



WORKSHOP ON PPR PREVENTION AND CONTROL
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PESTE DES PETITS RUMINANTS (PPR)
VACCINE QUALITY CONTROL IN
AFRICA

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- 2. IMPORTANCE OF VACCINE QC IN AFRICA**
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1. INTRODUCTION

PPR:

Is an acute contagious viral disease of mostly sheep and goats caused by a *Morbillivirus* belonging to the family Paramyxoviridae



1. INTRODUCTION

PPR occurs in most African countries south of the Sahara and north of the equator except southern Africa, the Arabian Peninsula, and in most of the Middle Eastern countries (Jordan, Israel, and Lebanon), in India and south-west Asia.



1. INTRODUCTION

The most efficient method of controlling trans-boundary animal diseases is the application of the **stamping out policy** which involves **restriction** of livestock movement, **slaughter** of infected and in-contact animals with **compensation** of stock owners as well as the application of other appropriate zoo-sanitary measures.

This is not feasible or affordable by most of countries in Africa



1. INTRODUCTION

The major tools currently available for the control PPR are:

- good quality vaccines and
- effective laboratory diagnosis.



1. INTRODUCTION

Presently several strains of natural PPRV are developed as homologous PPR vaccines:

1. PPR Sungri96 from Northern India- 60 psg
2. PPR Arasul87 from Southern India- 75 psg
3. Recombinant capripox-based PPR vaccines that protect against both capripox and PPR
4. **In Africa, Nigeria 75/1 strain (PPRV 75/1 LK6 BK2 Vero 70), - Recommended by the OIE is available at AU-PANVAC**



2. IMPORTANCE OF VACCINE QC IN DISEASE CONTROL IN AFRICA

QUALITY CONTROL

Part of GMP which is concerned with sampling, specifications and testing, and with the organization, documentation and release procedures which ensures that the necessary and relevant tests are actually carried out and that products are not released for sale or supply, until their quality has been judged to be satisfactory
(EU Guidelines on GMP).



2. IMPORTANCE OF VACCINE QC IN DISEASE CONTROL IN AFRICA

QUALITY ASSURANCE (QA) :

Sum total of the organized arrangements made with the objectives of ensuring that medicinal products are of the quality required for their intended use

(EU Guidelines on GMP).



2. IMPORTANCE OF VACCINE QC IN DISEASE CONTROL IN AFRICA

QA ensures that:

- Production and control operations are clearly specified and GMP adopted
- Arrangements are made for the manufacture, supply and use of the correct starting and packaging materials
- All necessary controls on intermediate products, and any other In-process controls and validations are carried out
- finished product processed and checked, according to the defined procedures



2. IMPORTANCE OF VACCINE QC IN DISEASE CONTROL IN AFRICA

QA ensures that:

- Medicinal products are not sold or supplied before quality certification by a Qualified Person.
- There is a procedure for self-inspection and/or quality audit, which regularly appraises the effectiveness and applicability of the QA system.

Ultimate goal: PRODUCTION OF GOOD QUALITY VACCINES

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2. IMPORTANCE OF VACCINE QC IN DISEASE CONTROL IN AFRICA

QUALITY ASSESSMENT: ASSESSMENT MUST BE DONE BY AN INDEPENDENT BODY.

AU-PANVAC IS RESPONSIBLE FOR INDEPENDENT QC OF VETERINARY VACCINES IN AFRICA



3. BRIEF OVERVIEW OF AU-PANVAC

- **1983 – 1986:** Concept of Independent Centre to ensure QC of all RP Vaccines batches to support PARC.
- **1986 – 1993:** FAO TCP (TCP/RAF/6766 & TCP/RAF/6767) awarded to IBAR: 2 Reg. Vac. QC and Training Center to ensure Vaccine QC;
 - Dakar (Senegal) for Central and Western Africa
 - Debre Zeit (Ethiopia) for Eastern and Southern Africa
- **1993:** The two centers were combined into one site at Debre Zeit (Ethiopia) as **Pan African Veterinary Vaccine Centre**



3. BRIEF OVERVIEW OF AU-PANVAC

- 11 – 15 April 1994: Addis Ababa, Ethiopia: 4th Conference of African Ministers responsible for Animal Resources: PANVAC as a technical center of the OAU.
- February 1998: Addis Ababa: 67th Ordinary OAU Council of Ministers decided to elevate PANVAC as a technical center of OAU for vaccines Quality Control.
- March 2004: The Centre was officially launched as an AU Regional Office of the Department of Rural Economy and Agriculture of African Union Commission (AUC), at Debre Zeit (Ethiopia).



3. BRIEF OVERVIEW OF AU-PANVAC

AU-PANVAC: Independent Entity reporting to The Department of Rural Economy and Agriculture of AUC.

Mission: Promote the availability of safe, effective and affordable veterinary vaccines and diagnostic reagents; facilitate the development and introduction of improved or new vaccine production technology into africa; and strengthen Africa's capacity building in veterinary vaccine development, production and quality assurance.

MANDATE: To provide **International Independent Quality Control** of all Veterinary Vaccines in Africa:



3. BRIEF OVERVIEW OF AU-PANVAC

Currently conducts QC on: Peste des Petits Ruminants (PPR), Contagious Bovine Pleuropneumonia (CBPP), Contagious Caprine Pleuropneumonia (CCPP), Rift Valley Fever (RVF), Sheep and Goat Pox (SGP), Lumpy Skin Disease (LSD), Newcastle Disease (ND), Infectious Bursal Disease (IBD), Black Leg (BL) and Hemorrhagic Septicemia (HS).

MAINTAINS: A repository of vaccine seeds and cells



4. PPR VACCINE QC AT AU-PANVAC

SN	Country	Laboratory	City
1	Cameroun	Laboratoire National Veterinaire	Garoua
2	Nigeria	National Veterinary Research Institute	Vom
3	Niger	Direction des Laboratoires Veterinaires	Niamey
4	Mali	Laboratoire Central Veterinaire	Bamako
5	Chad	Laboratoire de Recherches Vétérinaires et Zootechniques FARCHA	Farcha N'Djamena
6	Senegal	Laboratoire National d'Elevage et de Recherches Veterinaires	Dakar Hann
7	Sudan	Central Veterinary Research Laboratory Soba	Khartoum
8	Ethiopia	National Veterinary Institute	Debre Zeit
9	Kenya	Veterinary Vaccines Production Centre	Nairobi
10	Botswana	Botswana Vaccine Institute	Gaborone
11	Egypt	Vaccine & Serum Research Institute	Cairo



4. PPR VACCINE QC AT AU-PANVAC

Vaccine QC requirements

- Contact AU-PANVAC prior the shipment
- Submission forms to be filled and sent with the samples.
- Number of samples: 20 for freeze dried vials
- Shipment by DHL and any other reliable means
- Fees: Free for all AU MS and 700 US\$ for Non AU MS
- Time for delivery of QC report: 1 month



4. PPR VACCINE QC AT AU-PANVAC (CONT)

AU-PANVAC FACILITIES:

- Bio-safety Level (BSL) 2 Laboratory
- Bio-Safety Level (BSL) 3 Laboratory
- Molecular Biology Laboratory
- Laboratory Animal section



4. PPR VACCINE QC AT AU-PANVAC (CONT)

A. AU-PANVAC BSL

2 Laboratory:

1. Virology
2. Cell culture
3. Bacteriology
4. Media preparation
5. Wash up
6. Stores





B. BIO-SAFETY LEVEL (BSL) -3 Laboratory





B. BIO-SAFETY LEVEL (BSL) -3 Laboratory





C. Molecular Biology Laboratory





C. Molecular Biology Laboratory





D. Laboratory Animal section



Animal Breeding section



Animal Inoculation section



Laboratory Animal section



Lab Mice



Lab Rabbit



Laboratory Animal section



Guinea Pigs



Laboratory Animal section



Lab Animal: Small Ruminants and Cattle



AU-PANVAC VACCINE QC STAFF

**1. Veterinary Vaccine
Officer
Coordination of all
vaccine qc activities**

2



**2. Mrs. Ethel Chitsungo
Laboratory Technician
PPR vaccine potency**

3



**3. Mr. Baziki Jean Dedeu
Laboratory Technician
PPR vaccine
Identity/Sterility**

4





AU-PANVAC VACCINE QC STAFF

4. Mr. Jackson Cheserek 4
Laboratory Technician
PPR vaccine Stability/Safety



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5. Dr. Elizabeth Aguille
Veterinarian
PPR laboratory safety

6. Mr. Adama Diakite 6
Laboratory Technician
PPR laboratory safety



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7. Mrs. Mazareth G/Silassie
Laboratory Assistant
**Media preparation/ equipment
sterilization**



4. PPR VACCINE QC AT AU-PANVAC (CONT)

1. PPR VACCINE QC TESTS CONDUCTED AT AU-PANVAC

- a. IDENTITY : Group and specific rt-PCR**
- b. STERILITY : Freedom from bacterial, fungal and viral contamination**
- c. SAFETY in host and Laboratory animals**
- d. POTENCY : Titration in Vero Cells**
- e. STABILITY : Vacuum, Residual Moisture Estimation and accelerated Stability Studies**



PPR VACCINE QC TESTS CONDUCTED AT AU-PANVAC

1. IDENTITY TEST : Group and specific rt-PCR





PPR VACCINE QC TESTS CONDUCTED AT AU-PANVAC

2. STERILITY : Freedom from bacterial, fungal and viral contamination

**AU-PANVAC's
BIO-SAFETY
LEVEL (BSL) -3
Laboratory**





PPR VACCINE QC TESTS CONDUCTED AT AU-PANVAC

3. SAFETY TESTS in host and Laboratory animals



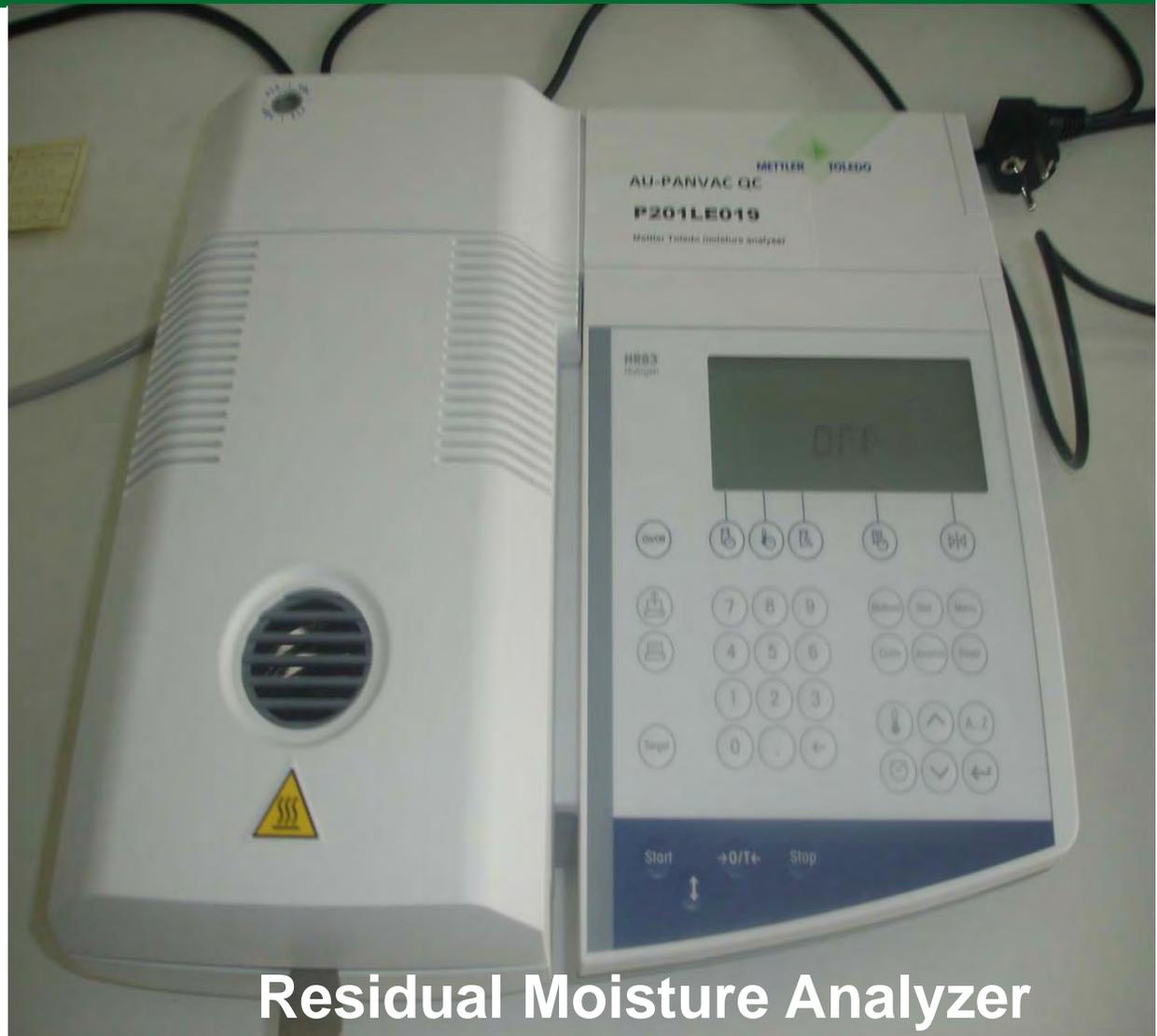


PPR VACCINE QC TESTS CONDUCTED AT AU-PANVAC

5. STABILITY

TEST

- a. Vacuum test
- b. Residual
Moisture
Estimation
- c. Accelerated
Stability Studies



Residual Moisture Analyzer



PPR VACCINE QC TESTS CONDUCTED AT AU-PANVAC

4. POTENCY TEST in Vero Cells





VACCINE QC ACTIVITIES: 2010 - 2012

☐ PPR Vaccines tested:

✓ **2010:** 29/122 batches: 72/67% Pass

✓ **2011:** 29/106 batches: 70/88% Pass

✓ **2012:** 20/153 batches: 85/80% Pass



REQUESTS FOR VACCINE SEEDS AND BIOLOGICALS FROM AUMS

✓ 2010 - 59

✓ 2011 - 58

✓ 2012 - 72



CONCLUSION

1. AU-PANVAC presently continues to provide services to AU MS in line with its mandates and specific recommendations of the AUMS council of Ministers for animal health.
2. AU-PANVAC is more than ever committed to ensuring the quality of PPR vaccines in Africa
3. AU-PANVAC will continue to strengthen its capacity in order to meet up with the increasing challenges of PPR disease control and eradication on the African continent

**THANK
YOU**