African Union

AU-PANVAC Laboratories

World Organisation for Animal Health
Founded as OIE

26th Conference of the Regional Commission for Africa

Increasing the Adoption of Quality Vaccines for Livestock Diseases in Africa

Dr Charles BODJO, Ag Director AU-PANVAC

AU-PANVAC

Overview of the Presentation

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- Brief recall on AU-PANVAC's Mission & Activities
- Quality Control of Veterinary Vaccines in Africa
- Improvement of Quality Control and Production of Veterinary Vaccines
- Support for Veterinary Vaccines Registration
- AU-PANVAC Future New Facility Complex

Recall on AU-PANVAC's Mission & Activities

AU-PANVAC

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MISSION:

"To promote the use of **GOOD QUALITY VACCINES** and **DIAGNOSTIC REAGENTS** for the control, eradication and surveillance of animal diseases in Africa."

ACTIVITIES:

- **INTERNATIONAL INDEPENDENT QUALITY CONTROL** of all veterinary vaccines produced or imported into Africa.
- **PRODUCTION AND DISTRIBUTION OF DIAGNOSTIC REAGENTS** for surveillance of animal diseases
- **TRAINING AND TECHNOLOGY TRANSFER** in vet. vaccine production

AU-PANVAC International Status

- **Collaborating Center For Quality Control of Veterinary Vaccine** (*WOAH Gen. Assembly Resolution 32, Paris, May 2013*)
- **Reference Centre for Technical Assistance in Quality Control of Veterinary Vaccine** (11th May, FAO Rome, 2015)
- **Rinderpest Holding Facilities (to maintain Africa Free from Rinderpest)**

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Quality Control Tests of Veterinary Vaccines

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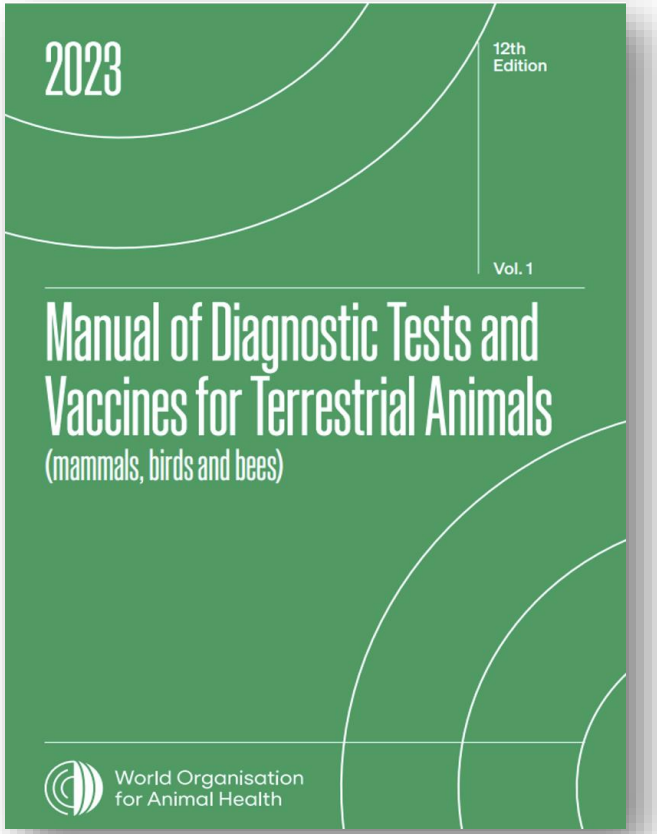
Vaccine QC Tests conducted following the World Organisation for Animal Health Founded as OIE "*Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*"



1-Identity

2-Purity/Sterility

3-Safety/Innocuity

4-Potency/Efficacy

5-Stability

Trend of Vaccines Tested at AU-PANVAC

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- **1986 - 1996: 2 Vaccines**
  (RP and CBPP for cattle)

- **To date : More than 50 types of Vaccines**
  - **All Animal Species** (*except Fish*)
  - *300 - 400 batches annually*

- *Bacterial & Viral Vaccines*
- *Live & Inactivated vaccines*

Trends in the Origin of Vaccines Tested

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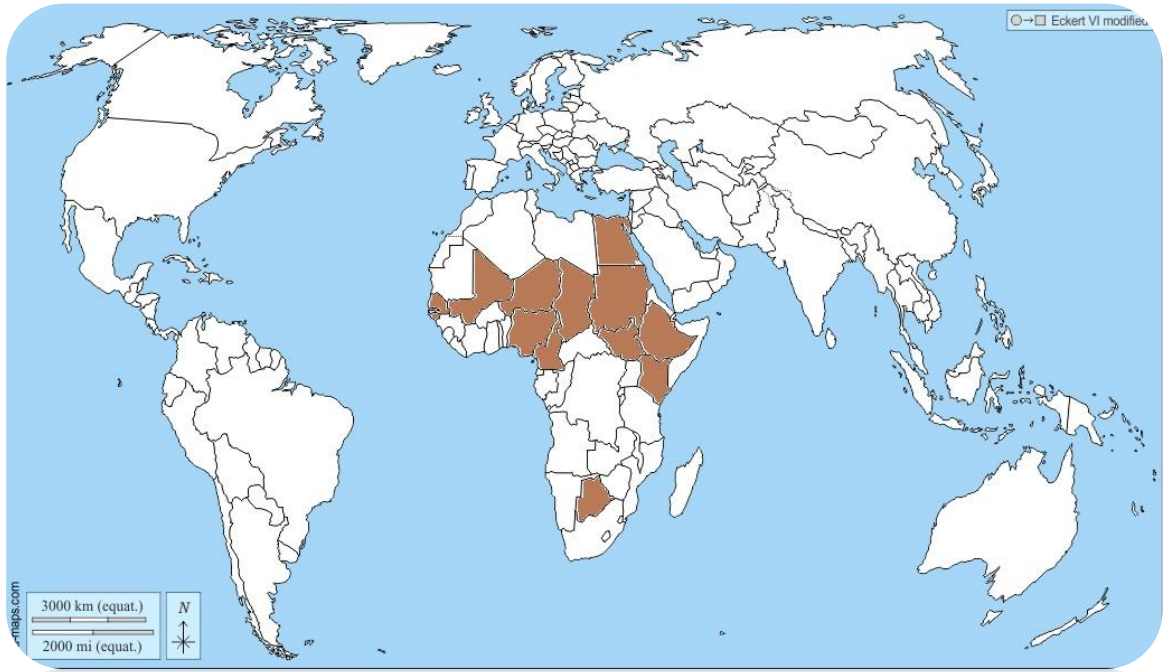
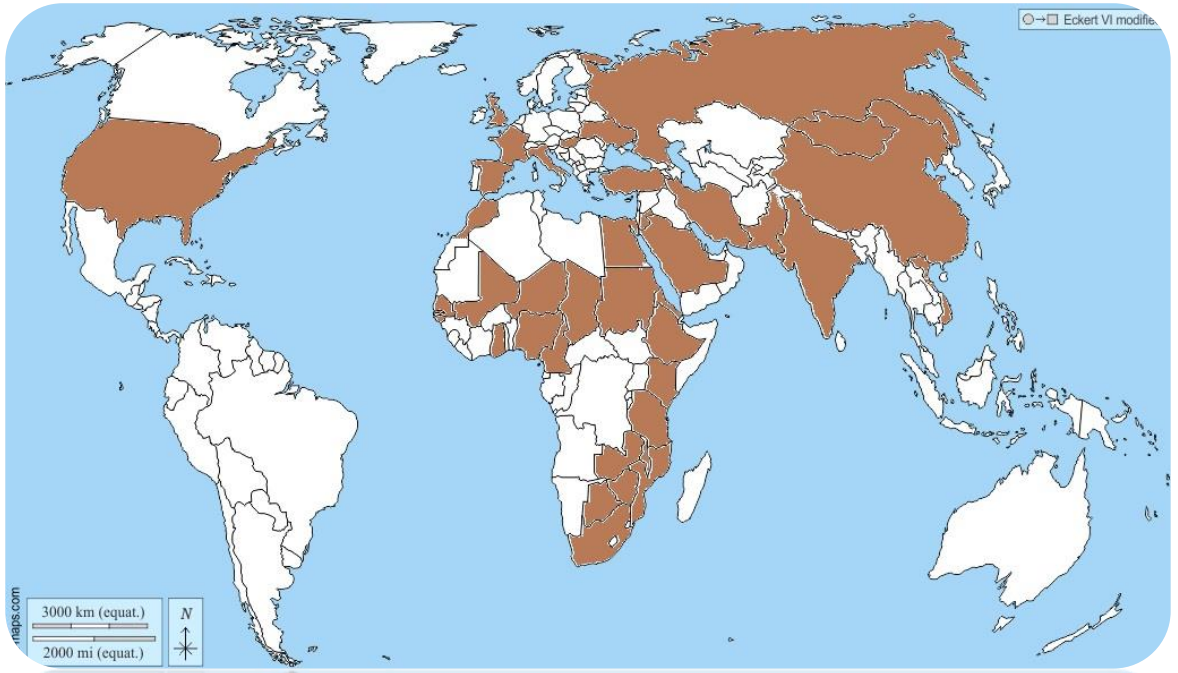
❑ 1986 - 1996



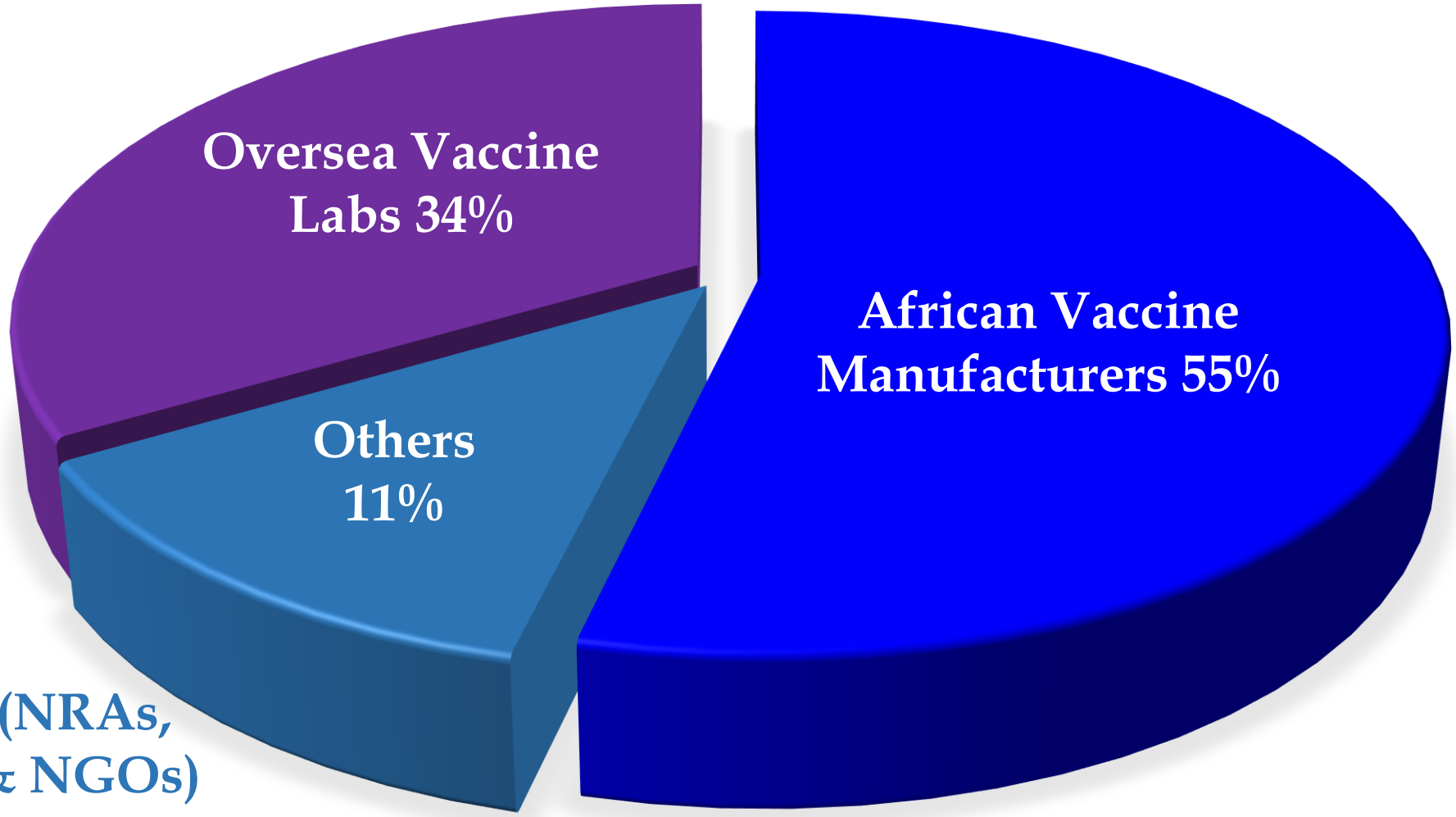
- African Manufacturers (11 countries)

❑ To date



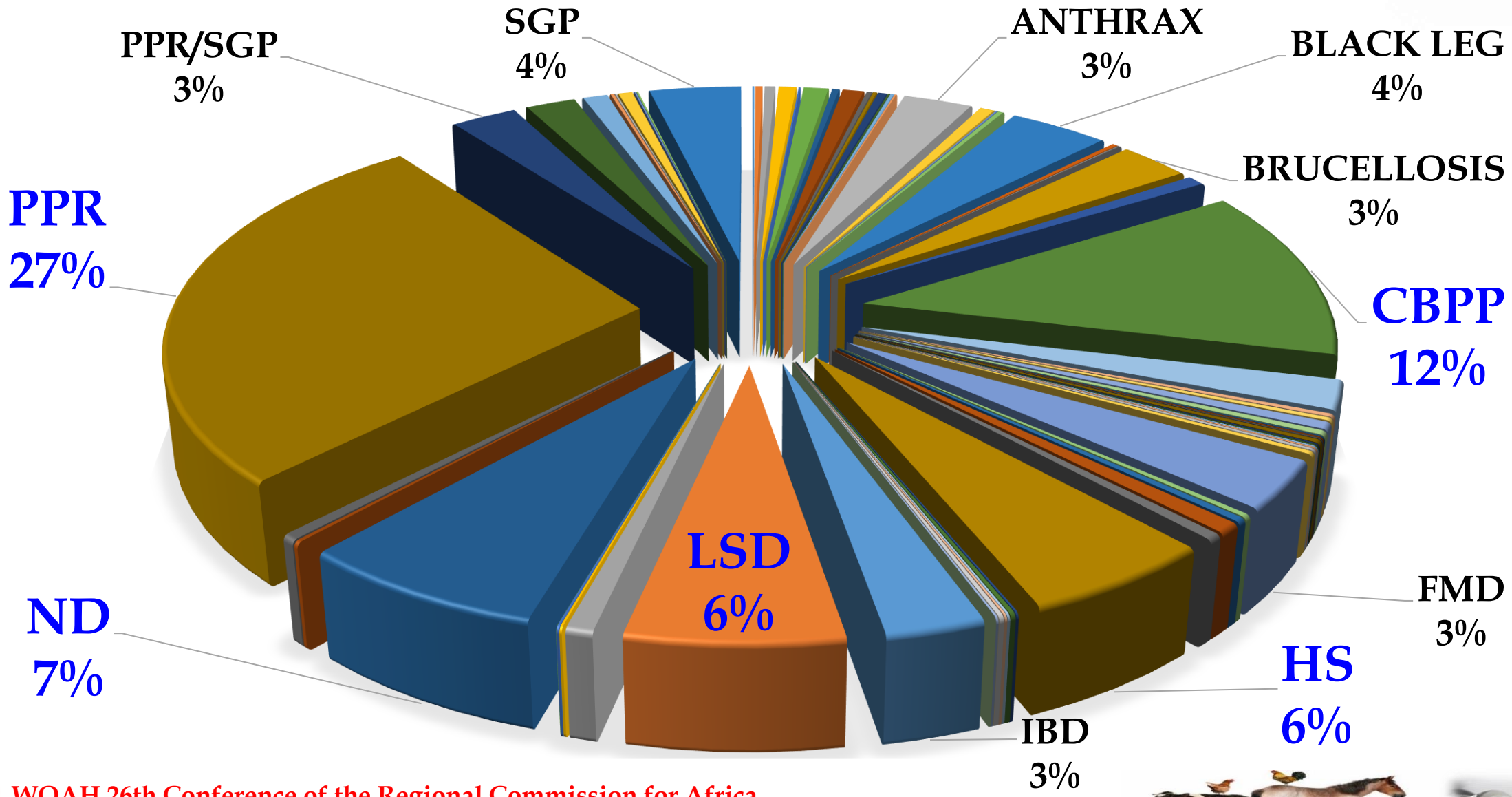
- African Manufacturers (20 countries) & Nat. Regulatory bodies
- Oversea Manufacturers (24 countrries)

Origin of Tested Vaccines: 2019 - 2023

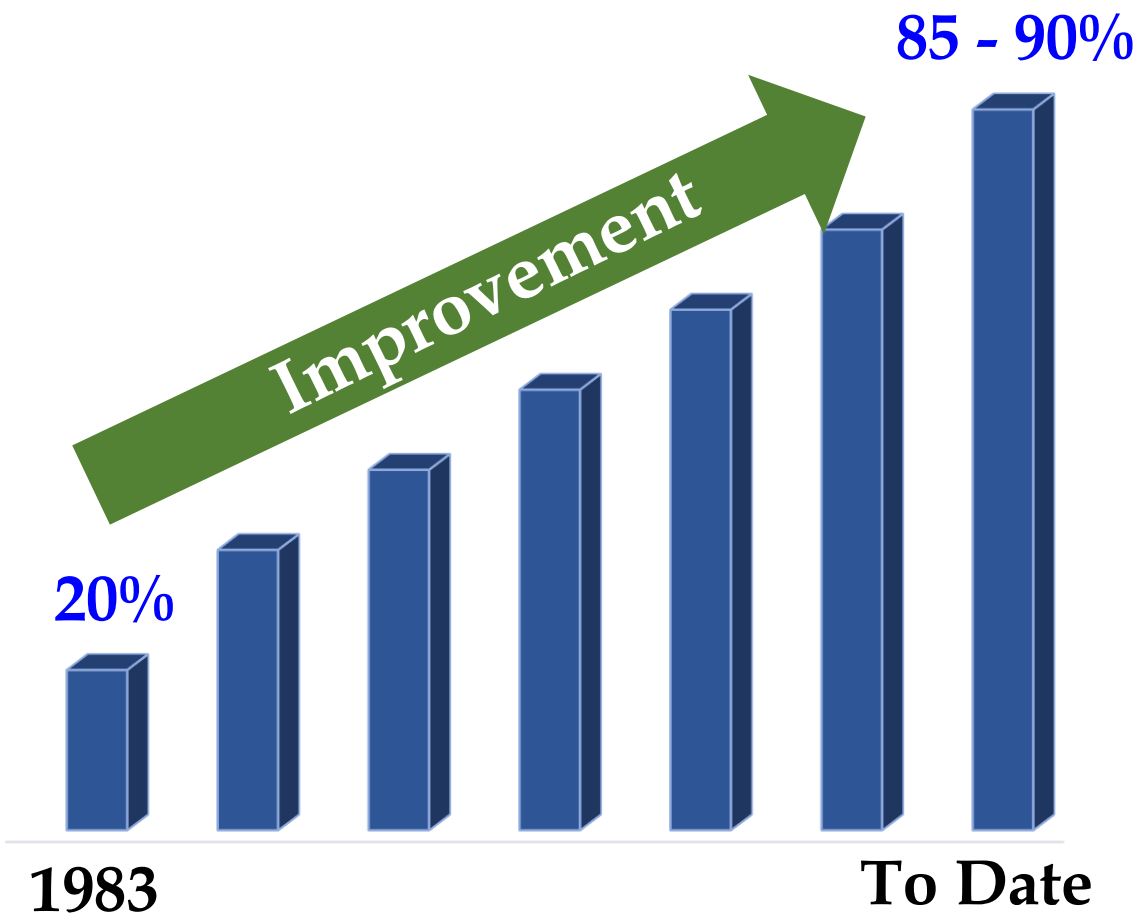


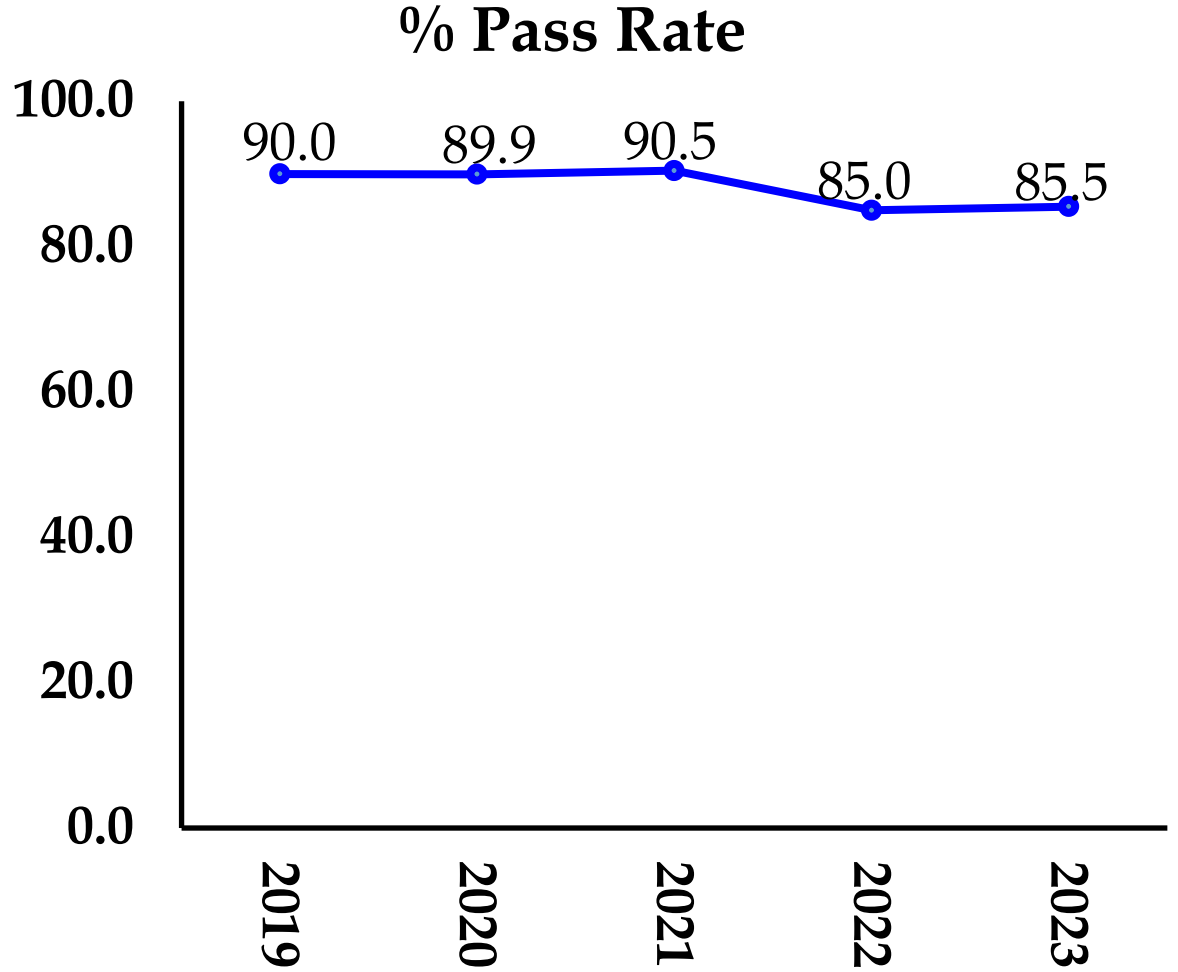
Other (NRAs, DVS & NGOs)

Main Types of Vaccines Tested: 2019-2023



Vac. Quality Control Pass Rate: 2019 - 2023





Effort for Securing of the QC Test Certificate

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- Publication of vaccine QC Certificates on Website:

WWW.AUPANVAC.ORG

- New report with QR Code under process to:

- **Improve Accessibility**
- **Enhance Integrity**

Improvement of Quality Control and Production of Veterinary Vaccines

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- Project on Quality Control of FMD vaccine
- Genetic Stability of PPR Vaccine
- Characterization of RVF vaccines
- Development of standards for PPR Thermotolerant vaccines
- CBPP Vaccine quality

Project on Quality Control of FMD vaccine

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

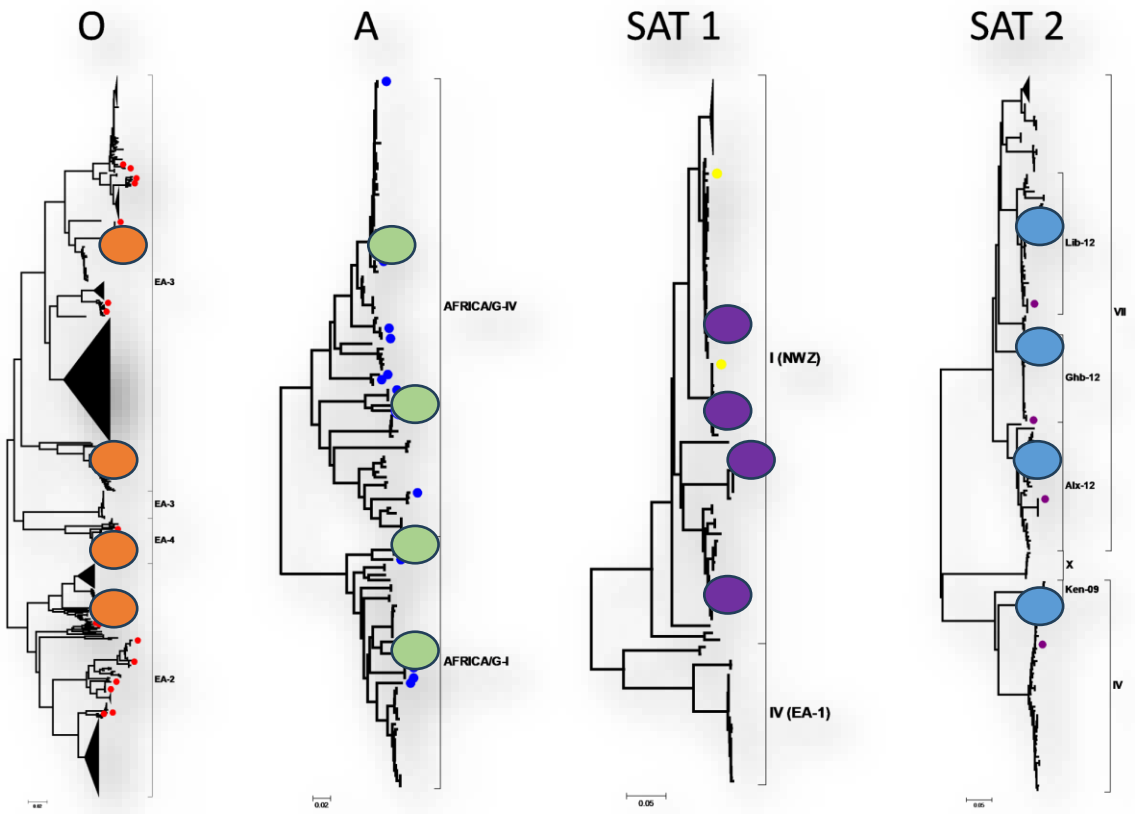
  - Parent Laboratory: THE Pirbright INSTITUTE

  - Candidate Laboratory: African Union Pan African Veterinary Vaccine Centre AU-PANVAC

- **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

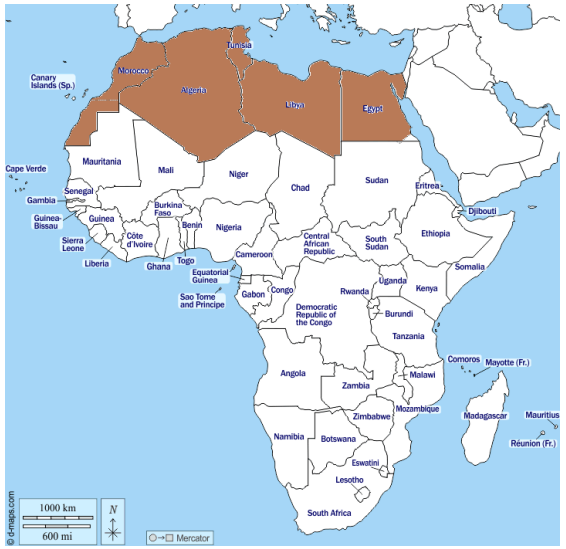
Reference panels for Quality Control of FMD



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

QC of FMD vaccine for the other Regions

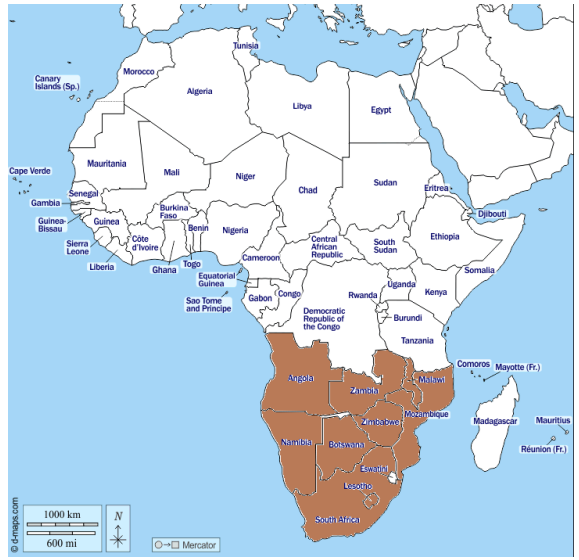
Similar approach should be developed for selection of FMD virus panel for each African region



Northern

Western

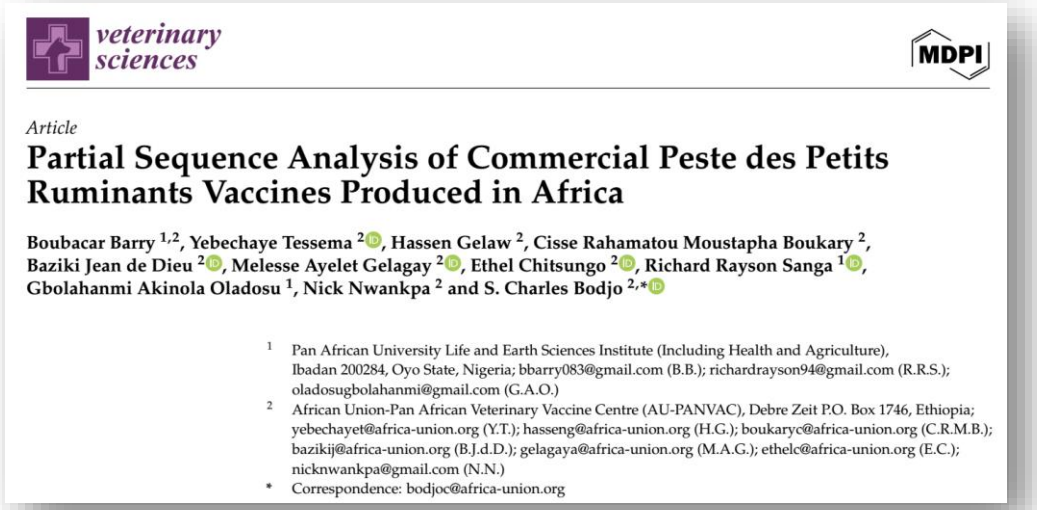
Central



Southern

Genetic Stability of PPR Vaccine

- Partial Sequence analysis of the hypervariable region (C-terminus domain) of the nucleoprotein of PPR Vaccine75/1 strain from 10 African vaccine manufacturers were analysed.



veterinary sciences — MDPI

Article

Partial Sequence Analysis of Commercial Peste des Petits Ruminants Vaccines Produced in Africa

Boubacar Barry [1,2], Yebechaye Tessema [2], Hassen Gelaw [2], Cisse Rahamatou Moustapha Boukary [2], Baziki Jean de Dieu [2], Melesse Ayelet Gelagay [2], Ethel Chitsungo [2], Richard Rayson Sanga [1], Gbolahanmi Akinola Oladosu [1], Nick Nwankpa [2] and S. Charles Bodjo [2,*]

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[2] African Union-Pan African Veterinary Vaccine Centre (AU-PANVAC), Debre Zeit P.O. Box 1746, Ethiopia; yebechayet@africa-union.org (Y.T.); hasseng@africa-union.org (H.G.); boukaryc@africa-union.org (C.R.M.B.); bazikij@africa-union.org (B.J.d.D.); gelagaya@africa-union.org (M.A.G.); ethelc@africa-union.org (E.C.); nicknwankpa@gmail.com (N.N.)
* Correspondence: bodjoc@africa-union.org

- Sequence data analysis revealed **100% homology** between commercial vaccines and the seed in PANVAC.
- Indicating the **genetic stability of the PPR vaccine Nigeria 75/1** over decades

- The full genome sequencing (*using NGS NextSeq 2000, Illumina Inc*) confirmed the **100% homology** of PPR vaccines from the 5 manufacturers.

Characterization of RVF Vaccines

- RVF vaccine seed (at AU-PANVAC repository) and 2 commercial vaccines were sequenced for comparison with RVF Vaccine Smithburn Reference sequence.

	Production date
AU-PANVAC RFV Vaccine seed (A) PANVAC RVF01_1197	MAY 1997
Commercial RVF Vaccine (B): PANVAC RVF02_109	01/08/2012
Commercial RVF Vaccine(C): PANVAC RVF03_010	17/11/2010

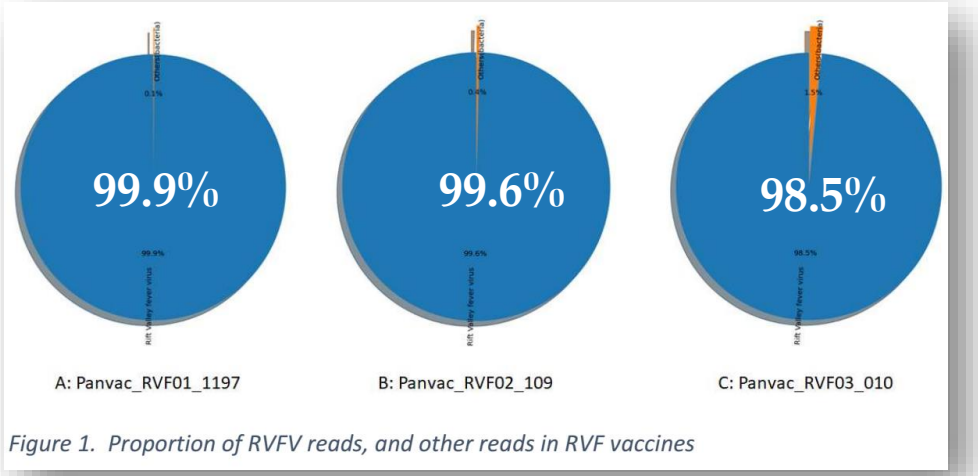

Figure 1. Proportion of RVFV reads, and other reads in RVF vaccines

The RVF vaccine seed (A), commercial RVF vaccines (B) & (C) showed ***99.9%, 99.6% and 98.5% homology*** *respectively with the RVF Smithburn vaccine reference sequence.*

Need to review production and assist manufacturers to minimise mutations in RVF vaccines

Testing of PPR Thermotolerant Vaccine

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S/N	2021/2022
1	SKIM MILK
2	SKIM MILK
3	SUCROSE - PEPTONE
4	SUCROSE - PEPTONE
5	LACTALBUMIN - SUCROSE
6	LACTALBUMIN - SUCROSE
7	LACTALBUMIN - SUCROSE
8	LACTALBUMIN - SUCROSE
9	LACTALBUMIN - SUCROSE
10	LACTALBUMIN - SUCROSE-SODIUM GLUTAMATE
11	STABILIZER 30 ???

S/N	2023
1	SKIM MILK
2	SUCROSE-PEPTONE
3	LACTALBUMIN - SUCROSE
4	LACTALBUMIN - SUCROSE
5	LACTALBUMIN - SUCROSE
6	LACTOSE & N-Z AMINE
7	LACTOSE & N-Z AMINE
8	LACTOSE & N-Z AMINE
9	WEYBRIDGE
10	WEYBRIDGE
11	TREHALOSE

S/N	2024
1	SKIM MILK
2	SKIM MILK
3	SUCROSE-PEPTONE
4	SUCROSE-PEPTONE
5	LACTALBUMIN - SUCROSE
6	LACTALBUMIN - SUCROSE
7	LACTALBUMIN - SUCROSE
8	LACTALBUMIN - SUCROSE
9	LACTALBUMIN - SUCROSE
10	LACTALBUMIN - SUCROSE
11	WEYBRIDGE
12	WEYBRIDGE
13	WEYBRIDGE
14	WEYBRIDGE
15	LACTOSE & N-Z AMINE
16	LACTOSE & N-Z AMINE

38 PPR Vaccines (with 7 stabilizers) tested

Following Exposure temperature at	40° C
Titration after Incubation (Days)	▪ 3 ▪ 5

PPR Vaccine titer loss following incubation at 40°C

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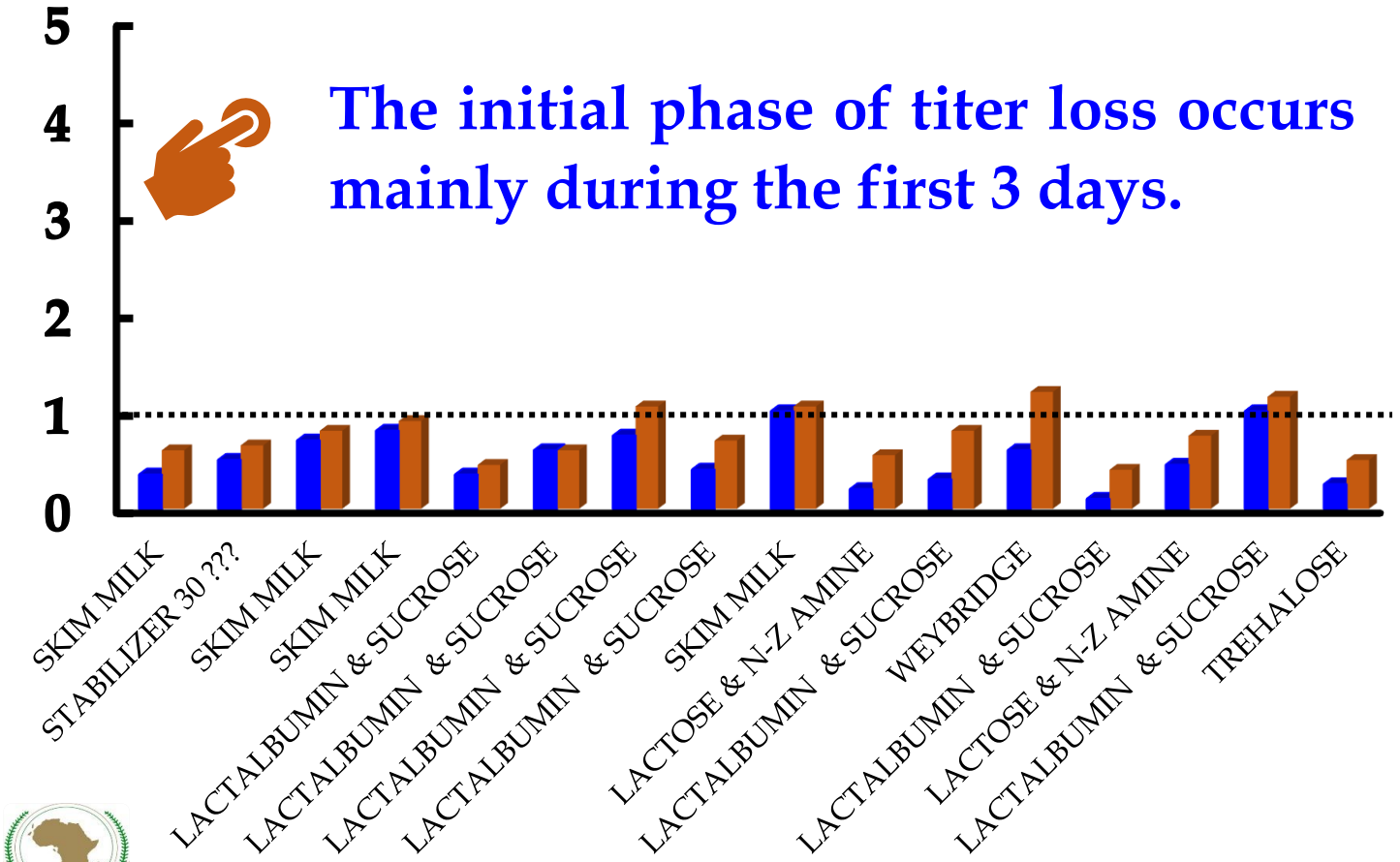
- 16 batches-maintained titer ≥ 2.5 log10 (reference value) at day5
- Titer loss Day3: 0.1 - 1 log10
- Titer loss Day5: 0.4 - 1.2 log10



	Day0 - Day3	Day0 - Day5	D3 - Day5
Titer Loss (Median)	0,48	0,73	0,25
SD	0,27	0,2	0,16
Median+SD	0,75	0,98	0,41

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Standards for PPR Thermotolerant Vaccine

- (1) Titer (dose) ≥ **$10^{2.5}$ TCID (50)/ml** after post exposure at **40°C/ 5 Days**
- (2.1) Titer loss after post exposure at **40°C/ 5 Days ≤ 1 log10**

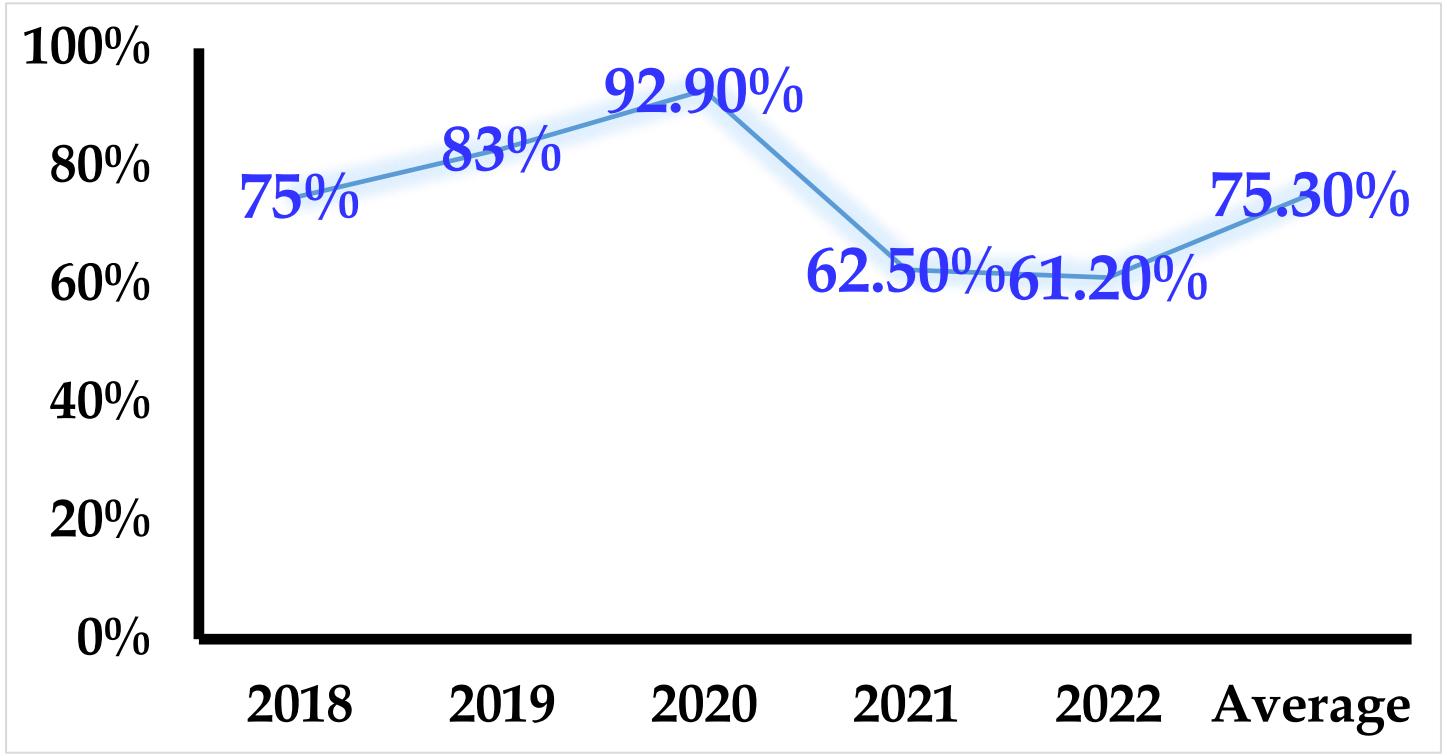
OR

- (2.2) Titer loss after post exposure at **40°C Day3-Day5** should be **≤ 0.4 log10** to guarantee vaccine potency if cold chain is not maintained

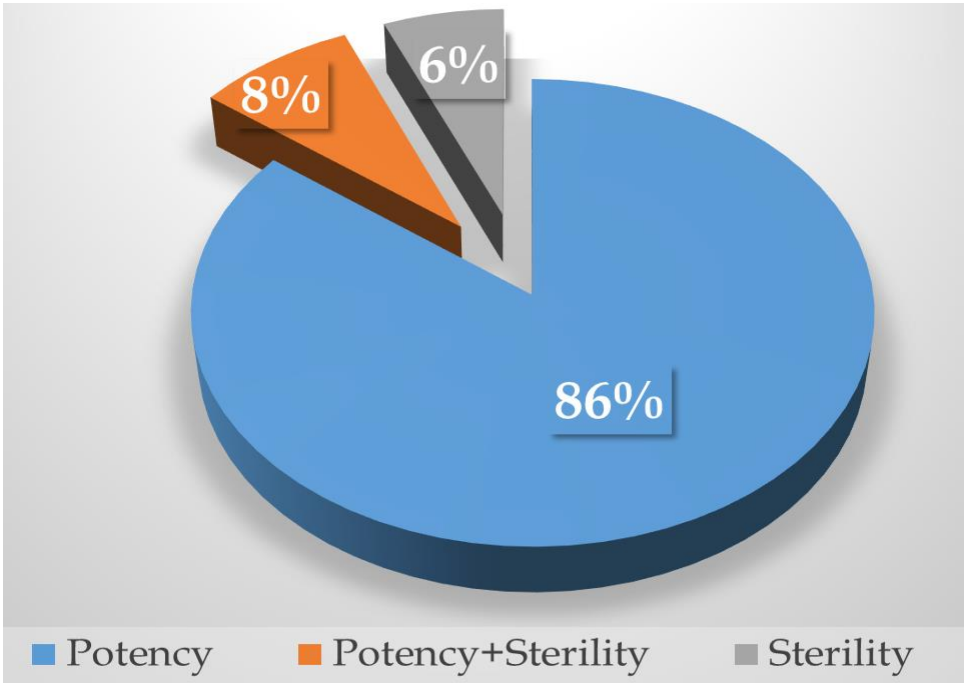
- Transportation of such vaccine (W/O maintaining the cold chain) up to **21 days** and guarantee vaccine potency
- Comparison to the WHO Standard for Thermostability of Measle vaccine
  - *Vaccine titer ≥ **3 log10/dose** after incubation **7 days at 37°C**;*
  - *Vaccine titer loss **≤ 1 log10** after the incubation period.*
  - *Storage of such vaccines at 37°C remain potent up to **21 days***

CBPP Vaccine Quality

CBPP Vaccine Pass Rate



Reasons for the failure of vaccines



Pilot study was conducted to optimize the Incubation Conditions and Harvest Time to Improve Vaccine Production

Support for Vaccine Registration

AU-PANVAC QC Test Report is used to support the Registration of Veterinary vaccines and immunologicals to ensure that products are in

GOOD QUALITY:

PURE, SAFE and **EFFICACIOUS**

Harmonization of Standards for Vaccine Registration in Africa and Auditing of Facilities

- *Nairobi (Kenya) meeting* ***Nov. 2019***
- *Abuja (Nigeria) meeting* ***July 2023***

Participants: RECs, NRAs of AUMS, Vet. Vaccine Manufacturers, CVOs, AU-IBAR, GALVmed, Secretariat African Continental Free Trade Area (AfCFTA) & WOAH.

Workshop Recommendation from Harmonization of Standards for Vaccine Registration

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- **Abuja Meeting Report Recommendation**
  - Use of the **Guideline developed for vaccine registration for the EAC** "*Technical Documentation Required in the Dossier for Registration of Immunological Veterinary Product*" as **Harmonised Template for PPR Vaccine Registration in Africa**
  - Support (*with AU-IBAR & GALVmed*) the **"Establishment of a Network of African Regulatory Authorities"** for information exchange and capacity building on vaccine registration
  - In collaboration with NRAs and RECs to initiate the **"Development of a Harmonised Guideline for Audit and Certification of vaccine manufacturers".**
- **Endorsed by the Executive Council 44th Ordinary Session (AU Summit 2024): Decision EX.CL/Dec.1234(XLIV)**

AU-PANVAC Future New Facility Complex

- Design & Construction Fully supported by US-DTRA

- Laboratories Block: Vaccine Quality Control laboratory, Biological Reagent Laboratory, Process development laboratory, Biosafety Level 3 Laboratory
- Vaccine bank, Vaccine seeds and for pathogens storerooms
- Training & Technology Transfer Center, Conference and Recreation/Canteen facility
- Offices and meeting rooms

Groundbreaking Ceremony of the Construction New Facility

- Held on **21st Feb. 2024** with AUC, Ethiopian and US Officials







- Construction completion expected in **2028**

AU-PANVAC !

ADDING VALUE TO ANIMAL HEALTH AND HUMAN LIVES!!

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