African Union

Independent Vaccine Quality Control Concept and Essential Diagnostics Production Initiative

Drs BODJO Charles

OUTLINE

- Brief Recall on AU-PANVAC
- Importance of Animal Vaccines
- AU-PANVAC Concerns on Biosecurity/Biosafety
- Quality Control of Veterinary Vaccines in Africa
- Diagnostics Production Initiatives in Africa
- Interlaboratory Comparison activities

AU-PANVAC

Rinderpest and Establishment of AU-PANVAC

- **1986:** Establishment of an initiative for quality control of vet. vaccines
  - As a result of the FAO Rinderpest Vaccine Quality Audit in 1983 to support to support the Pan-African Rinderpest Campaign (PARC): **Only 20% Good Quality Vaccines**
  - FAO-TCP supported **2 Centers for Quality Control of RP Vaccine**
    - ✓ *Dakar, Senegal: West and Central Africa*
    - ✓ *Debre-Zeit, Ethiopia: East and Southern Africa*
- **1993:** Merging of the 2 Centers to establish the Pan African Vet. Vaccine Centre (PANVAC)
- **2004:** PANVAC became AU Technical Centre as **AU-PANVAC**

AU-PANVAC

AU-PANVAC Current Mission & Activities

❑ MISSION:

"To promote the use of **Good Quality Vaccines** and **Diagnostic Reagents** for the control and eradication of animal diseases in Africa."

❑ TWO MAIN ACTIVITIES

1. **International Independent Quality Control** of veterinary vaccines produced or imported into Africa
2. **Production of Essential Diagnostics**

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AU-PANVAC: Special Mandates

3 **Harmonization of Vet. Vaccine registration on the continent**

4 **Maintaining Africa free from Rinderpest:** "Sequestration of all Rinderpest material from African laboratories and maintaining an emergency vaccine stock"

- Category A and B Rinderpest Holding Facilities for Africa
- Maintain a Continental Vaccine Reserve for Rinderpest

AU-PANVAC

AU-PANVAC Quality Management System

- ISO 9001:2015 Certified
- ISO/IEC 17025 Accredited

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

IQNet and
DQS GmbH Deutsche Gesellschaft zur Zertifizierung von Managementsystemen
hereby certify that the company

Pan-African Veterinary Vaccine Centre
(AU-PANVAC)
Debre Zeit
P.O. Box 1748
Ethiopia

has implemented and maintains a **Quality Management System**.

Scope:
Provision of Quality Control Service for veterinary vaccines, and production and distribution of essential biological reagents for animal disease diagnosis

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 9001 : 2015

Valid from 2017-02-22
Valid until 2020-02-21
Date of certification 2017-02-22

Registration number: DE-40100077 QM15

Michael Drechsel
President of IQNet

Frank Graichen
Managing Director of DQS GmbH

IQNet Partners**:
AENOR *Spain* AFNOR Certification *France* AIB-Vincotte International *Belgium* APCER *Portugal* CCC *Cyprus* CISQ *Italy* CQC *China* CQM *China* CQS *Czech Republic* Cro Cert *Croatia* DQS Holding GmbH *Germany* FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* IMNC *Mexico* Inspecta Certification *Finland* INTECO *Costa Rica* IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland* PCBC *Poland* Quality Austria *Austria* RR *Russia* SIGE *México* SII *Israel* SIQ *Slovenia* SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

* This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document
** The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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DAkkS
Deutsche Akkreditierungsstelle
D-ZM-16074-01-00

DQS GmbH

Frank Graichen
Managing Director

Accredited Body: DQS GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany
Administrative Office: DQS Holding GmbH, Konrad-Adenauer-Allee 8-10, 61118 Bad Vilbel, Germany

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ETHIOPIAN NATIONAL ACCREDITATION OFFICE

ETHIOPIAN NATIONAL ACCREDITATION OFFICE

ACCREDITATION CERTIFICATE

PAN AFRICAN VETERINARY VACCINE CENTRE
(AU-PANVAC)

Debre zeit
Ethiopia
Facility Accreditation No: T0025

Is accredited by the Ethiopian National Accreditation Office (ENAO) to perform tests in accordance with the attached *Scope of Accreditation* in the field of
Veterinary Vaccine Testing (Molecular Biology and Microbiological Testing)

The facility is accredited in accordance with the requirements of ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*. The accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system. While this certificate remains valid, the Accredited Facility named above is authorized to use the relevant ENAO accreditation symbol to issue test reports and/or certificates.

Date of issue: 16/11/2018
Expiry date: 15/05/2023

Ato Ardya Fesseha
Director General
Ethiopian National Accreditation Office

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Certification & Accreditation show that QC services and Production of Biological Reagent are done under QMS

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AU-PANVAC Concerns on Biosecurity/Biosafety

- Accidental loss or spread of Valuable Biological Material that may be responsible for infectious and/or contagious diseases.
- The use of biological materials for malicious purposes
- Protection of Laboratory Staff and the Environment from exposure or spread of pathogens.
- Handling selected agents such as Rinderpest virus/Vaccine seeds/Hybridoma cells…

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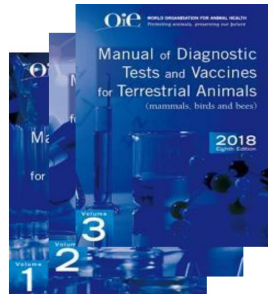
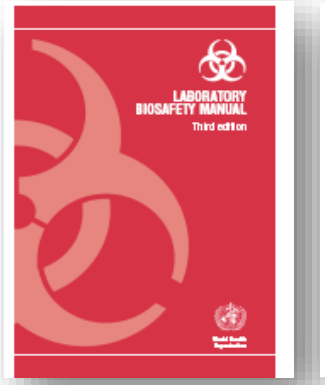
Standards used for Biorisk Management System

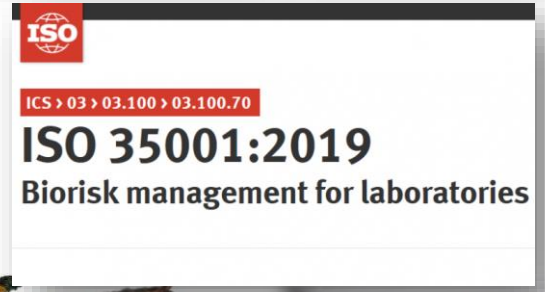
- **WOAH (OIE):** Biosafety and biosecurity: standard for managing biological risk in the veterinary laboratory and animal facilities (*Chapter 1.1.4 of the OIE's Terrestrial Manual*)



- **WHO:** Biorisk Management Laboratory biosecurity guidance
  - *Laboratory Biosafety Manual, Third edition (WHO, 2004)*
  - *Biorisk management - Laboratory biosecurity guidance (WHO, 2006)*



- **ISO 35001:2019:** to define the process to identify, assess, control, and monitor the risks associated with hazardous biological materials



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Capacity building of staff in Biorisk Management

➢ **Support received from the US-DTRA** & Sandia National Laboratories

- **Module 1** - Risk Assessment and Hazard Identification
- **Module 2** - Standards, Guidelines & Emergency Response
- **Module 3** - Facility Design & Large-scale Biosafety Issues
- **Module 4** - Disinfection, Decontamination & Sterilization
- **Module 5** - Work Practices, Equipment Biohazards, Personal Protective Equipment
- **Module 6** - Equipment, Biological Safety Cabinets

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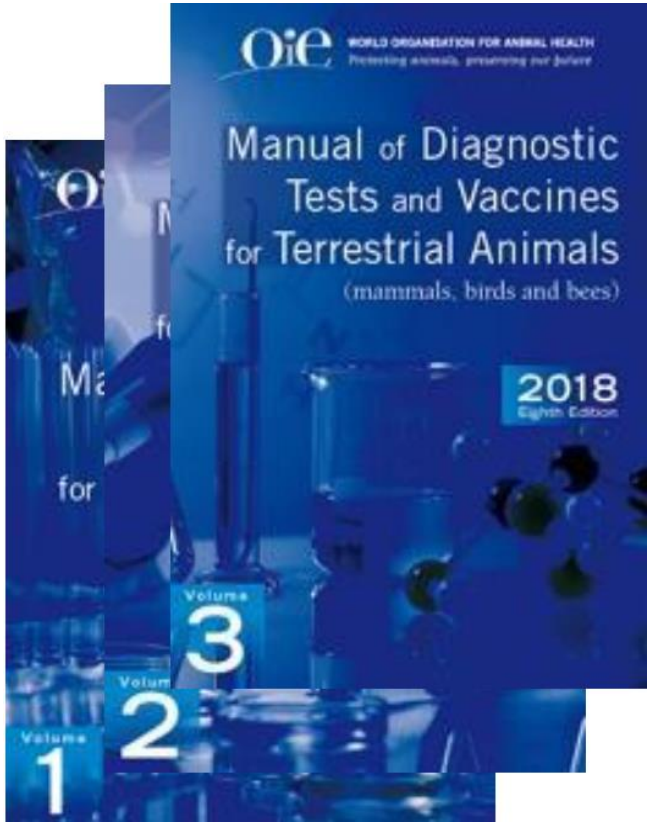
Standard for Vaccine Quality Control Test

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



1. Identity
2. Sterility
3. Innocuity
4. Efficacy
5. Stability

5 main QC tests

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Vaccine Quality Control Activities

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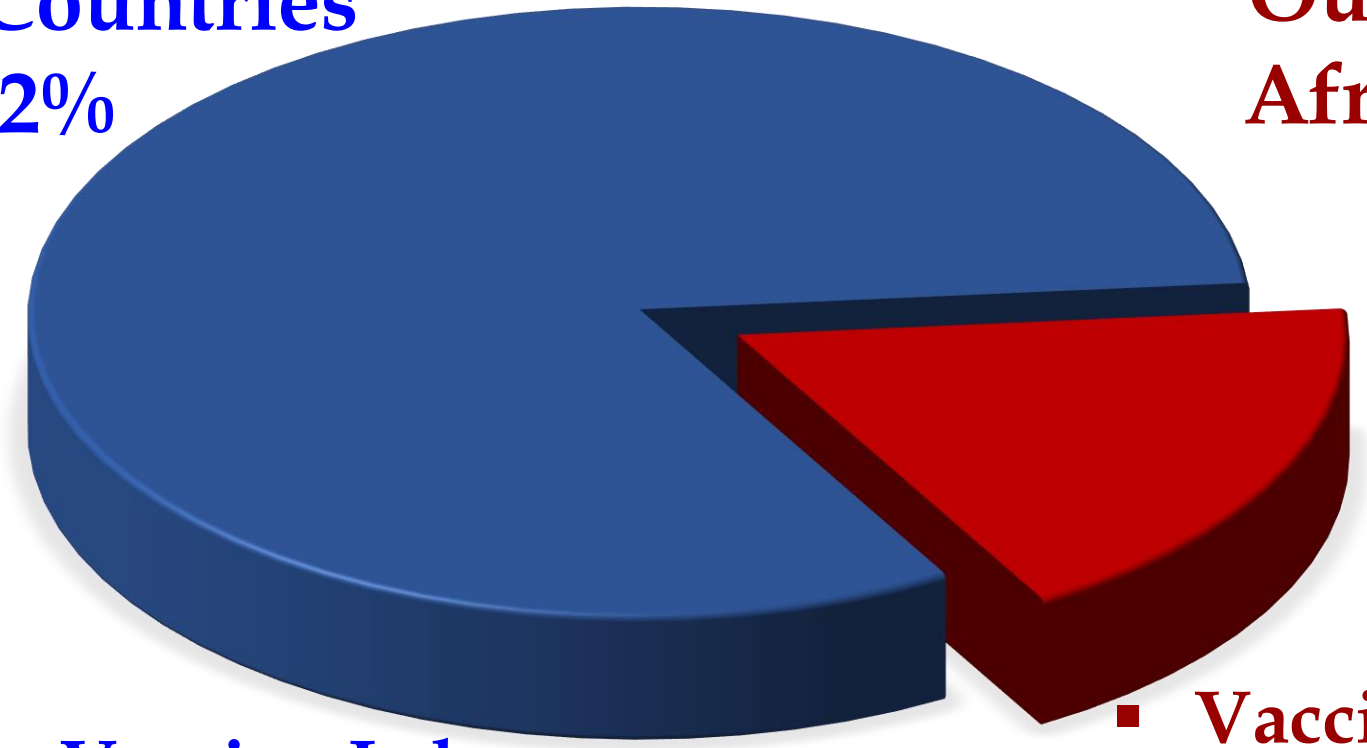
The Africa we Want

Africa Countries 82%

Outside of Africa 18%



- African Vaccine Labs
- CVOs, Drug authorities & NGOs

- Vaccine Producers: Middle-East, Asia, Europe & USA

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Vaccine Quality Control Activities…

- More than 40 Types of Veterinary Vaccines tested
- ≈ **350 batches** received **Yearly** (*One Month to finalize QC tests for each batch*)
- **Vaccines Quality Pass Rate: 87.4%**
- **Failure: 12.6 %**

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Quality Control Test Report & Certificate

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Vaccine Quality Control Test

FAILS → Test Report

PASS → Test Report & Certificate

Test Report & Certificate → **BATCH RELEASE**

Publication Certificates of batches PASS QC tests :

WWW.AUPANVAC.ORG

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Development of a framework document for the production of reagents for priority diseases

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The Africa we Want

❑ 2013

- ➢ Participation of 12 AU-MS Diagnostic Laboratories
- ➢ Priorities Animal Diseases and Reagents/Assays to be development for Production were identified

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Diagnostics Currently Developed & in Production

1- PPR bELISA for diagnosis of Pest des Petits ruminant's disease (2018).

- *Detection of antibodies against PPR H protein in sheep and goat serum samples.* ***Virology Journal, https://doi:10.1007/s00705-018-3782-1****.*
- *Reduce by* ***75% the cost*** *of testing small ruminants sera for PPR serology diagnosis*

2- Contagious Caprine Pleuropneumonia (CCPP)-bELISA for detection antibodies against Mycoplasma capricolum subsp. capripneumoniae (*Mccp*). (2019) ***Veterinary sciences, https://doi:10.3390/vetsci6040082***

3- Immuno-Capture ELISA (ICE) for quantification of Mccp protein in CCPP vaccine. (2020) ***Veterinary Medicine International, https://doi.org/10.1155/2020/4236807***

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Development & Distribution of Diagnostics…

❑ Production of diagnostics

- Automate platform (pre-coating plate) for production of **ELISA Kits**

- **ELISA Kits Production Capacity:**

➢ **25 kits/Day (a kit allows to test 2000 sera)**

➢ **Testing 1.000.000 animal sera monthly**

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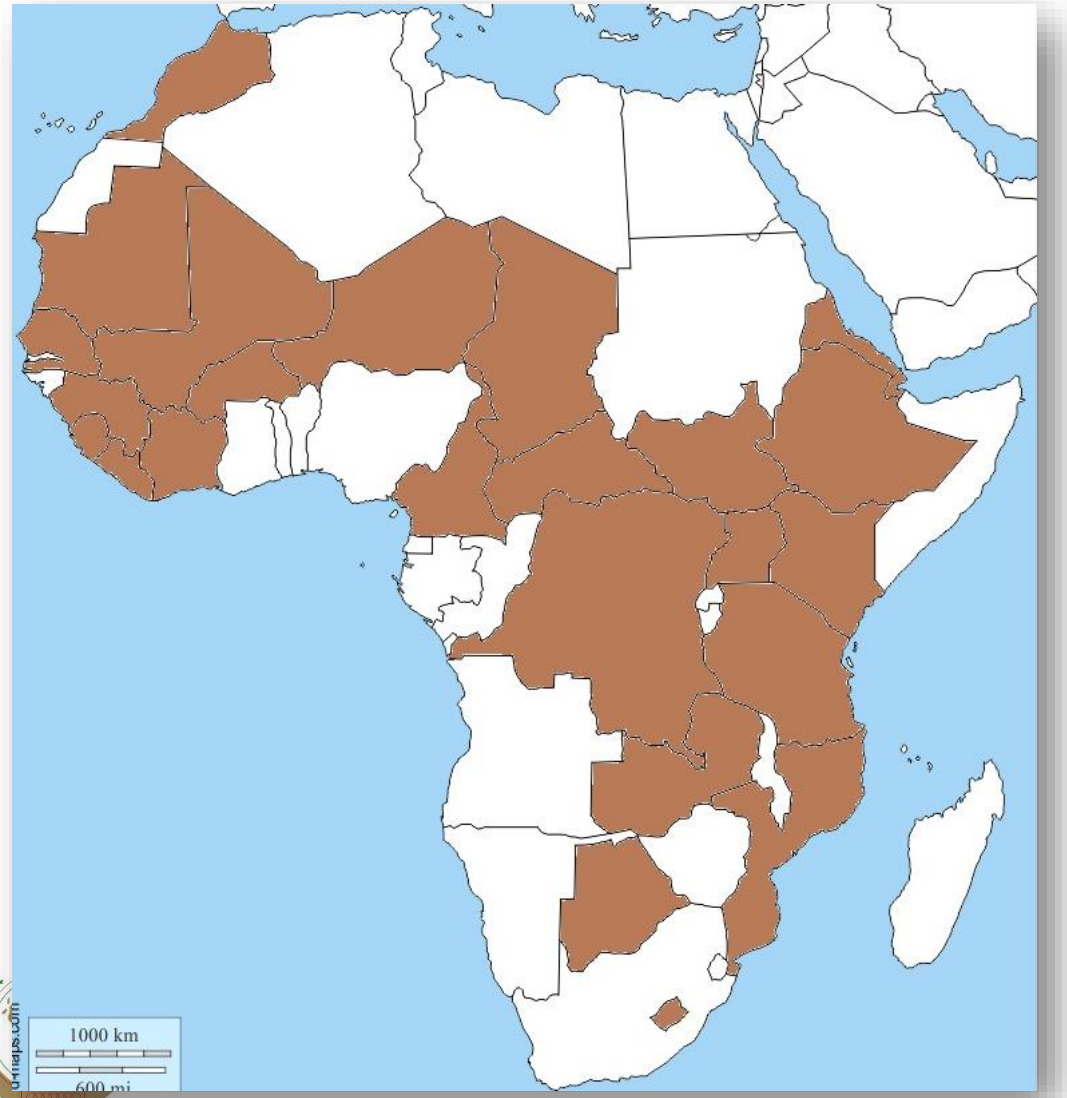
Diagnostics Distribution for PPR Surveillance



- Production of PPR-bELISA financial supported by FAO.
- **2018- 2022:**
  - **60 kits** distributed to **24 Countries** in Africa for testing up to 120 000 Sera
  - **12 kits** distributed to **6 countries** outside of Africa: *(Brunei, Tajikistan, Mongolia, Bhutan, Nepal, Georgia)*

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Interlaboratory Comparison

❑ Vaccine Quality Control

- ➢ Conducted annually in compliance with ISO/IEC 17025
- ➢ Vaccines laboratories are invited to participate to the programme
- ➢ Panel of vaccine samples are sent to countries with temperature data logger
- ➢ Tests Performed :
  - Vaccine potency
  - Vaccine identity = by PCR
  - Freedom from contamination (bacteria/fungi, mycoplasma and BVDv)

❑ Inter-Laboratories Test Comparison (ILTC) for diagnostic labs.

Development of PT panels to support external quality assurance of diagnostics and surveillance tests

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Synergies and partnerships in Projects Implementation

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AFRICAN UNION
INTERAFRICAN BUREAU FOR ANIMAL RESOURCES

AFRICA CDC
Centres for Disease Control and Prevention
Safeguarding Africa's Health

AU-MSD

AU-MS Vaccine Producing Labs

Regional Animal Health Centre in the RECs

World Organisation for Animal Health
Founded as OIE

Food and Agriculture Organization of the United Nations

US-DTRA

Sandia National Laboratories

BILL & MELINDA GATES foundation

giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

GALVmed

ILRI
INTERNATIONAL LIVESTOCK RESEARCH INSTITUTE

CGIAR

OIE Collaborating Center for Quality Control Of Veterinary vaccine (OIE Gen. Ass. Resolution 32, May 2013)

FAO Reference Centre for Technical Assistance in Quality Control of Veterinary Vaccines (11th May 2015)

THANKS FOR YOUR ATTENTION