



**AU-PANVAC
Laboratories**



Quality Control of PPR Vaccines & Criteria for Assessing Thermotolerance

Dr Charles Bodjo/Hassen Belay, AU-PANVAC

Outline

- ❑ **Current PPR Vaccines and Quality Control at AU-PANVAC**
- ❑ **Criteria for Assessing Thermotolerance of PPR Vaccines**
- ❑ **Support the Registration of PPR Vaccine in Africa**
- ❑ **Update on the construction of AU-PANVAC New Laboratory Complex**



AU-PANVAC's Mission & Mandates

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

 MANDATES

- 1 **INDEPENDENT QUALITY CONTROL** of vet. vaccines.
- 2 Development and Production of **DIAGNOSTICS**
- 3 **TRANSFER OF VACCINE PRODUCTION TECHNOLOGIES**
- 4 **STANDARDIZATION** of production and **HARMONIZATION** of the quality control techniques in Africa
- 5 **CAPACITY BUILDING** to veterinary laboratories.
- 6 **AUDITING AND CERTIFICATION of Vaccine Manufacturing Facilities** *in collaboration with National Regulatory Authorities in Africa.*



Current PPR vaccines

- ❑ PPRV Nigeria 75/1 Strain (*Diallo et al. 1989; Diallo 2004*): Lineage II, **Most widely used in the world (ONLY currently used in AFRICA)**
- ❑ PPRV Sungri/96 (*Singh et al. 2009; Saravanan et al. 2010*): Lineage IV, **used only in India**
- ❑ Duration of immunity: **immunity for at least 3 years.**
- ❑ Vaccine produced in freeze-dried form,
 - Heat sensitive
 - Need to **maintain cold chain** to guarantee vaccine efficacy for field use

Peste des Petits Ruminants Vaccine (Nigerian Strain 75/1) Confers Protection for at Least 3 Years in Sheep and Goats

Aamer Bin Zahur¹, Hamid Irshad^{1*}, Aman Ullah¹, Muhammad Afzal², Asma Latif¹, Riasat Wasee Ullah¹, Umer Farooq¹, Muhammad Humayoon Samo², Muhammad Jahangir¹, Giancarlo Ferrari³, Manzoor Hussain², M. Munir Ahmad⁴

¹Animal Health Research Laboratories, Animal Sciences Institute, National Agricultural Research Centre, Islamabad, Pakistan

²FAO-UN Pakistan (GCP/PAK/127/USA) NARC, Park Road, Islamabad, Pakistan

³AGAH, FAO (Hq), Rome, Italy

⁴Divisional Diagnostic Laboratory, Livestock and Dairy Development Department, Multan, Pakistan

Email: hamidirshad@hotmail.com

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Abstract

The present study reports the duration of immunity and protective efficacy of Peste des Petits Ruminants (PPR) vaccine (Nigerian strain 75/1) in sheep and goats. A total of 105 sheep and goats were divided into three groups A, B and C. Group A received normal recommended dose (1.0 ml) of PPR vaccine, group B received half dose (0.5 ml) of PPR vaccine and group C was kept as unvaccinated control group in contact with vaccinated animals. The post vaccination dynamics of antibodies against PPR virus was studied. It was found that significant antibody titres persisted for 3 years post vaccination in sheep and goats vaccinated with either full dose or half dose of PPR vaccine. The challenge protection studies were carried out in experimental animals at 24 and 36 month post vaccination. The vaccinates withstood challenge and were found completely resistant clinically and virologically to virulent PPR virus for 24 and 36 months post vaccination. The unvaccinated control animals developed typical clinical signs of PPR and the challenged virus was detected in ocular, nasal and oral secretions of these animals. This study demonstrated that a single immunization with PPR vaccine conferred solid protection in sheep and goats for 3 years.

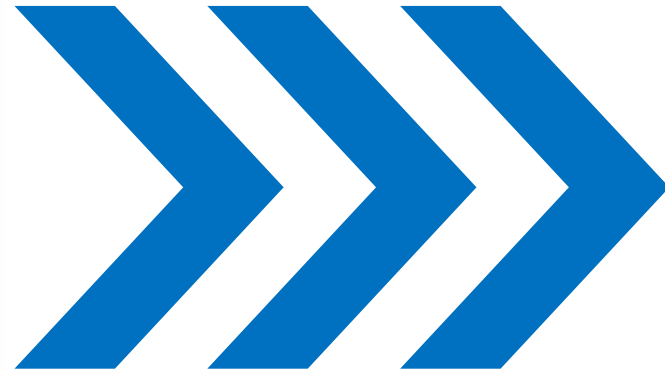
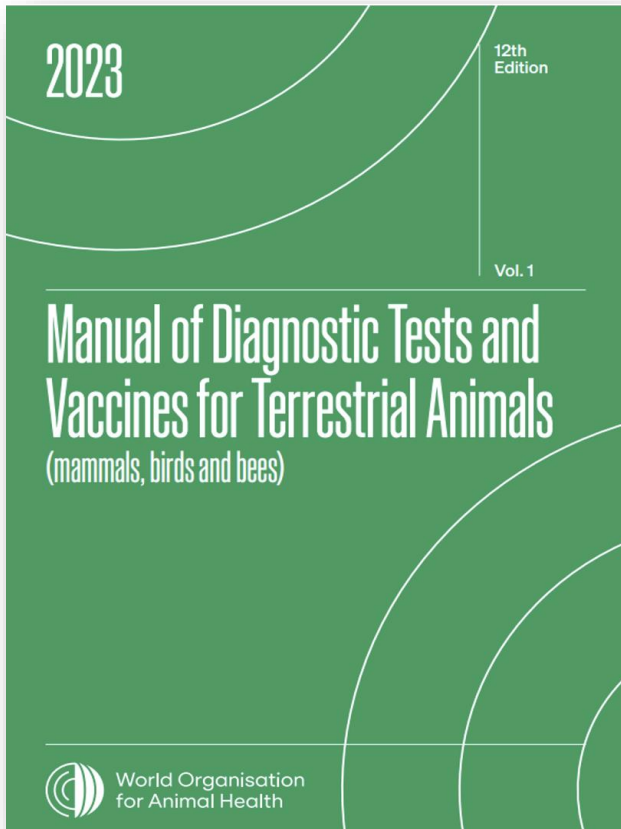
Keywords

PPR Vaccine, Small Ruminants



Quality Control Tests of Veterinary Vaccines

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



1-Identity



2-Purity/Sterility



3-Safety/Innocuity



4-Potency/Efficacy

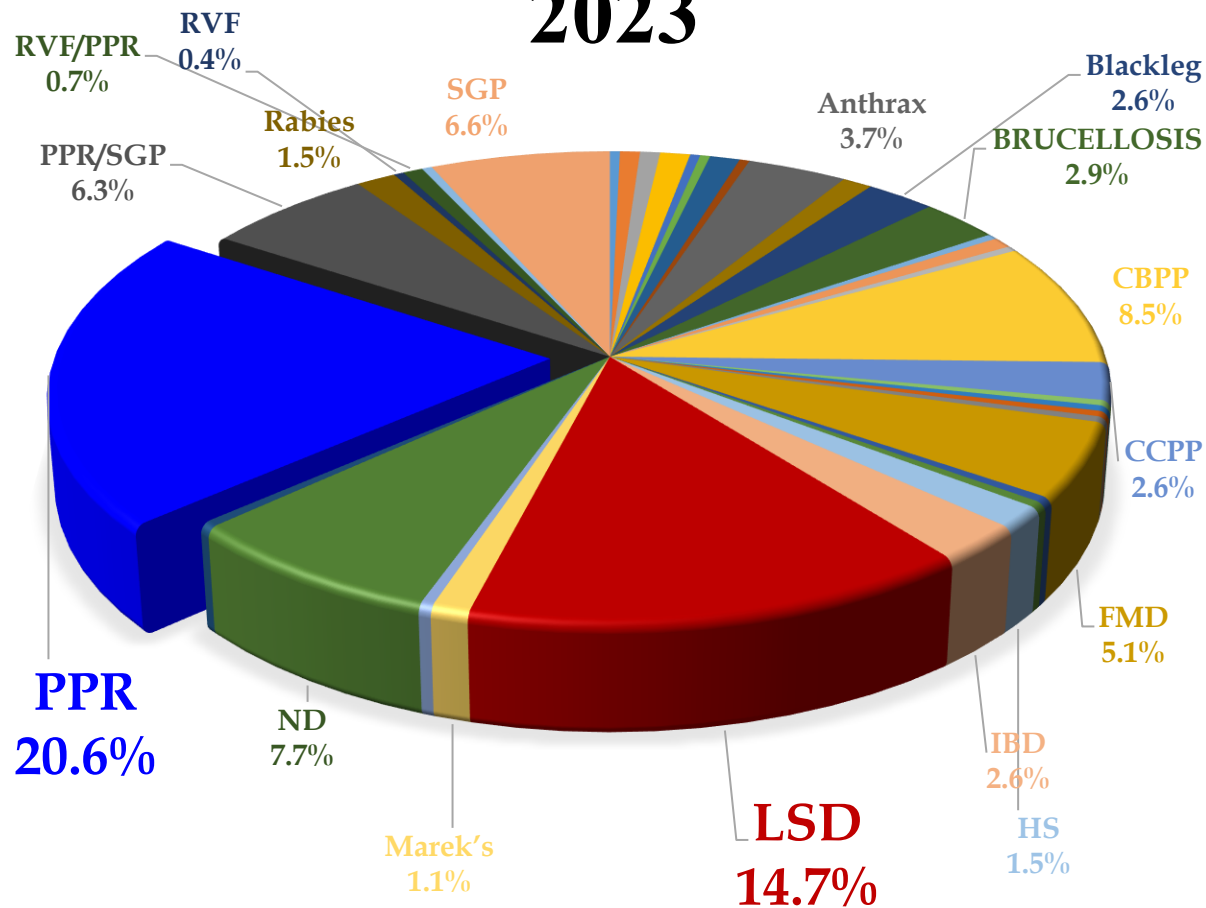


5-Stability

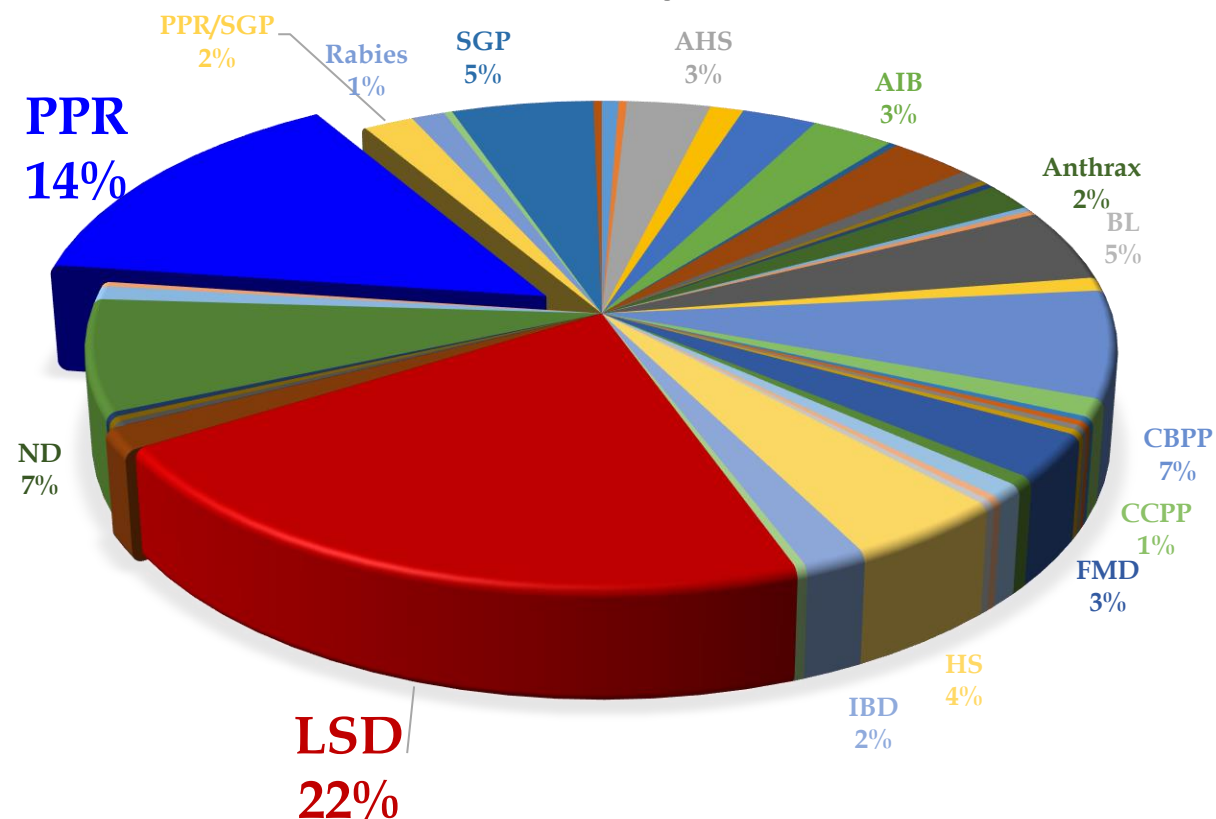


Proportion of PPR Vaccines

2023



2024



PPR vaccine was the major vaccine tested throughout the years, however this seems to be declined in favor of LSD vaccines



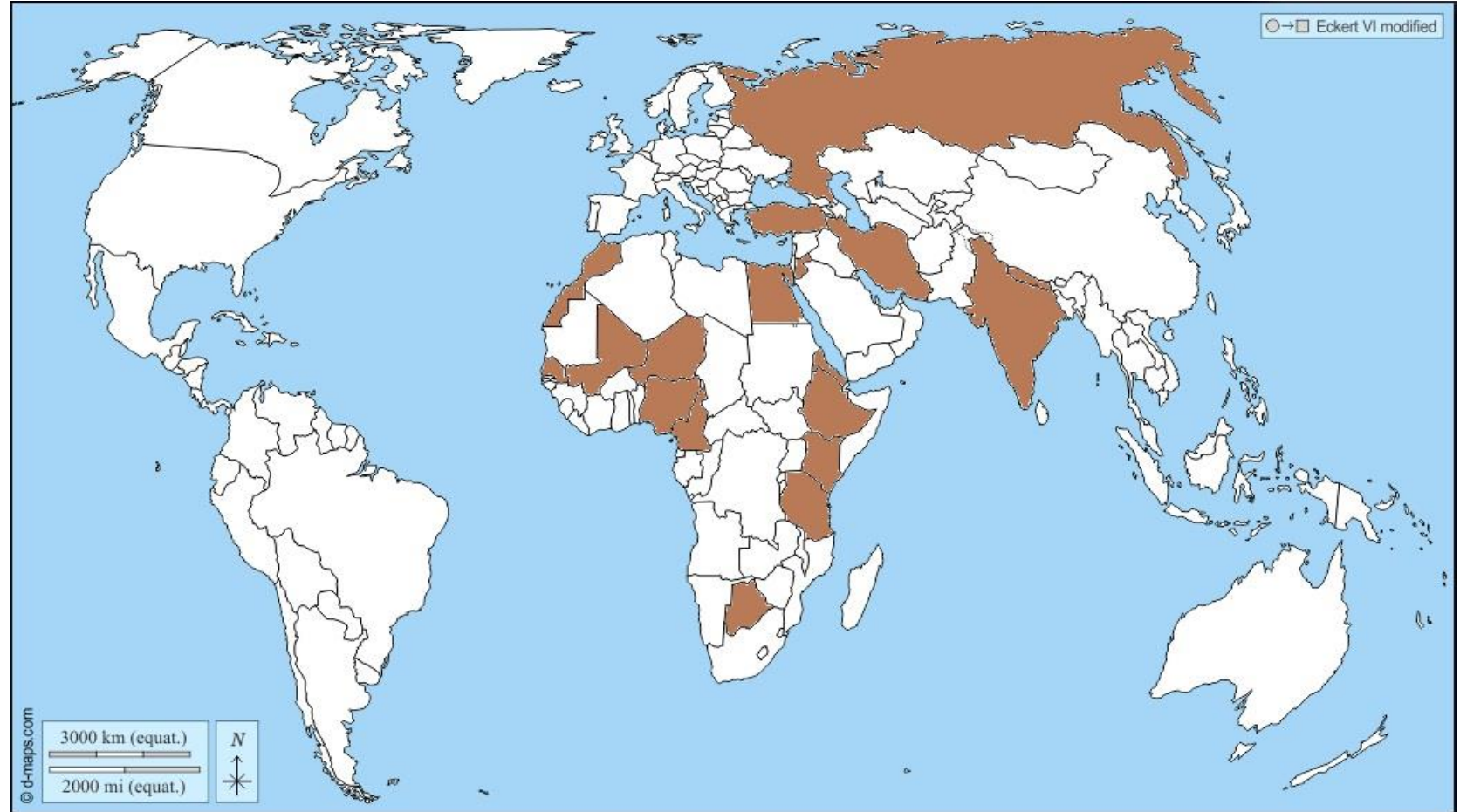
Origin of PPR Vaccine Tested at AU-PANVAC

13 AFRICAN LABS

- ✓ MEVAC & SRVI (Egypt)
- ✓ MCI & BIOPHARMA (Morocco)
- ✓ ISRA-Production (Senegal)
- ✓ LCV (Mali)
- ✓ NVRI (Nigeria)
- ✓ LANAVET (Cameroun)
- ✓ NVI (Ethiopia)
- ✓ NAPHL (Eritrea)
- ✓ KEVEVAPI (Kenya)
- ✓ HESTER (Tanzania)
- ✓ BVI (Botswana)

9 OVERSEA LABS

- ✓ HESTER (Nepal)
- ✓ JOVAC (Jordan)
- ✓ VETAL & DOLLVET (Turkey)
- ✓ FGBI ARRIAR, (Russia)



- ✓ RaziVSRI & Vira Vaccine Shaya (Iran),
- ✓ Indian Immunologicals & BIO-MED (India): PPRV Sungri/96 Vaccine



PPR Vaccines Quality Control Pass Rate

Year	Batches received	Pass Rate (%)
2020	61	96.7
2021	78	98.7
2022	88	84.1
2023	43	80
2024	70	93.3



Testing PPR Vaccine Thermotolerance

□ In December 2017, FAO and WOAHA PPR-Secretariat, with the support of the Global Alliance for Livestock Veterinary Medicines (GALVmed), organised a workshop on PPR thermotolerant vaccines at the FAO Headquarters in Rome:



- Define criteria for evaluation of PPR Thermotolerant vaccine
- Proposal to use an average temperature of **40°C for 5 days** to evaluate thermotolerant PPR vaccines



Processes to improve PPR Vaccine Thermotolerance

Xerovac Technique – PANVAC

Worrwall E.E et al., (2001). -An ultra rapid method for the dehydration and preservation of live attenuated Rinderpest and Peste des Petits Ruminants vaccines. *Vaccine*, 19:834–839

IBET Technique- Portugal

Silva A.C. et al., (2011). – Strategies for improved stability of Peste des Petits Ruminants vaccine. *Vaccine*, 29:4983-4991

Mariner JC, Gachanja J, Tindih SH, Toye P.

Mariner et al., (2017). -A thermostable presentation of the live, attenuated Peste des Petits Ruminants vaccine in use in Africa and Asia, 2017. *Vaccine*, 35:3773-3779)

Trehalose

Titer > $10^{2.5}$ (TCID₅₀)/mL for:

- 45°C/5 Days (0.7log titer lost using 2% Trehalose)
- 45°C/5 Days (0.45log titer lost using 4% Trehalose)

Tris-Tréhalose

Titer > 10^4 (TCID₅₀)/mL at:

- 37°C/6 Days (0.6log titer lost)
- 45°C/5 Days (1log titer lost)

Lactalbumin hydrolysate and Sucrose (LS).

Vaccine shelf-life:

- 37°C/ Up to 177.6 Days (*)
- 56 °C/13.7 Days (*)

(*): titer lost not Found

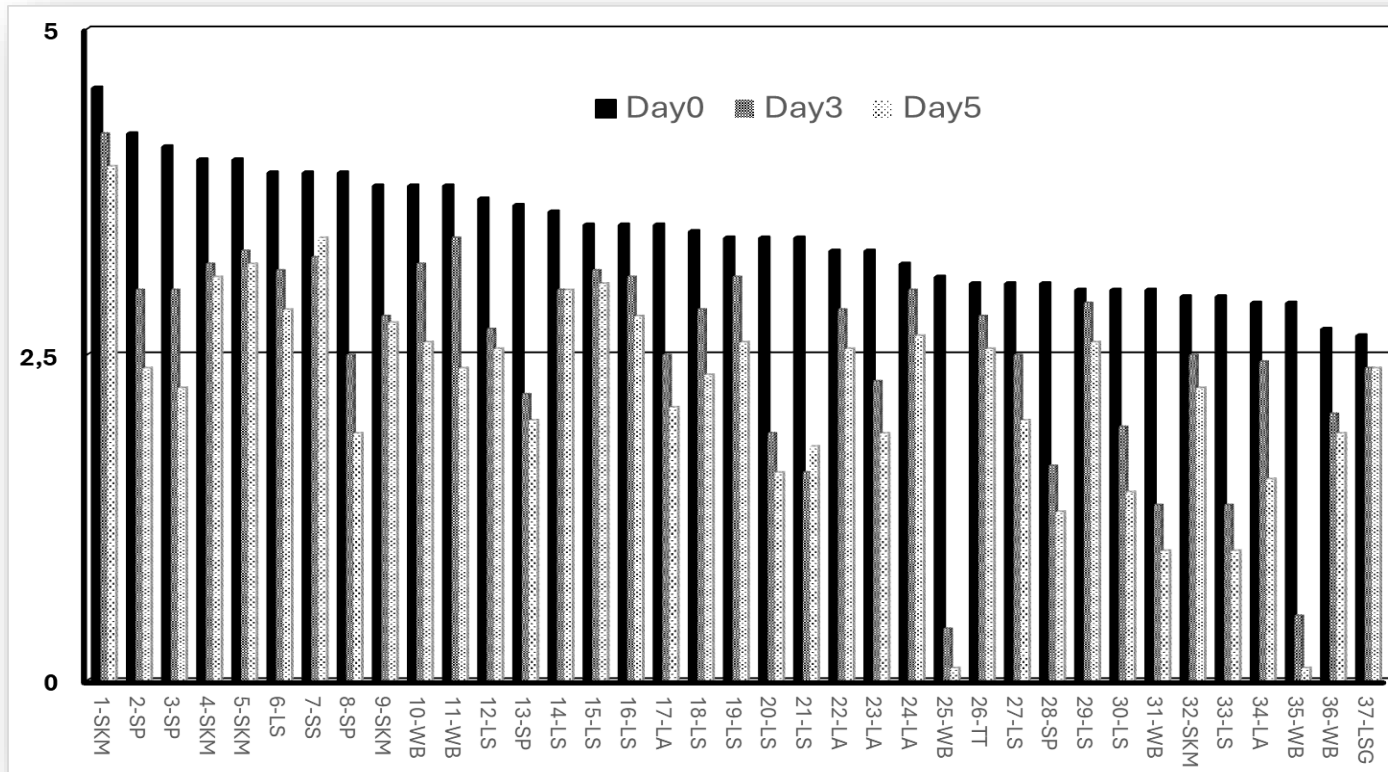


Defining criteria for thermotolerant PPR vaccines

- ❑ **37 freeze-dried PPR vaccine batches** (lineage II virus Nigeria 75/1 strain) from 10 vaccine manufacturers (*from Africa, the Middle East, and Asia were used for the thermotolerance study*)
 - 8 were submitted as Thermotolerant (ThT) PPR vaccines,
 - 29 batches were conventional PPR vaccines requiring to maintain cold chain
 - All PPR vaccines vials were stored at -20 °C until testing
- ❑ The vaccine batches produced using **8 different stabilizers**: *skimmed milk (SMK); lactalbumin-sucrose (LS); lactalbumin-sucrose-sodium glutamate (LSG), sucrose-peptone (SP), Lactose-NZ Amine (LA), Trehalose (TT), Weybridge medium (WB), and one unnamed product (Stabiliser30: SS)*
- ❑ PPR Vaccines incubation: PPR vaccines vials were incubated at **40 °C and titrated at day 3 and day 5 post-incubation**



Impact of 40°C Temperature on Vaccine Titer



□ Day0: all the **37 batches (100%)** have titer $\geq 2.5 \log_{10}$

- Highest titer: $4.55 \log_{10}$
- Lowest titer: $2.65 \log_{10}$

□ Day3: **20 batches (54.1%)** - maintained titer $\geq 2.5 \log_{10}$

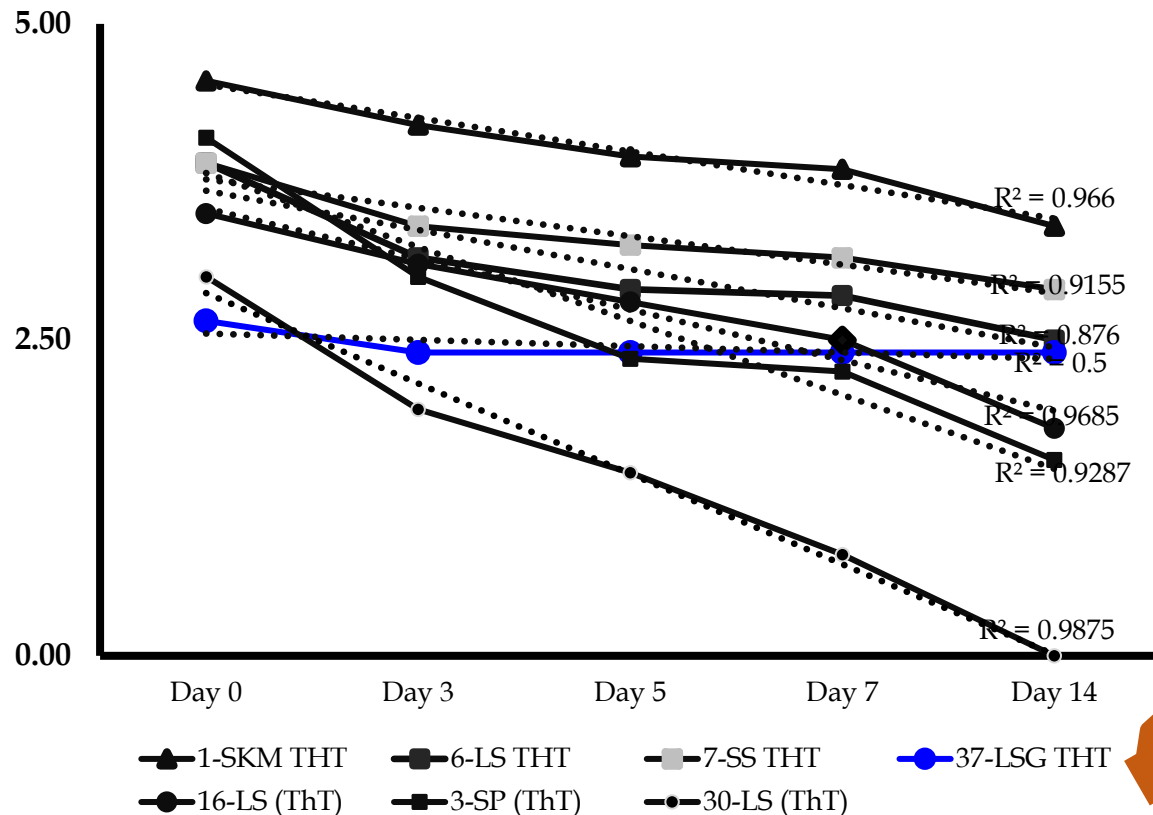
□ Day5: **16 batches (43.2%)** - maintained titer $\geq 2.5 \log_{10}$

□ PPR vaccines formulated using 5 stabilizers maintained titer $\geq 2.5 \log_{10}$ on day 5: **(1)-Skimmed milk (SMK); (2)-Lactalbumin-Sucrose (LS); (3)-Lactose - N-Z Amine (LA); (4)-Weybridge Medium (WM); (5)-Trehalose (TT)**



Degradation Curve of PPR Vaccines titre at 40 °C

❑ Incubation period for 7 PPR batches submitted as ThT was extended to 14 days



❑ Most of PPR ThT vaccines at 14-day exhibited a degradation curve (R^2) values from **0.876 to 0.98**, indicating a consistent and significant decline of the titre

❑ ONLY the vaccine formulated with **lactalbumin-sucrose-sodium glutamate stabilizer** showed degradation curve (R^2) value of **0.5**, indicating resistance to titre decline

It is important to include titre loss in the evaluation criteria for PPR ThT vaccines



Average of Titer loss following incubation at 40°C

- ❑ The mean titre loss of PPR vaccines with a titer $\geq 2.5 \log_{10} \text{TCID}_{50}/\text{mL}$ after incubation at 40 °C on Day 3 and Day 5

	Day 0–Day 3 (20 PPR Vaccines Batches)	Day 0–Day 5 (16 PPR Vaccines Batches)
Average Titre Loss	0.52 log ₁₀	0.72 log ₁₀
SD	0.26	0.27
Average Titre Loss + SD	0.78 log₁₀	0.99 log₁₀



Standard for PPR Thermotolerant Vaccine

□ Criteria Standards for Testing PPR Thermotolerant Vaccine

- (1) **Titer $\geq 2.5 \log_{10}$** (TCID₅₀/ml) after incubation at **40°C/Day-5**
- (2) **Titer Loss** after post exposure should be **$\leq 1 \log_{10}$**

□ Criteria Standards for comparison with other viral vaccines:

- *Rinderpest Thermostable vaccine*: **Titer $\geq 2.5 \log_{10}$** (TCID₅₀/ml) after incubation **45°C/14 Days** & **Titer loss $\leq 1.6 \log_{10}$**
- *Measles-Mumps vaccine*: **Titer $\geq 3 \log_{10}$** (TCID₅₀/ml) after incubation **37°C/7Days** & **Titer loss $\leq 1 \log_{10}$**





Article

Peste des Petits Ruminants Vaccine: Criteria for Assessing Its Thermotolerance

Charles S. Bodjo ^{1,*}, Hassen Belay Gelaw ¹, Zione D. Luhanga ¹, Yebechaye Degefa Tessema ¹, Jean-De-Dieu Baziki ¹, Cisse R. Moustapha Boukary ¹, Gelagay Ayelet Melesse ¹, Ethel Chitsungo ¹, Nick Nwankpa ^{1,2}, Simon Kihu ², Felix Njeumi ³, Satya Parida ³ and Adama Diallo ⁴

¹ African Union-Pan African Veterinary Vaccine Centre (AU-PANVAC), Debre Zeit P.O. Box 1746, Ethiopia; hasseng@africanunion.org (H.B.G.); zioneluhanga0@gmail.com (Z.D.L.)

² World Organisation for Animal Health (WOAH), Sub-Regional Representation for Eastern Africa, Nairobi P.O. Box 19687, Kenya; s.kihu@woah.org

³ Food and Agriculture Organization of the United Nations (FAO), Viale delle Terme di Caracalla, 00153 Rome, Italy; felix.njeumi@fao.org (F.N.); satya.parida@fao.org (S.P.)

⁴ Independent Researcher, Hahngasse 24-26/02 07, 1090 Vienna, Austria; a.diallob@outlook.com

* Correspondence: bodjoc@africanunion.org

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Criteria for Testing Thermotolerant PPR Vaccine Submitted to the WOAHA Biological Commission

- ❑ Presentation on the criteria and the SOP for testing Tht PPR vaccines was made in Sept. 2025 to WOAHA Biological Commission
- ❑ The WOAHA Biological Commission agreed to:
 - Incorporate the criteria for assessing thermotolerance of PPR vaccine in the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Chapter 3.8.8 (Section C.2.2.4 or C.2.3.3 on batch release)
 - Detailed step-by-step SOP for testing Tht PPR vaccines should be prepared and maintained through available platforms such as the [WOAHA PPR Reference Laboratory Network website](#)



AU-PANVAC Support in PPR Vaccine Registration

- ❑ African Union **"Harmonized Guideline for Registration of PPR vaccine in Africa"** developed with the support of NRAs and Manufacturers
- ❑ Support the **"Establishment of a Network of African Regulatory Authorities"** for information exchange and for capacity building: meeting held in Nairobi Kenya, last week
- ❑ AU-PANVAC in collaboration with NRAs and RECs to initiate the **"Development of a Harmonised Guideline for Audit and Certification of vaccine manufacturers"**.

The Abuja meeting report was endorsed by the Executive Council 44th Ordinary Session (AU Summit 2024): Decision EX.CL/Dec.1234(XLIV)



Nairobi, Kenya: *Dec 2019*



Abuja, Nigeria: *July 2023*



Dar Es Salaam, Tanzania, *July 2025*



AU-PANVAC New Facility Complex



❑ Fully supported
by **US - DTRA**



Enhance Biosafety and
Biosecurity measures



Expand Laboratory operation
Training & capacity

❑ Groundbreaking Ceremony
held on **21st Feb. 2024**
(presided by H.E Moussa Faki
Mahamat, Chairperson of
AUC)



Construction AU-PANVAC New Lab. Complex

❑ Construction work started in March 2025



Construction site visit by H.E. Moses Vilakati, Commissioner for Agriculture, Rural Development, Blue economy, and Sustainable Environment (ARBE)

❑ Construction completion expected in 2028





AU-PANVAC!

ADDING VALUE TO ANIMAL HEALTH AND HUMAN LIVES!!

Thank you

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