVE CCHF serum samples

- 6 prototypes versions taken to MoH virology department in Ankara, Türkiye
- Ran a small number of prospective PCR confirmed positive and negative CCHF serum samples on prototype tests

Sensitivity

75%

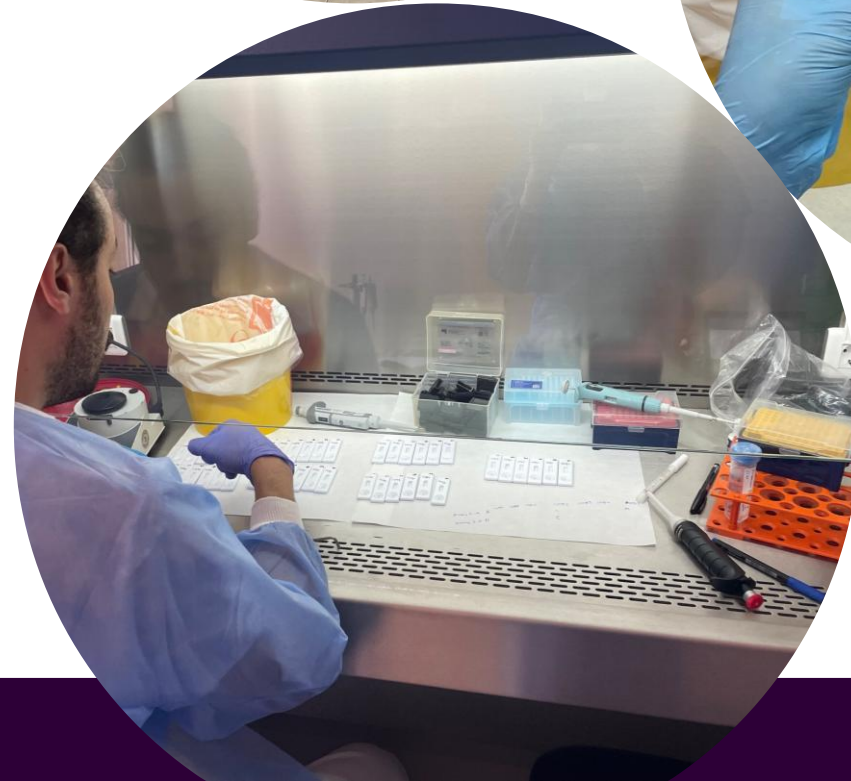
The proportion of people with a disease who test positive on a diagnostic test

Specificity

97%

The proportion of people without a disease who test negative on a diagnostic test

WHO TPP minimum Sens 80%/Spec 90%



Optimisation of an LFT for CCHF

- **Buffer**

Change salt conc, pH, Detergent

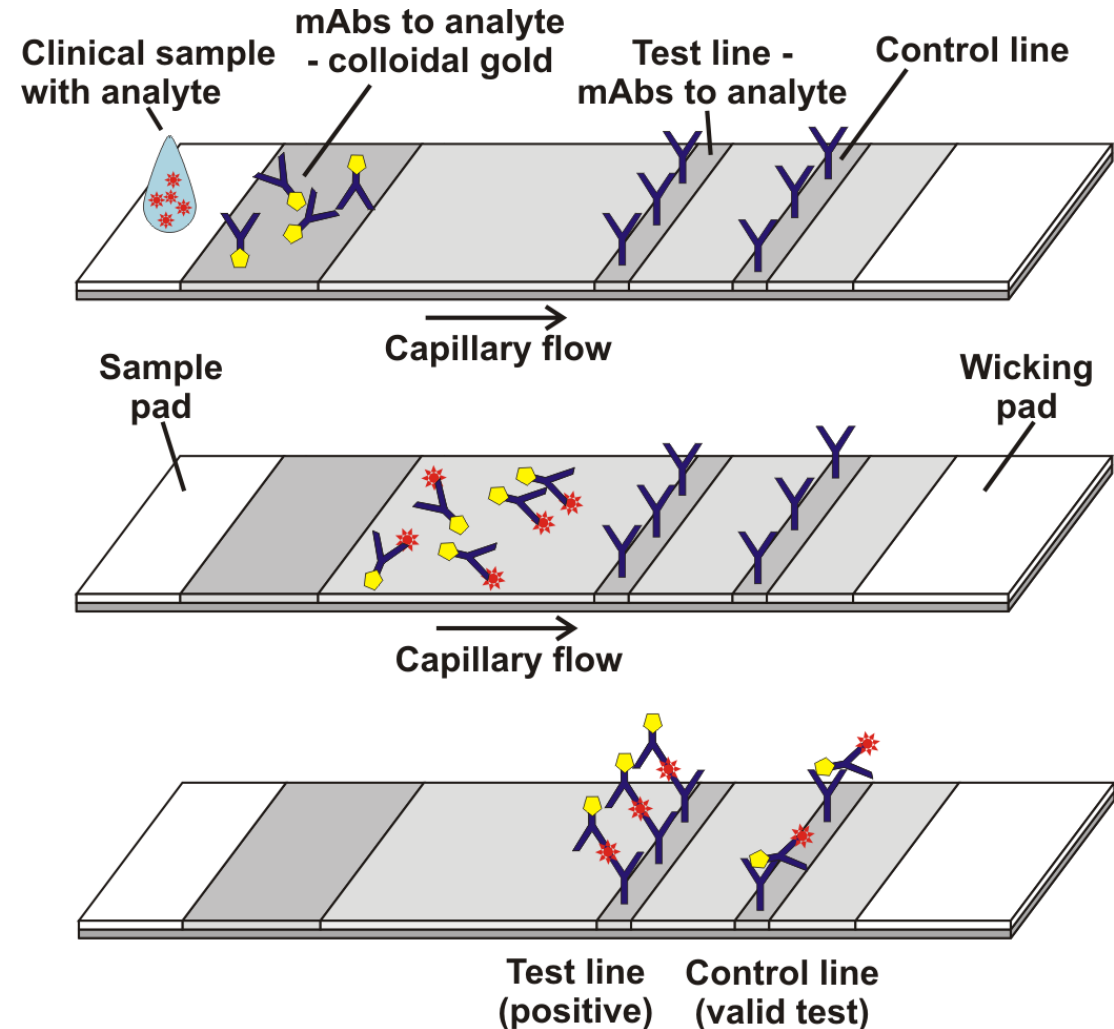
- **Gold particles/other particles**

Change size of gold particle, change to other particles

- **Materials**

Change materials – NC pad, conjugation pad

Inactive serum samples (UK) = Sens **86.4%**
(n=66) Spec **98%** (n=51)



Multi-site Clinical Evaluation

- Prospective samples collected in 6 site in Türkiye
July – October 2023
- 125 samples tested

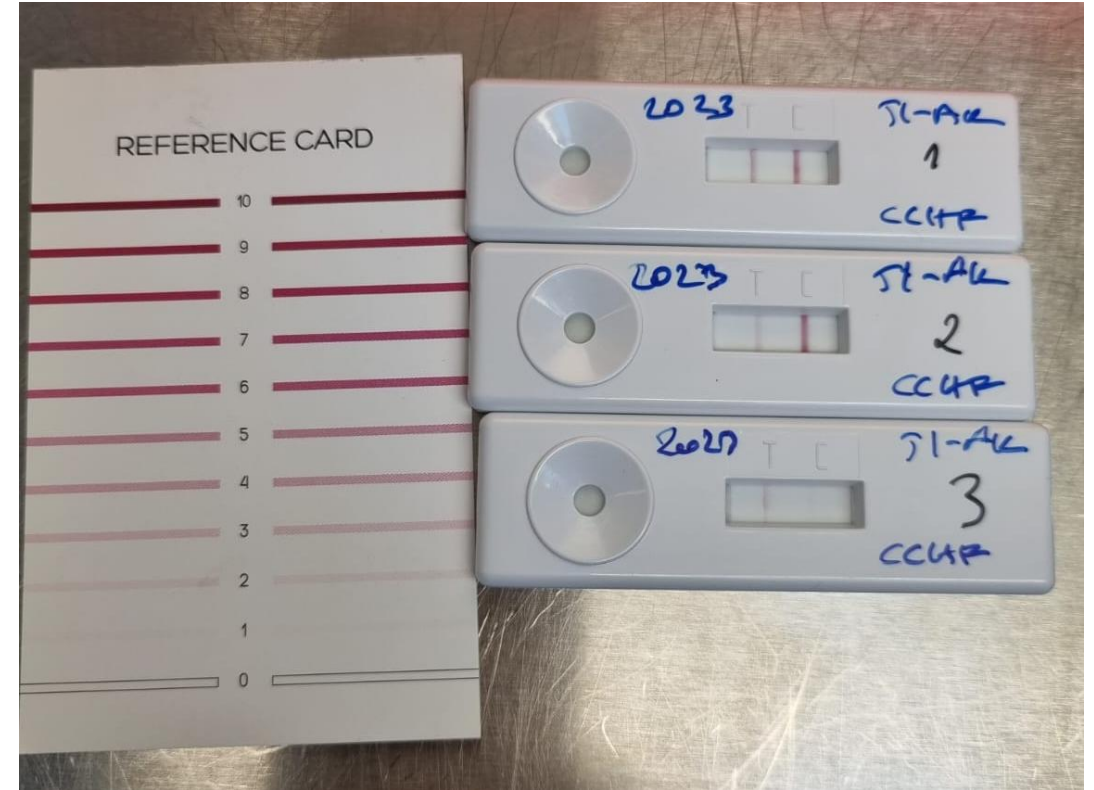
Sensitivity
90.4%

The proportion of people with
a disease who test positive on
a diagnostic test

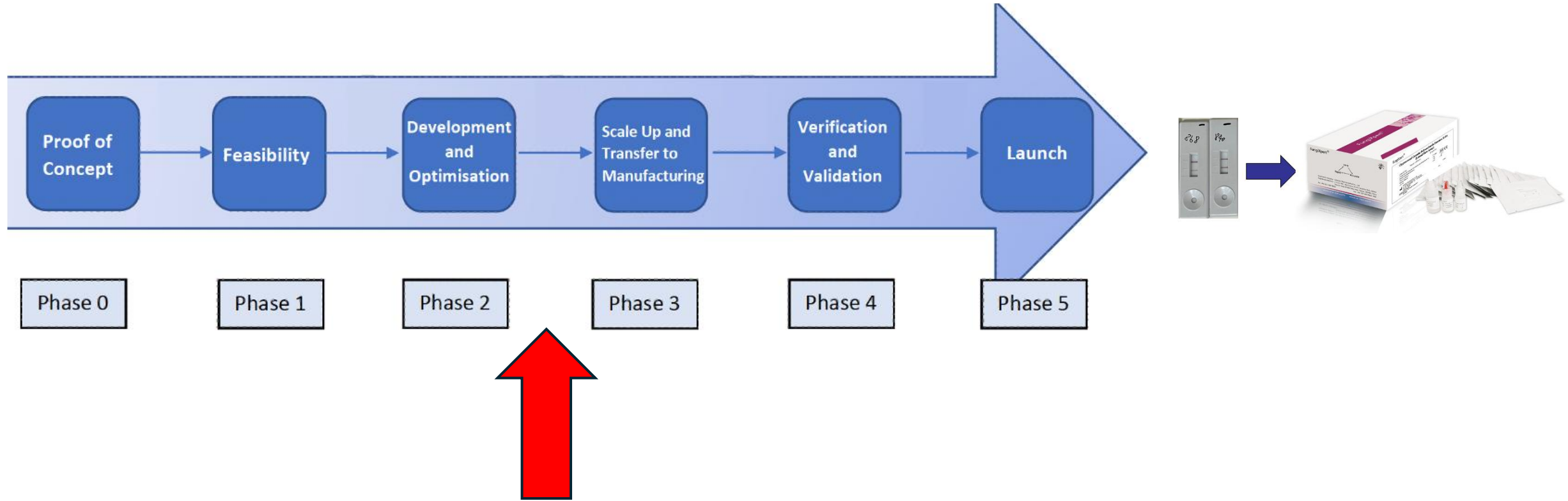
Specificity
96.2%

The proportion of people
without a disease who test
negative on a diagnostic test

WHO TPP Minimal Sens 80% / Spec 90%



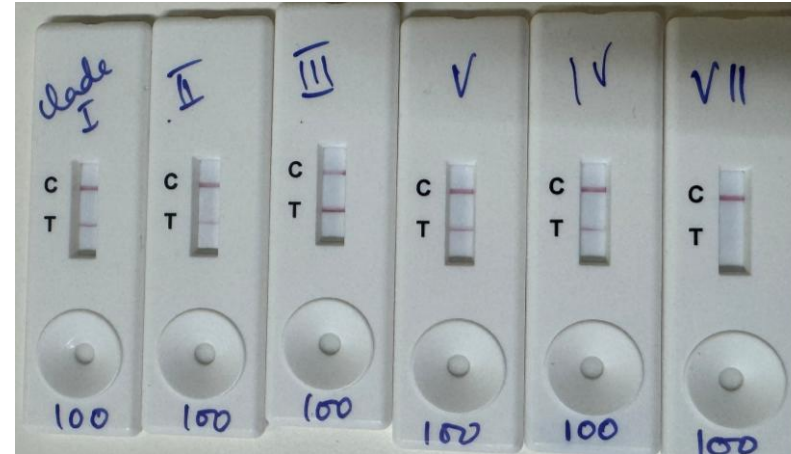
Development pipeline to launch



Lineage testing and interference

Detection of all CCHF lineages using NP recombinant protein including African lineages (I-III).

Clades	LOD in serum sample
I	50 ng/mL
II	10 ng/mL
III	1 ng/mL
IV	5 ng/mL
V	10 ng/mL
VII	100 ng/mL



No interference found with any of the non-CCHFV pathogens tested

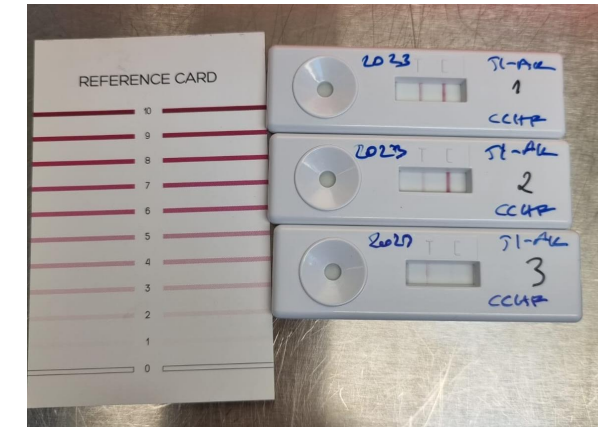
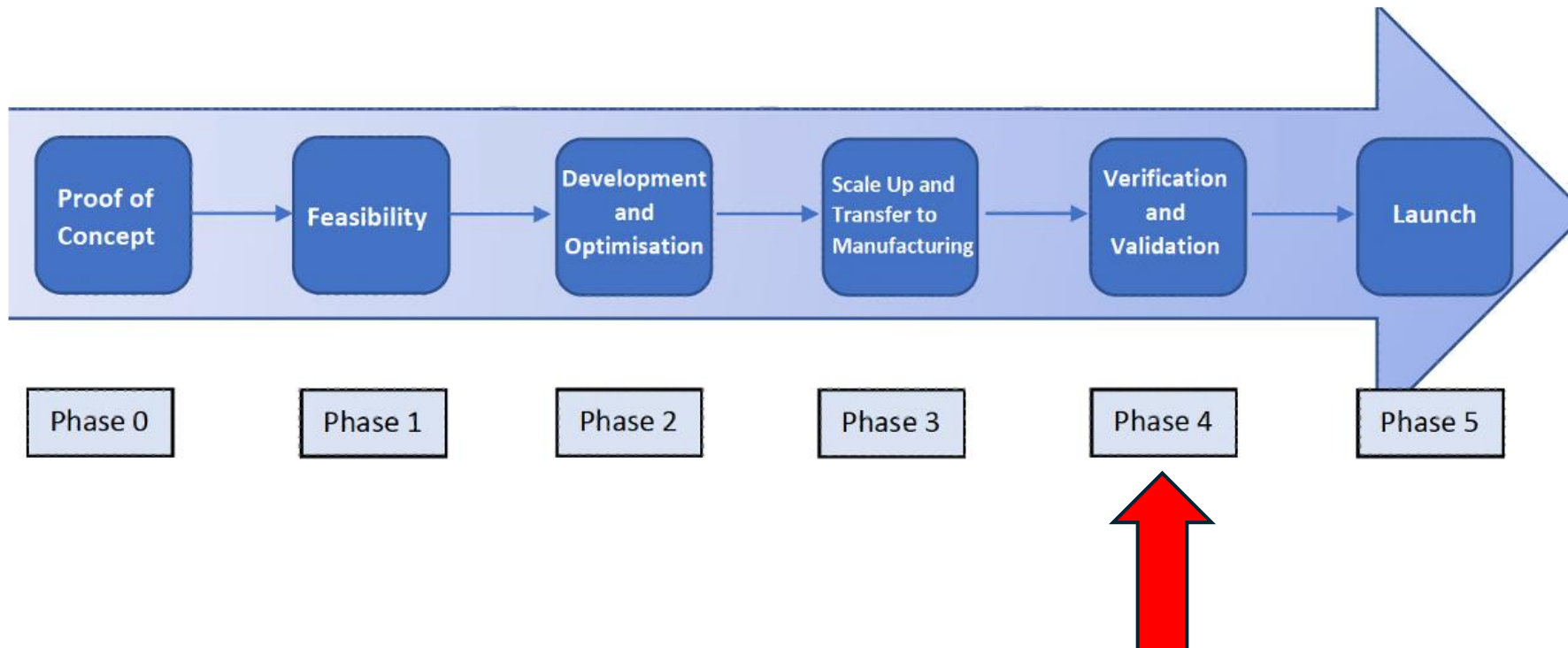
Hepatitis A, Influenza A&B, Parainfluenza, Hazara, Lassa, Marburg, Punta del Toro, Toscana, Sandfly fever, Ebola, Hantaan, Puumala, Yellow Fever, Rift Valley Fever, Adenovirus, Dengue, West Nile, *Plasmodium falciparum*, *Leishmania spp*, *Trypanosoma cruzi*, *Salmonella enterica*, *Leptospira wolfii*, *Leptospira interrogans*, *Mycobacterium spp*, *Borrelia burgdorferi*, *Legionella pneumophila*, *Ehrlichia chaffeensis*,

No interference found with any endogenous/exogenous substances

albumin, bilirubin, gamma, globulins, ribavirin, lithium heparin, EDTA

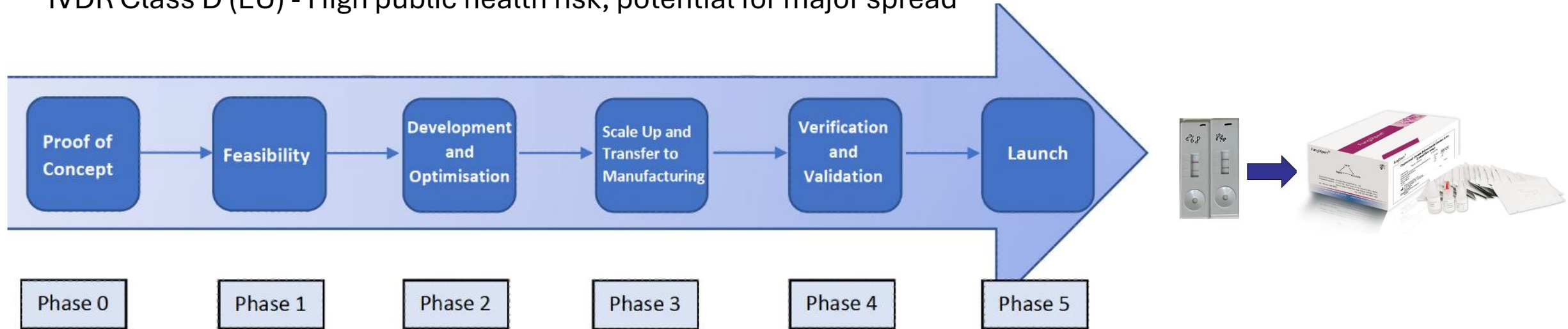
Prospective evaluation 2026

- Multi-site evaluation – 6 sites across Türkiye
- n=490
- Phase 4 – Final design product verification with field validation



Regulatory pathway for CCHF LFT

IVDR Class D (EU) - High public health risk, potential for major spread



Regulatory implications

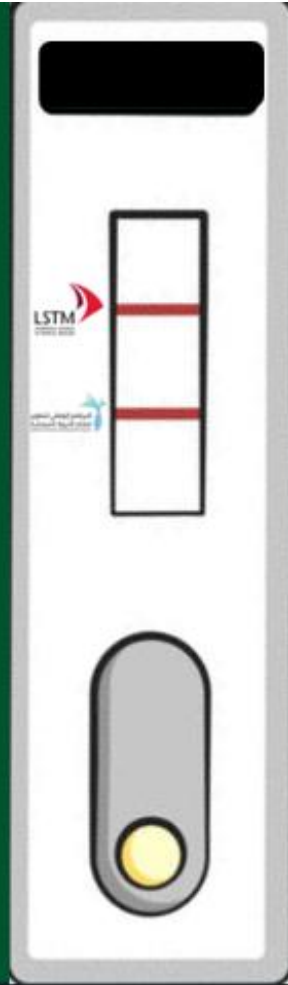
- **Highest oversight**
- Requires a **Notified Body + EU Reference Laboratory (EURL)** involvement
- Full design history file and documentation
- Batch release verification (in many cases)
- Full performance evaluation & post-market surveillance

Regulatory pathway: Human Vs Animal

Category	Human	Animal
Regulatory Framework	Comprehensive, globally harmonized standards across the product lifecycle (e.g., EU IVDR, US FDA regulations, SFDA Medical Devices Interim Regulation / Medical Devices Law).	Regulation is not harmonized , handled at national or local levels (e.g., US FDA CVM / USDA; UK VMD; Saudi Arabia: MEWA + SFDA).
Pre-market Approval	Requires rigorous pre-market evaluation , including demonstration of clinical validity and analytical performance, often involving risk classification (e.g., CE/UKCA, US 510(k)/PMA, SFDA Technical File Assessment & Marketing Authorization).	Pre-market clearance often not compulsory in many regions (e.g., US animal devices may bypass premarket review; MEWA may require registration, but many products have minimal premarket requirements).
Governing Bodies	Regulated by major national and international bodies: FDA (US), MHRA (UK), European Commission (EU), SFDA (Saudi Arabia).	Oversight varies (e.g., FDA CVM or USDA in the US; EU Member States; Saudi Arabia: MEWA, with SFDA involved for some categories).
Quality Management	Mandatory implementation of Quality Management Systems (QMS) and compliance with international standards (e.g., ISO 13485).	Quality assurance programs critical but often less formalized and not universally mandated
Market Entry Barriers	Higher barriers due to extensive documentation and clinical evidence requirements (e.g., CE/UKCA requirements, FDA evidence submissions).	Minimal barriers , enabling quicker, easier, and cheaper market launch.

OASIS

Optimal Lateral flow assays for Infectious diseases



Work package 1: Develop a procurement recommendation plan for a lateral flow assay prototype laboratory

- Establish a lateral flow assay (LFA) prototype laboratory in LSTM (OASIS-UK).
- Deliver a procurement recommendation for an antigen LFA prototype laboratory in KSA.

Work package 2: Establish a LSTM partnered LFA prototype laboratory in KSA

- Support the KSA team to procure essential equipment and identify infrastructure needed for a LFA prototype laboratory.
- Develop and implement a code of practice and specialised SOP for the sustainment of the laboratory.

Work package 3: Deliver a framework for antigen LFA prototype development

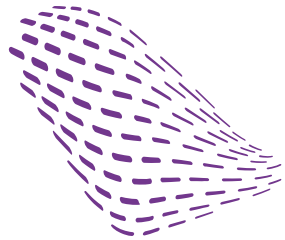
- Using Alkurhuma haemorrhagic fever virus (AHFV) as a model organism develop a pipeline to produce an LFA.
- Deliver a comprehensive research plan to evaluate the analytical and field performance of a LFA for AHFV.



Future collaboration...

- Focus of one health diagnostics
- Utilising Animal LFT for dual Human use
- A need for sustainable diagnostic development – avoid cycle of panic and then neglect
- Joined up thinking - WHO and WOAH, Academia (R&D) and Industry

Thank you



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