

African
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**AU-PANVAC
Laboratories**



GF-TADs
GLOBAL FRAMEWORK FOR THE
PROGRESSIVE CONTROL OF
TRANSBOUNDARY ANIMAL DISEASES

Africa



Food and Agriculture
Organization of the
United Nations



World Organisation
for Animal Health
Founded as OIE

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QUALITY CONTROL OF FMD VACCINE AT AU-PANVAC

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Outline

- **Background**
- **WOAH requirements for vaccine Quality control**
- **AU-PANVAC capacity building for FMD Vaccine QC**
- **Development of characterized FMD Panel for Africa**
- **Conclusion**



Background

- ❑ FMD is an important constraint to livestock with impact on global trade.
- ❑ Vaccination is a critical component of FMD control
- ❑ Constant evolving of antigenic diversity of FMD virus require that vaccine strains BE MATCHED with field strains.
- ❑ Vaccine Production & Quality Control:
 - ❖ Requires high biocontainment facilities under appropriate biosecurity measures
 - ❖ Seed Virus Management (maintenance of genetic characteristics) to ensure consistency and efficacy of the vaccine.



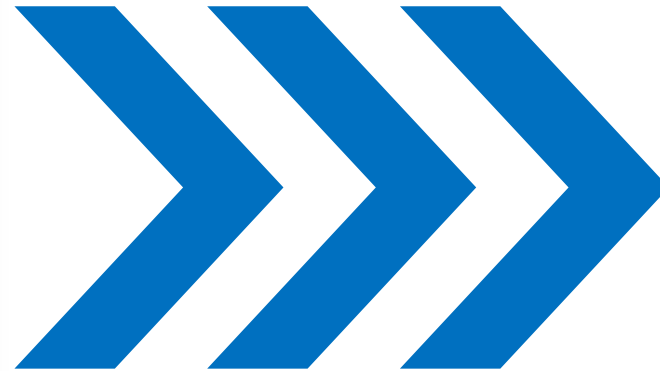
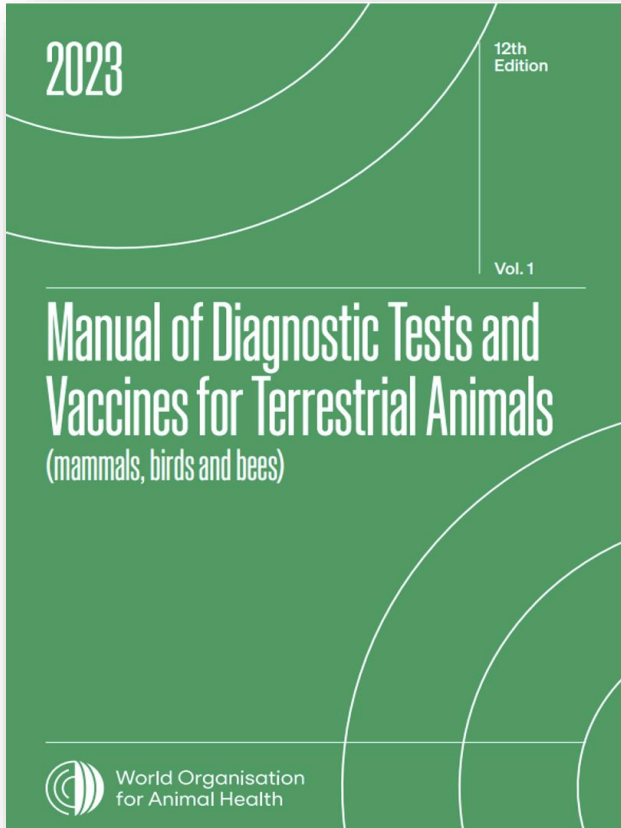


Vaccine QC Tests conducted following the *Tests and Vaccines for Terrestrial Animals*"



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"Manual of Diagnostic



-  **1-Identity**
-  **2-Purity/Sterility**
-  **3-Safety/Innocuity**
-  **4-Potency/Efficacy**
-  **5-Stability**



Quality Control Tests for FMD vaccine

1. Sterility/Purity

- *Sterility Testing*: Detect a wide range of organisms.
- Purified vaccines: Demonstrate level of purification from NSPs.

2. Safety

- Test in animals observed over 14 days.
- Cells culture to determine the absence of infectious virus.

3. Efficacy testing

3.1 . *Vaccination & Challenge in animal hosts*: required high containment facilities

3.2. *Serology tests (VNT) to correlate antibodies level and protection*

4. **Identity Testing (PCR, VNT)** : To ensure that relevant strains are present.

5. **Stability test** – Oil emulsion stability





Project on Quality Control of FMD vaccine

❑ **Twinning Project through the WOAAH, financially supported by the Bill & Melinda Gates Foundation (BMGF), ended in December 2022.**

- Parent Laboratory:



- Candidate Laboratory:



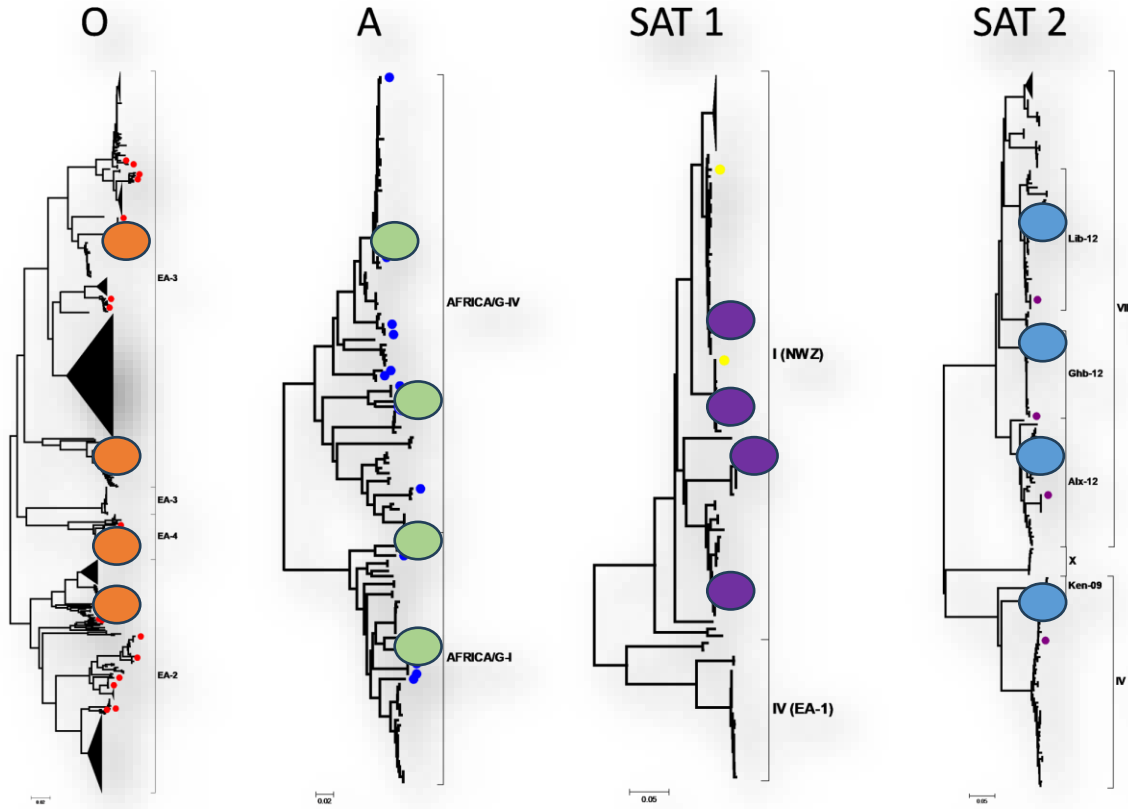
❑ **Overall Objective was to support the control of FMD vaccines in Africa:**

- Training and technology transfer of FMD QC test to AU-PANVAC
- Establishment of serological methods to evaluate FMD Vaccine Potency
- Use of Reference panels of FMD Virus strains





Reference Panels for Quality Control of FMD



Selection of a panel of 16 FMD Viruses covering the genetic diversity circulating in **Eastern African countries (O, A, SAT1 & SAT2)** used for VNT



East African Region FMD Virus Panel

16 VIRUSES SELECTED

Serotype A	Serotype O	Serotype SAT 1	Serotype SAT 2
SUD/9/2018	ETH/4/2015	TAN/22/2013	ETH/16/2015
ETH/2/2018	ETH/9/2019	KEN/10/2013	KEN/19/2017
UGA/28/2019	ETH/30/2016	TAN/27/2012	EGY/1/2018
ETH/19/2019	KEN/4/2018	TAN/22/2014	ETH/11/2018



Publication

Rev. Sci. Tech. Off. Int. Epiz., 40 (1)

A.B. Ludi, V. Mioulet, L. Bakkali Kassimi, D.J. Lefebvre, K. De Clercq,
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*Sélection et utilisation des panels de référence : à partir de l'exemple
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*Selección y uso de paneles de referencia: estudio de las carencias
de los paneles disponibles actualmente a partir del ejemplo de la fiebre
aftosa (resumen)..... 248*



FMDV Panel for other African Regions Africa

Similar approach of FMD virus panel should be developed for:



Northern



Western



Central



Southern



Requirements for Testing FMD Vaccine at AU-PANVAC

- ❑ Vaccinal serum should be produced in cattle with no previous exposure to FMD virus
- ❑ Vaccine used should be the same as the final formulated vaccine
- ❑ Serum should be collected at day 0, day 21, and day 31 if a booster is given
- ❑ At least 5 individual cattle sera should be submitted (not pooled)
- ❑ Results Interpretation
 - Individual sera titer **GREATER THAN 1/32 (1.5 log₁₀)** will be considered as positive
 - **80% (4/5 of sera)** meeting the above criteria will be used for FMD vaccine quality acceptance.



Conclusion

- The AU-PANVAC Twinning Project successfully enhanced the capacity for FMD vaccine quality control in Africa through strategic collaborations, training, and the establishment of robust testing methods.
- Establishing panels of characterized reference FMD viruses and vaccine viruses for Africa is important.
- AU-PANVAC is FULLY CAPACITED using serological approach to conduct quality control of FMD vaccine.





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Thank you

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