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INDEPENDENT RIFT VALLEY FEVER VACCINE QUALITY CONTROL AT AU/PANVAC

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OUTLINE

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2. IMPORTANCE OF VACCINE AND ITS INDEPENDENT QUALITY CONTROL IN DISEASE CONTROL IN AFRICA
3. RIFT VALLEY FEVER VACCINE QC REQUIREMENTS BY AU/PANVAC
4. RVF QUALITY CONTROL AT AU/PANVAC

1. INTRODUCTION

RVF: A peracute or acute Zoonotic disease of domestic ruminants in Africa, caused by a single serotype of a mosquito-borne bunyavirus of the genus Phlebovirus (OIE).

Control Tools: Vaccines and Diagnostics.

Vaccines: Two types of RVF vaccines: Attenuated RVF vaccine prepared from Smithburn's attenuated strain (for use in non pregnant cattle and sheep) and Inactivated vaccines prepared from virulent field strains (for use on pregnant animals).

2. IMPORTANCE OF VACCINES AND ITS INDEPENDENT QUALITY CONTROL IN DISEASE CONTROL IN AFRICA

It universally recognized that the most efficient method of controlling transboundary 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 affordable by most of countries in Africa

Livestock heath in Africa, with regard to major infectious vaccine preventable diseases, can be dramatically improved by the use of good quality vaccines and good laboratory diagnosis support.

GOOD QUALITY VACCINE: PURE – SAFE – POTENT – EFFICIOUS = Vac. Production under Quality Assurance (QA)

2. IMPORTANCE OF VACCINES AND ITS INDEPENDENT QUALITY CONTROL IN DISEASE CONTROL IN AFRICA (Cont.)

QUALITY ASSURANCE (QA)

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 to GMP).

QA ensures:

- 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
- The finished product is correctly processed and checked, according to the defined procedures

2. IMPORTANCE OF VACCINES AND ITS INDEPENDENT QUALITY CONTROL IN DISEASE CONTROL IN AFRICA (Cont.)

QA:

- Medicinal products are not sold or supply 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

QUALITY ASSESSED: INTERNAL (MUST BUT RESULTS CAN BE BIASED)

FINAL: INDEPENDENT QC DONE BY AN INDEPENDENT BODY.

2. IMPORTANCE OF VACCINES AND ITS INDEPENDENT QUALITY CONTROL IN DISEASE CONTROL IN AFRICA (Cont.)

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 to GMP) .

IN AFRICA INDEPENDENT QC BY PANVAC

2. IMPORTANCE OF VACCINES AND ITS INDEPENDENT QUALITY CONTROL IN DISEASE CONTROL IN AFRICA (Cont.)

Brief Overview on Independent vaccine Quality Control in Africa:

- **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), 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**

2. IMPORTANCE OF VACCINES AND ITS INDEPENDENT QUALITY CONTROL IN DISEASE CONTROL IN AFRICA (Cont.)

Brief Overview on Independent vaccine Quality Control in Africa:

- 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).

2. IMPORTANCE OF VACCINES AND ITS INDEPENDENT QUALITY CONTROL IN DISEASE CONTROL IN AFRICA (Cont.)

Brief Overview on Independent vaccine Quality Control in Africa:

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 the introduction of improved or new vaccines and strengthen Africa's capacity building in veterinary vaccine development production and quality assurance.

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

2. IMPORTANCE OF VACCINES AND ITS INDEPENDENT QUALITY CONTROL IN DISEASE CONTROL IN AFRICA (Cont.)

Brief Overview on Independent vaccine Quality Control in Africa:

Currently QC on Veterinary vaccines: 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 and Hemorrhagic Septicemia.

REPOSITORY OF VACCINE SEEDS AND CELLS: UPON REQUEST

RVF vaccine producing laboratories: OBP (SA), KEVEVAPI (Kenya) and VSVRI (Egypt)

3. RIFT VALLEY FEVER VACCINE QC REQUIREMENTS BY AU/PANVAC

- Submission Form to be filled in and sent with the samples.
- Number of samples: 20 for freeze dried vaccines (Attenuated) and 10 bottles for liquid (Inactivated) vaccines
- Shipment by DHL and any other reliable mean
- Contact AU/PANVAC prior the shipment
- Fees: Free for AU MS and 700 US$ for Non AU MS
- Time for QC: 1 month

4. RVF QUALITY CONTROL AT AU/PANVAC

1. FACILITIES
2. STAFF
3. TESTS

4. RVF QUALITY CONTROL AT AU/PANVAC (CONT)

AU/PANVAC FACILITIES FOR RVFV QC

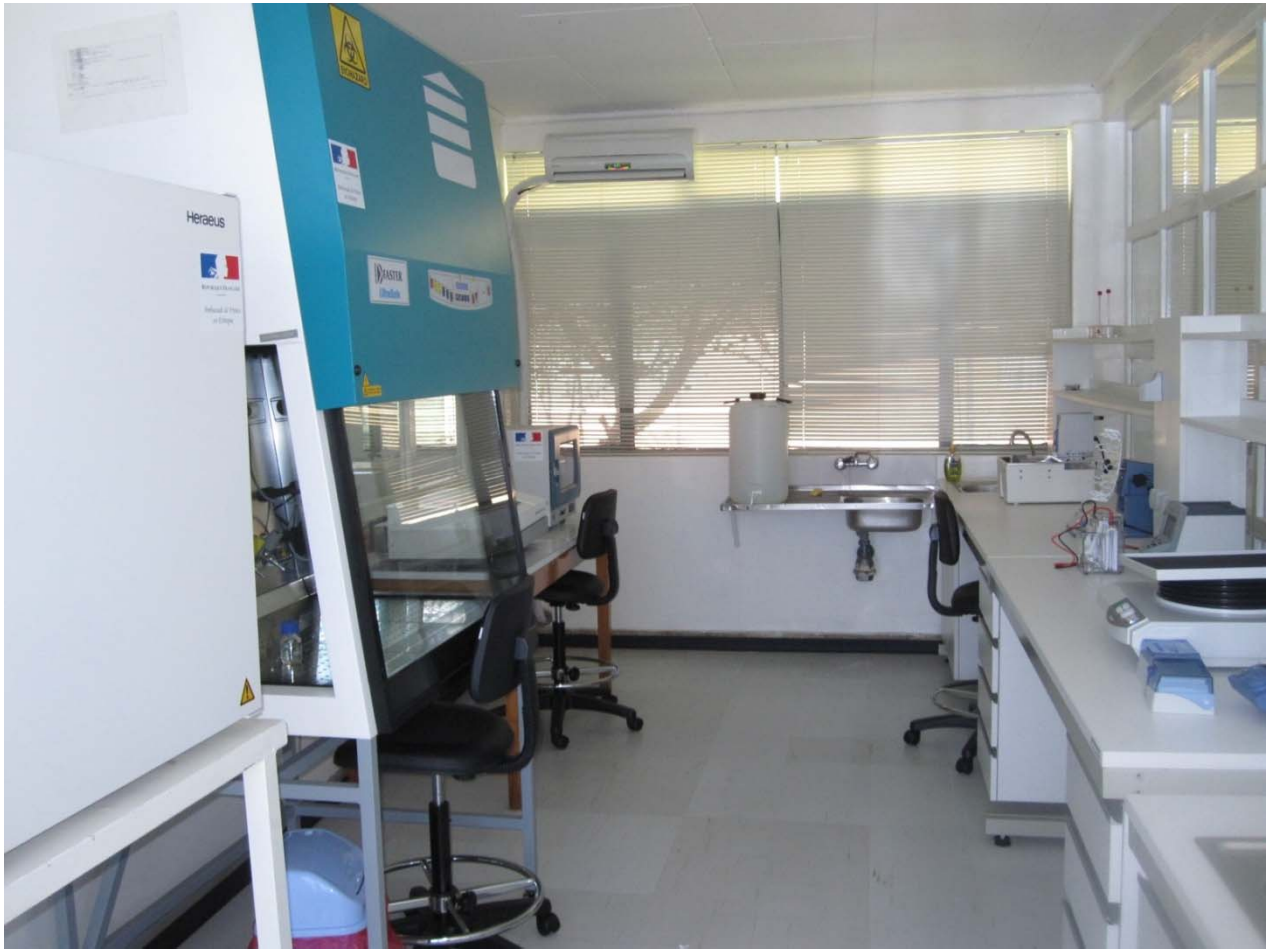
- Bio-Safety Level 3 Laboratory

- Molecular Biology Laboratory

- Laboratory Animal Unit (Large and Small)

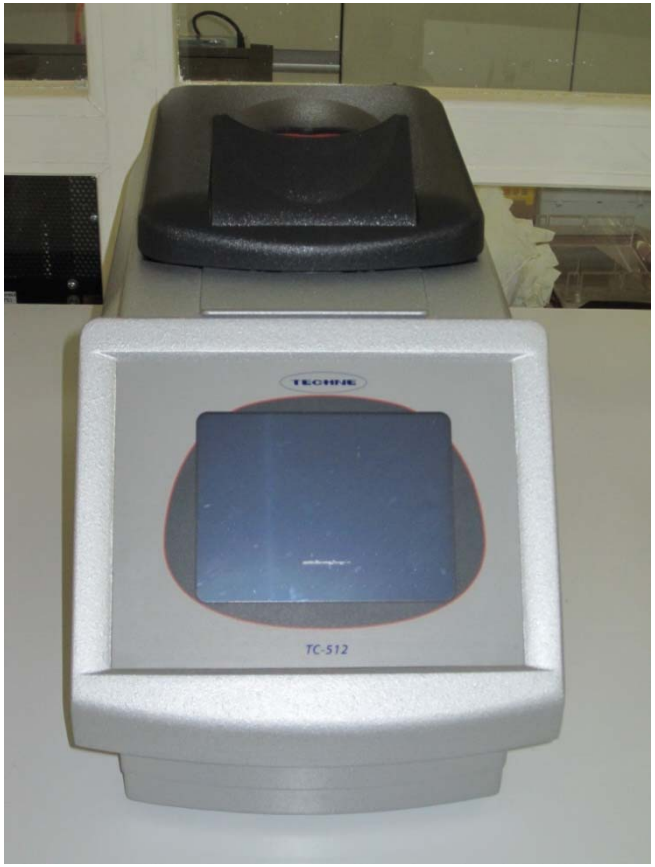
Molecular Biology Laboratory

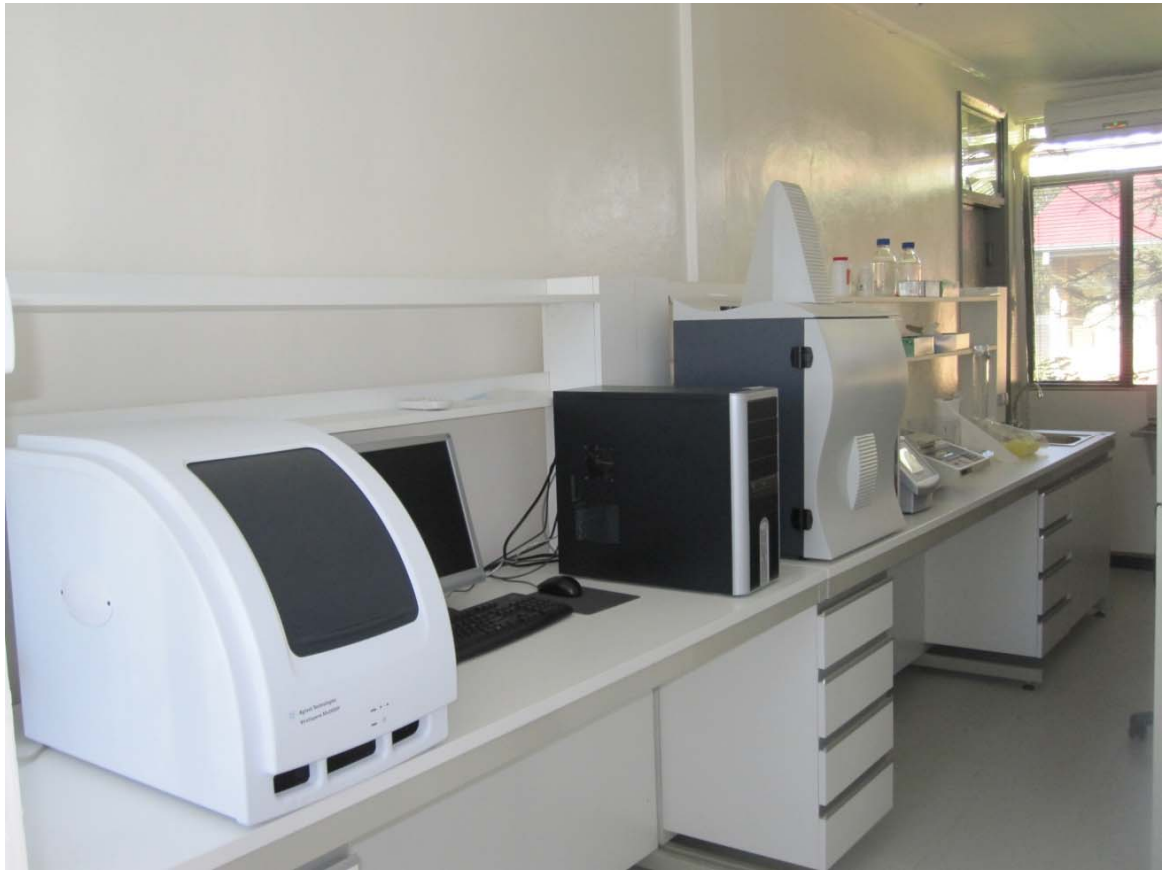
PANVAC



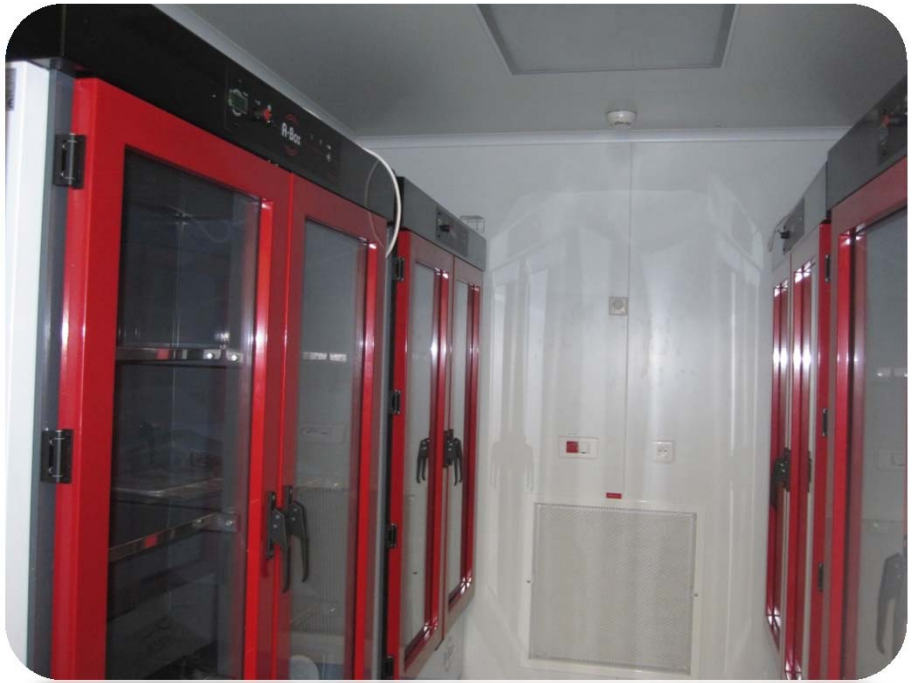
Molecular Biology Laboratory

PANVAC

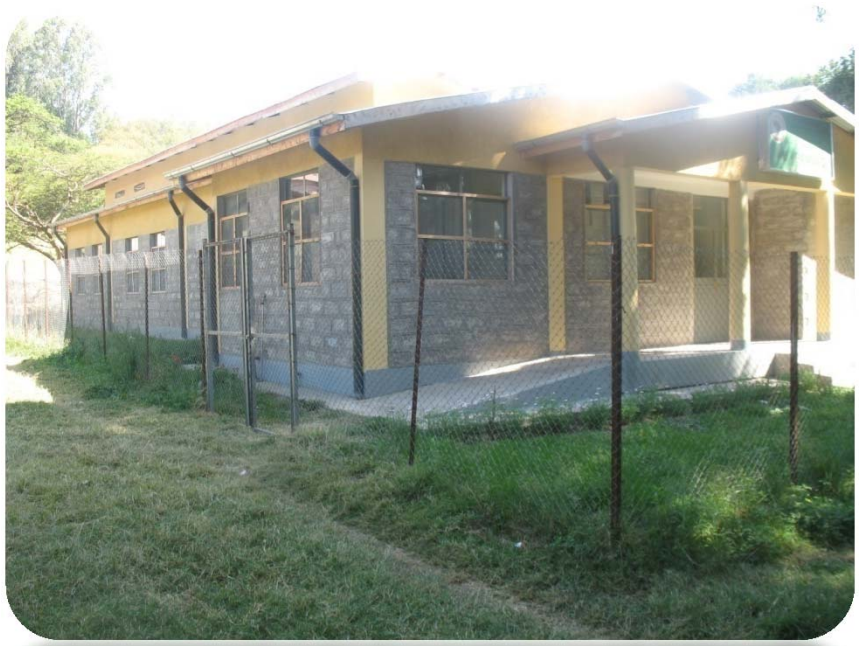




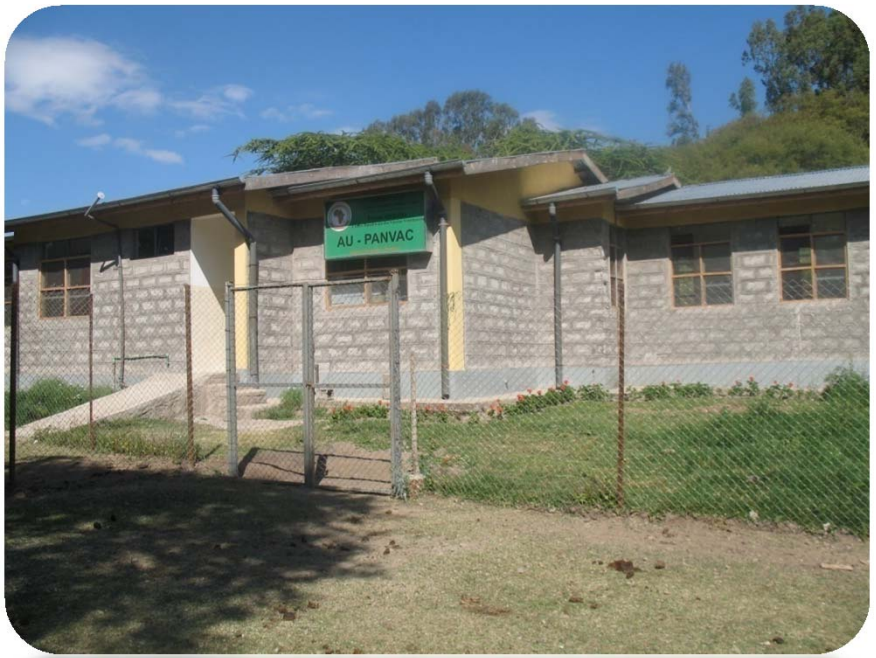
BSL-3 Laboratory



Animal's Laboratory: small animal (Mice, Rabbit & guinea pig)



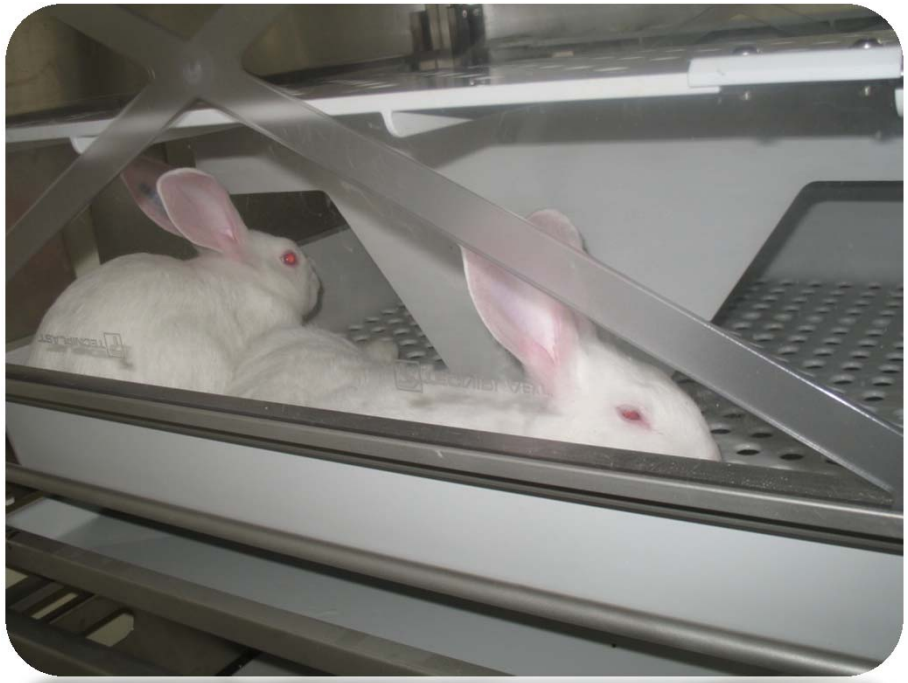
Breeding Animal Lab



Inoculation Animal Lab

Animal's Laboratory Breeding

Lab Mice

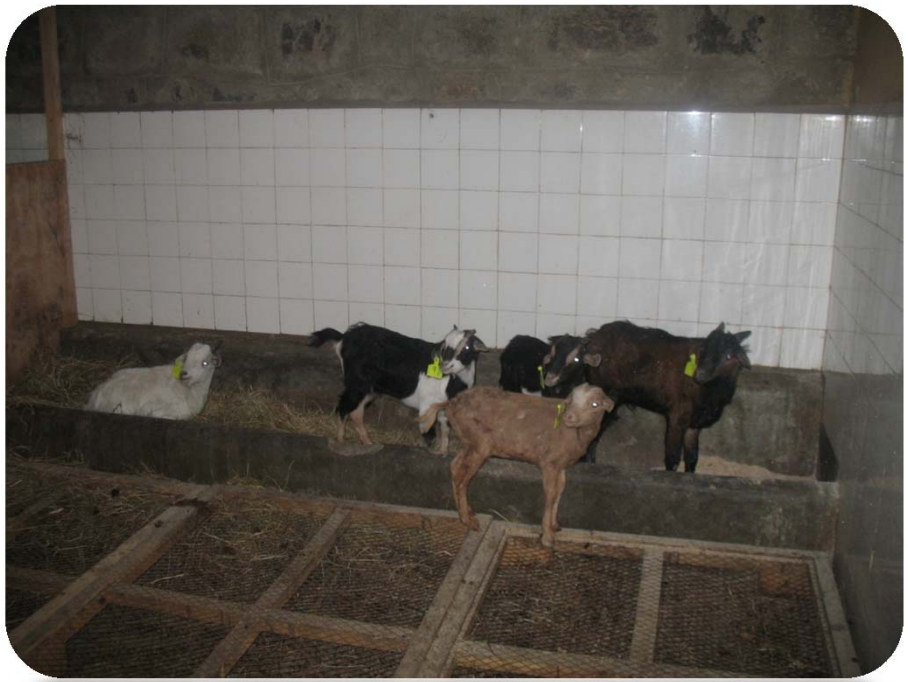


Lab Rabbit

Animal’s Laboratory Breeding

Lab Guinea Pig

Animal's Laboratory



Lab Animal: Small Ruminants and Cattle

4. RVF QUALITY CONTROL AT AU/PANVAC (CONT)

1. QC OF LIVE ATTENUATED RVF VACCINE (OIE)

- Freedom from bacterial, fungal and viral contamination .
- Safety on susceptible animals and laboratory animals.
- Identity: using Reverse Transcriptase-Polymerase Chain Reaction.
- Potency using intracerebrally inoculation of vaccine in infant mice or Vero Cells and assessment of immune response on vaccinated sheep.
- Stability test using assessment of potency after incubation of the RVF vaccine at 37oC for one week.
- Residual Moisture content using the gravimetric method

4. RVF QUALITY CONTROL AT AU/PANVAC (CONT)

2. QC OF INACTIVATED RVF VACCINE (OIE)

- Freedom from bacterial, fungal and viral contamination.
- Safety on susceptible animals and laboratory animals.
- Identity test using Reverse Transcriptase-Polymerase Chain Reaction.
- Potency: using assessment of immune response on vaccinated sheep.
- Completion of inactivation using inoculation of vaccine into susceptible cell culture.
- Residual Inactivant content using colorimetric method.

THANK YOU