Ensuring Diagnostic Reliability

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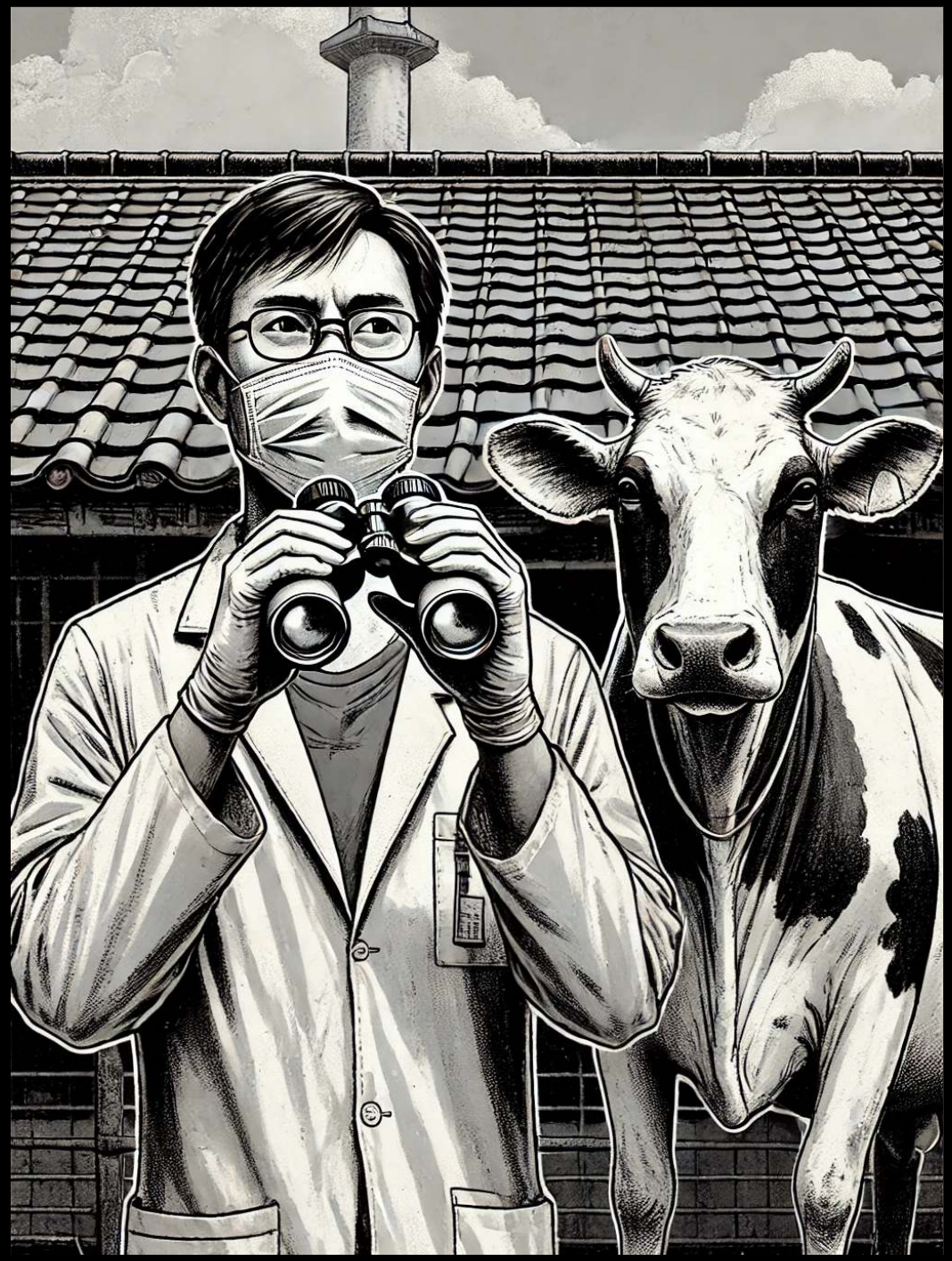
QUESTION 1

Do we need novel and fancy Diagnostics for FMD?



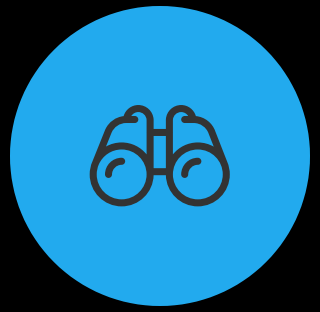
Why Do We Need FMD Diagnostics?

Disease Confirmation

FMD diagnostics are crucial for confirming the presence of the disease in affected animals.

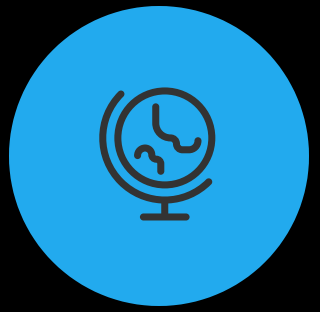
Serotype Identification

Serotype identification is essential for selecting the appropriate vaccine strain to prevent of control outbreaks.



Post-Vaccination Monitoring

FMD diagnostics enable monitoring of the immune response after vaccination, ensuring the effectiveness of the control measures.



Trade Freedom

Reliable FMD diagnostics are a prerequisite for regaining and maintaining disease-free status, which is crucial for trade and economic recovery.

Who are the target audience for this type of diagnostics ???

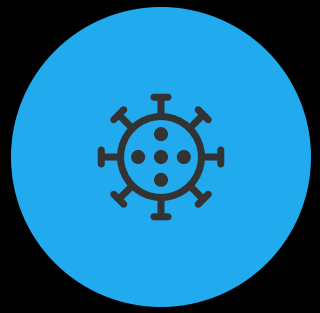
QUESTION 2

If target is NOT the farmer but government and vaccine manufacturers, what is needed?

Key Diagnostic Needs for FMD

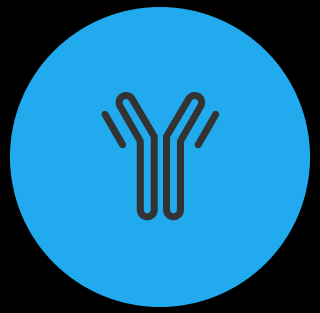
Fast and reliable data

Government requires fast and reliable data on FMD virus characteristics and serological status for effective disease control and trade.



Know the virus

Identify the specific FMD virus serotype/genotype for vaccine matching.



Know serological status

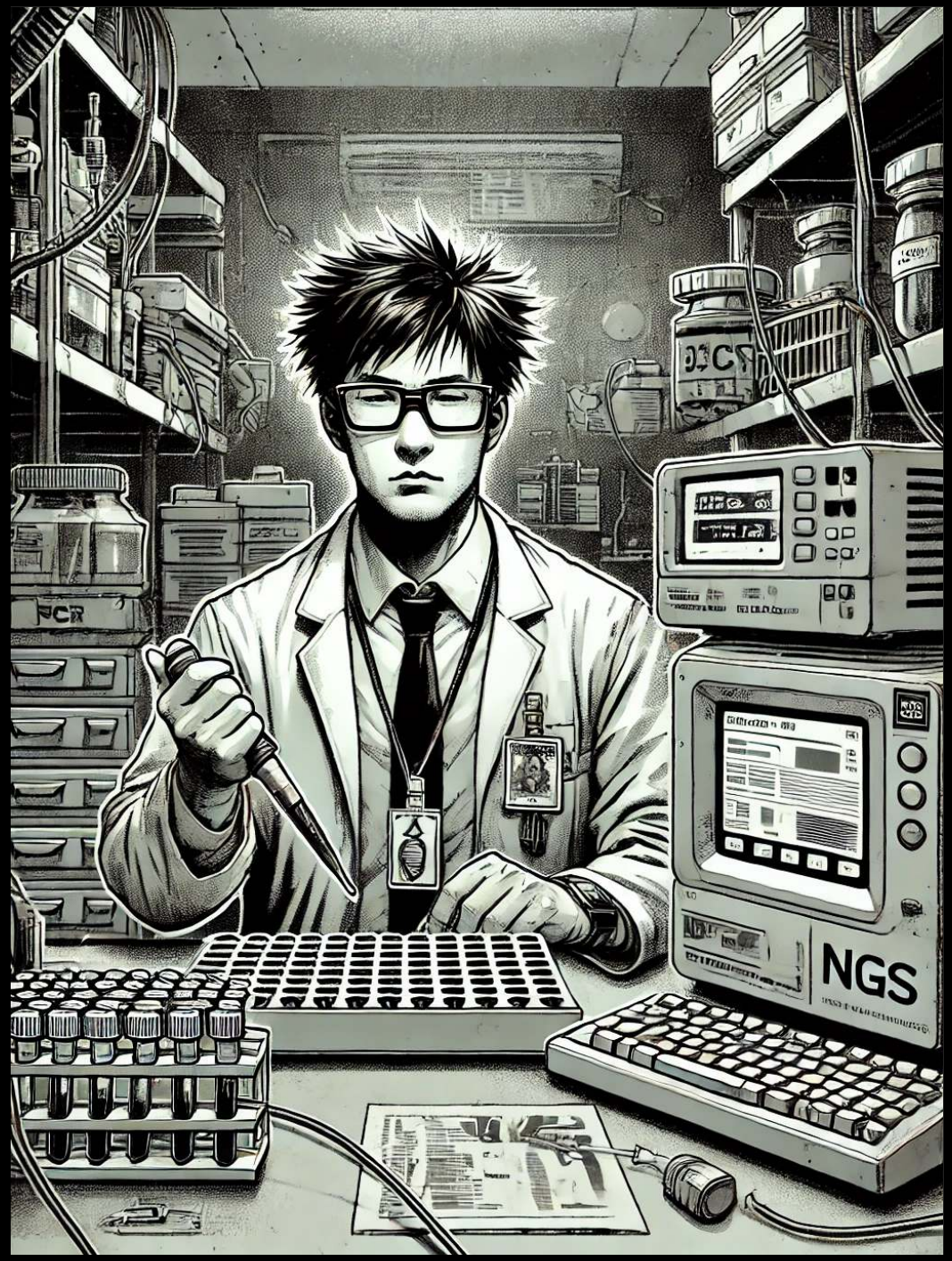
Differentiate between infected and vaccinated animals, and monitor post-vaccination immunity.

Status in and outside country

Determining the FMD status within the country as well as monitoring the disease situation in neighboring regions to enable effective trade decisions.

QUESTION 3

Soooo ... what tools do we have?



Diagnostic Tools for FMD

Ag-ELISA

Antigen-capture Enzyme-Linked Immunosorbent Assay - Detects the presence of FMD viral antigens

Ab-ELISA [Serotype or NSP]

Antibody-ELISA - Detects antibodies against FMD virus, useful for post-vaccination monitoring

PCR and qPCR

Polymerase Chain Reaction - Molecular technique to detect and identify FMD virus genetic material

Classic Sequencing VP-1

Sanger sequencing to determine the genetic sequence of FMD virus strains for serotype identification

Next-Generation Sequencing

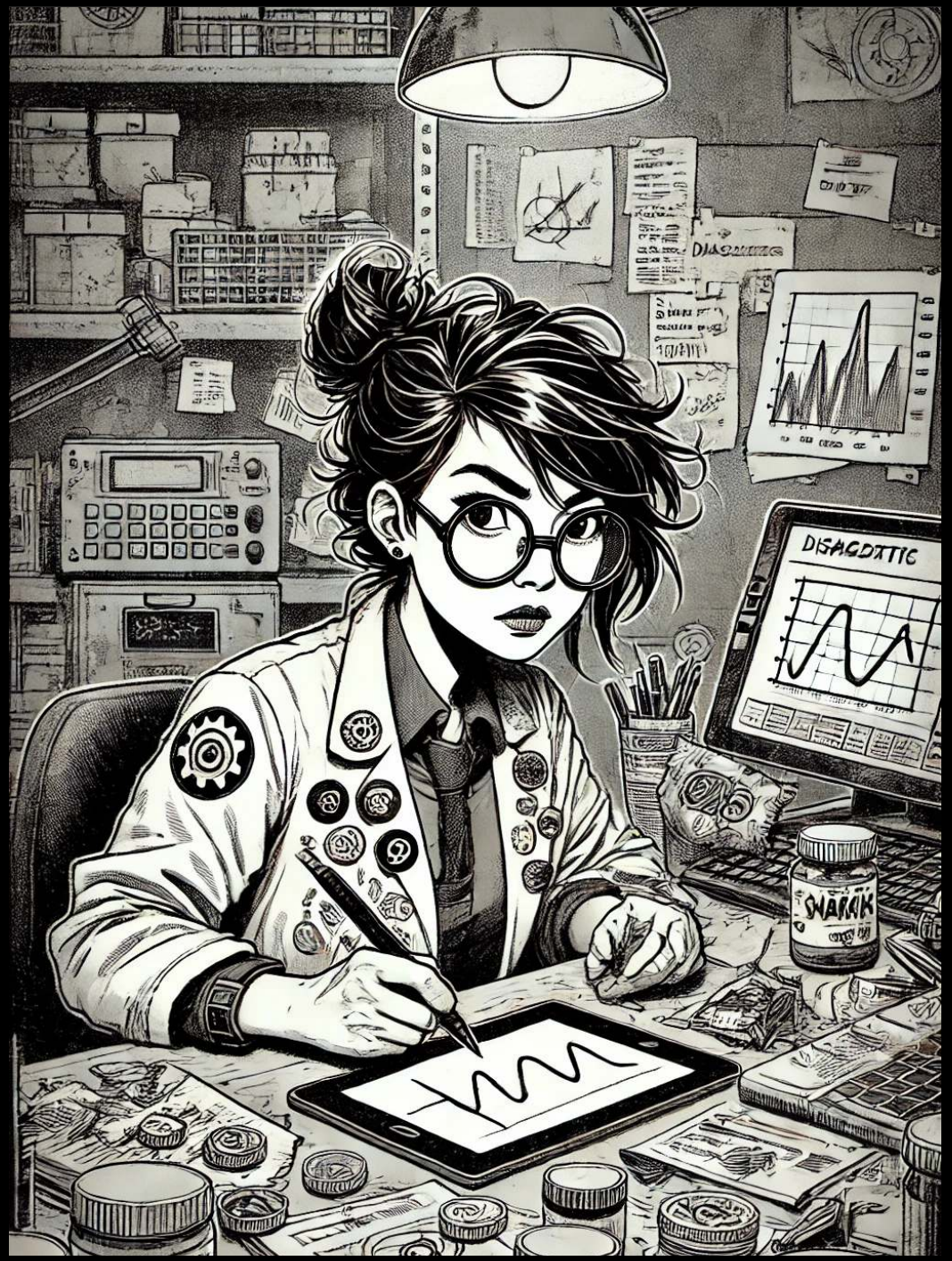
High-throughput sequencing methods to rapidly characterize the entire FMD virus genome

But it's not just about tests but also samples

... and where to test them

Sampling in wild and captive animals as well as within the bushmeat trade

...and even remote



QUESTION 4

How do we ensure diagnostic reliability?

Ensuring Diagnostic Reliability

Analytical Sensitivity

The **ability** of a diagnostic test **to detect the target** analyte (e.g., virus, antibody) at low concentrations.

Analytical Specificity

The ability of a diagnostic test to detect **only the target** analyte and not cross-react with other similar substances.

Diagnostic Sensitivity

The ability of a diagnostic test to correctly **identify positive** samples

Minimize false negatives

Risk: false positives

Diagnostic Specificity

The ability of a diagnostic test to correctly **identify negative** samples

Minimize false positives

Risk: false negatives

Test Validation

The process of ensuring a diagnostic test meets established performance criteria, including accuracy, precision, and reliability.

CALCULATING DIAGNOSTIC

Sensitivity
Specificity

Common Diagnostic Test Performance Indices

Test Result	Disease: Present	Disease: Absent	
Positive	*TP*	*FP*	*TP* + *FP*
Negative	*FN*	*TN*	*FN* + *TN*
	TP + *FN*	*FP* + *TN*	

TP: True-positive; *FP*: False-positive

FN: False-negative; *TN*: True-negative

$$Sensitivity = \frac{TP}{TP + FN}$$

$$Specificity = \frac{TN}{TN + FP}$$

$$Positive\ Predictive\ Value = \frac{TP}{TP + FP}$$

$$Negative\ Predictive\ Value = \frac{TN}{TN + FN}$$

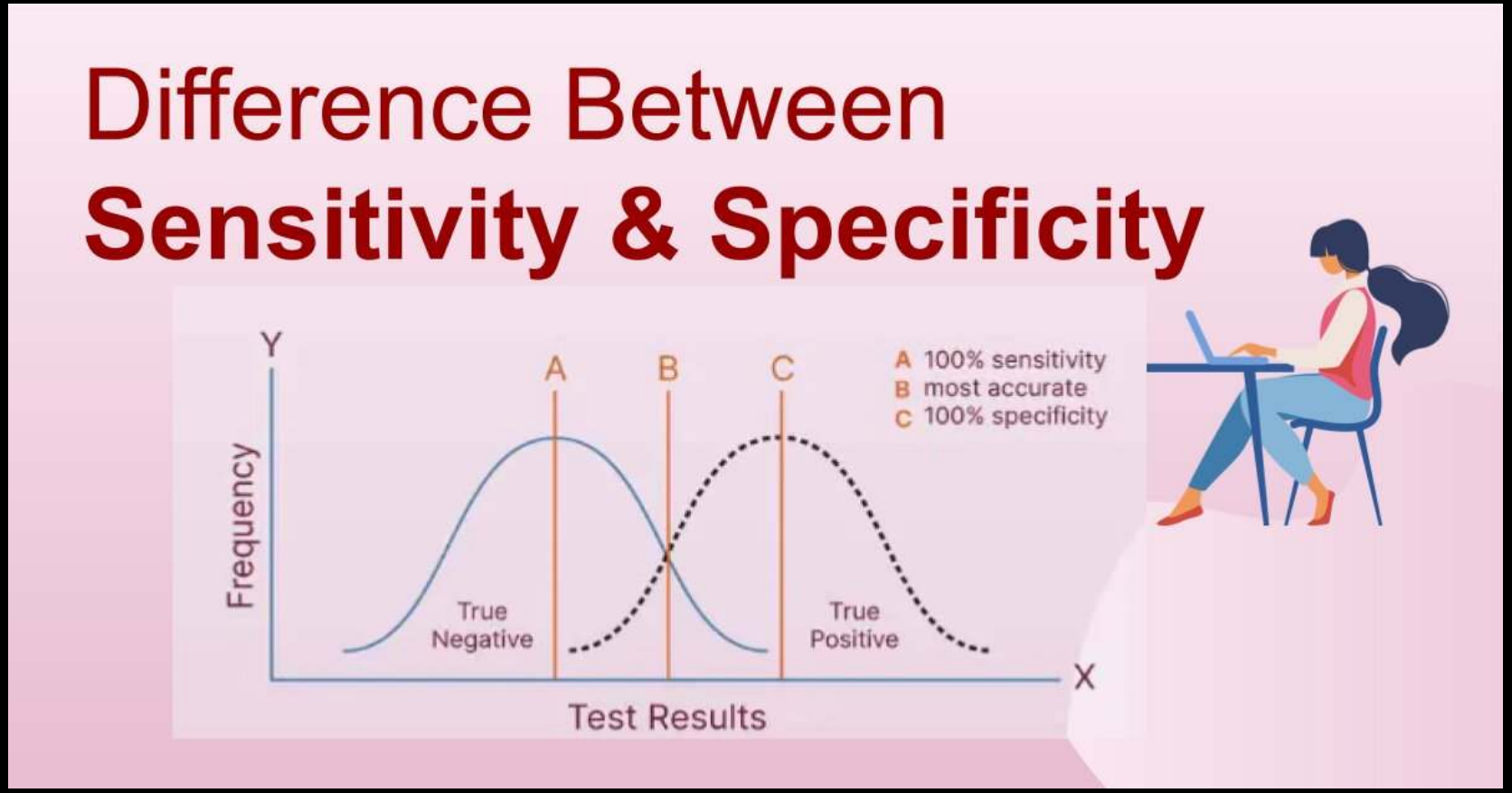
$$Positive\ Likelihood\ Ratio = \frac{Sensitivity}{1 - Specificity}$$

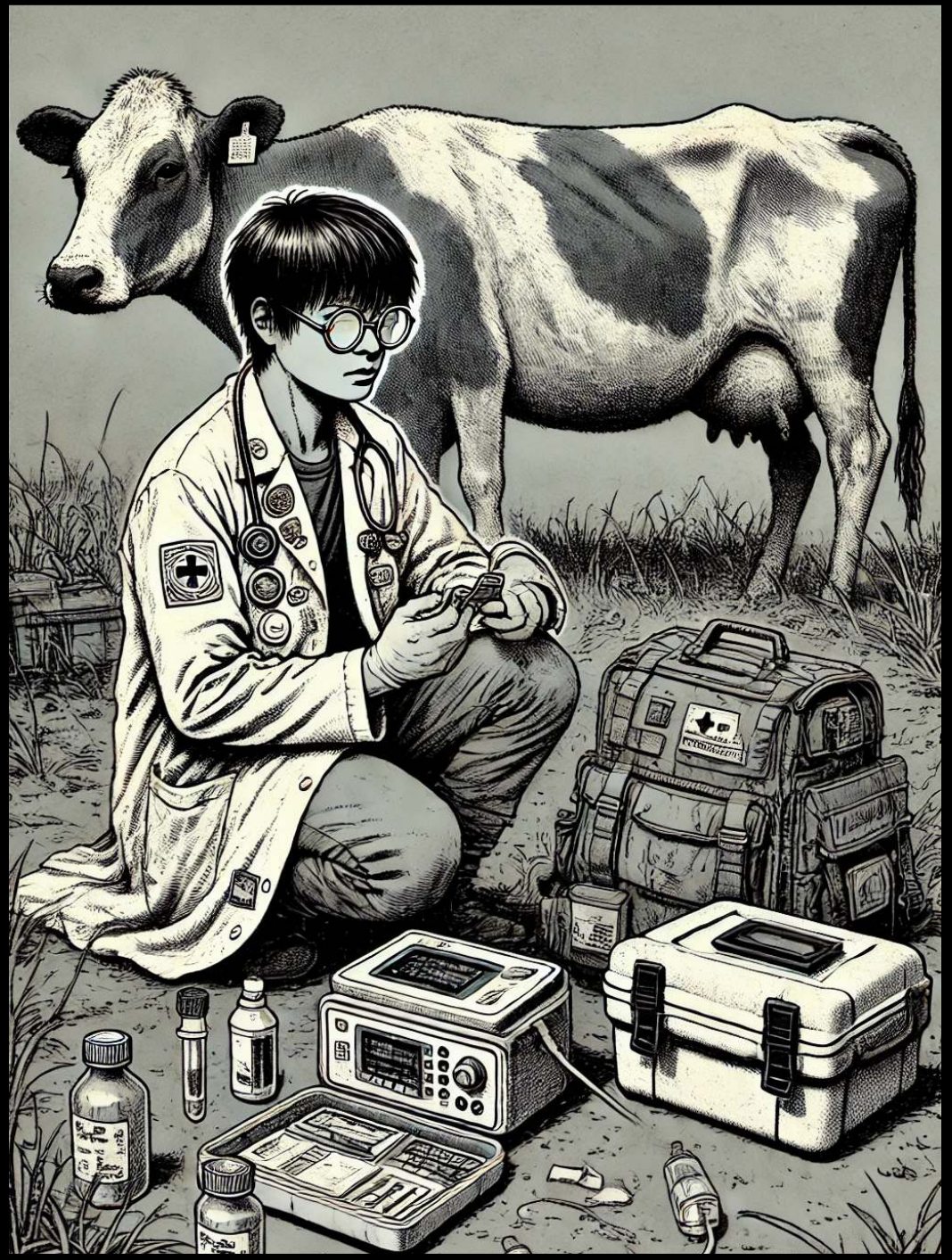
$$Negative\ Likelihood\ Ratio = \frac{1 - Sensitivity}{Specificity}$$

WHAT IS MORE IMPORTANT TO YOU?

Sensitivity

Specificity





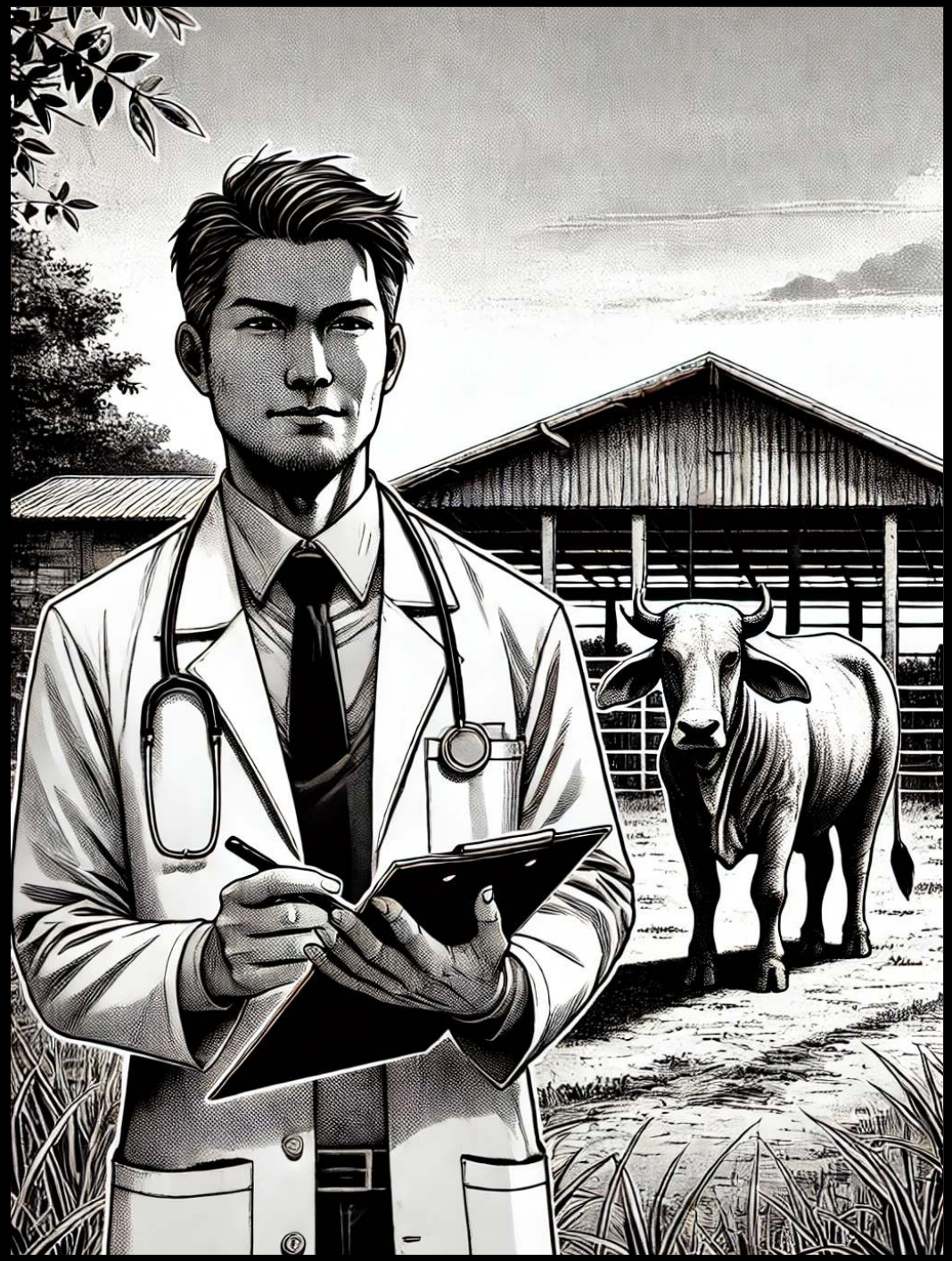
QUESTION 5

So how will this help us with real life issues?

Tamao mountain					qPCR _F
Type of samples	Number	Date Riceive	Extraction Date	Testing Date	3D(Cq)
Aerosol Sense-Air 1	1	26-Dec-24	27-Dec-2024	27-Dec-2024	32.13
Aerosol Sense-Air 2	1	26-Dec-24	27-Dec-2024	27-Dec-2024	37.81
Aerosol Sense-Air 3	1	26-Dec-24	27-Dec-2024	27-Dec-2024	ND
Aero-collect-Air 4	1	26-Dec-24	27-Dec-2024	27-Dec-2024	ND
Aero-collect-Air 5	1	26-Dec-24	27-Dec-2024	27-Dec-2024	ND
Coge swap 1	1	26-Dec-24	27-Dec-2024	27-Dec-2024	34.25
Coge swap 2	1	26-Dec-24	27-Dec-2024	27-Dec-2024	38.04
Swimming water	2	26-Dec-24	27-Dec-2024	27-Dec-2024	ND

QUESTION 6

Conclusions



Next Steps for FMD Diagnostics

Ensure Fitness for Purpose

Diagnostics must be fit for the intended use, whether it's disease confirmation, serotype identification, or post-vaccination monitoring.

Embrace 21st-Century Advancements

Leverage modern technologies like next-generation sequencing to enhance speed, accuracy, and data-driven decision-making.

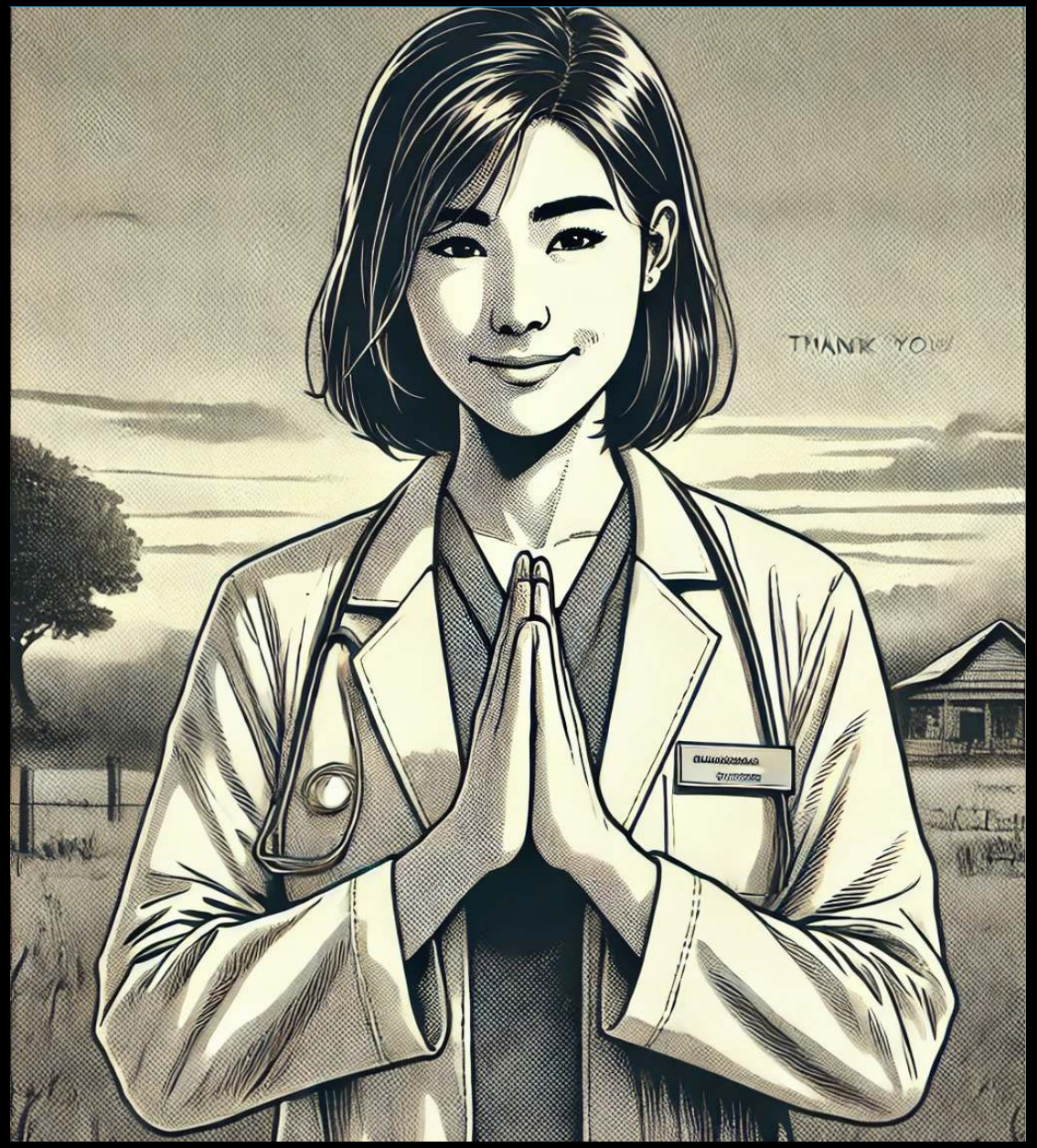
Improve Data Sharing and Accessibility

Establish collaborative platforms and protocols to facilitate the exchange of crucial FMD data across regions and stakeholders.

Use Data for Effective Control

Harness the power of diagnostic data to inform disease control strategies, vaccine matching, and outbreak response.

Ensuring reliable FMD diagnostics is essential for effective disease control and trade.

By leveraging cutting-edge tools and data, we can empower stakeholders to make informed decisions.

This will strengthen global biosecurity, and secure a brighter future free from the devastating impacts from FMD.