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WOAH Collaborative Centre Reports Activities 2024

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CENTRE INFORMATION

*Title of WOAHCollaborating Centre	Quality Control of Veterinary Vaccines in the Middle East
*Address of WOAHCollaborating Centre	Central Laboratory for Evaluation of Veterinary Biologics (CLEVB), Cairo, Egypt
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Website:	www.clevb-arc.com
*Name Director of Institute (Responsible Official):	Prof. Dr. Samir Abdel Moez Nassef
*Name (including Title and Position) of Head of the Collaborating Centre (WOAH Contact Point):	Prof. Dr. Samir Abdel Moez Nassef, Director of CLEVB
*Name of the writer:	Prof. Dr. Samir Abdel Moez Nassef

TOR 1 AND 2: SERVICES PROVIDED

1. Activities as a centre of research, expertise, standardisation and dissemination of techniques within the remit of the mandate given by WOAHC

Category	Title of activity	Scope
		* Veterinarians of post graduated, and

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Training, capacity building (true)	Training about Veterinary Biologics Evaluation	from different Research Institute and Centers * Students of Faculties of Veterinary Medicine, Agriculture and Science * Veterinarians from Different Middle East Countries
Veterinary medicinal products (true)	Evaluation of Veterinary Biologics	Evaluation of different veterinary biologics e.g. Vaccines, Serum, Antigens and diagnostics
Vaccines (true)	Evaluation of Veterinary Biologics	Evaluation of all types of veterinary vaccines either poultry or large animals etc.

TOR 3: HARMONISATION OF STANDARDS

2. Proposal or development of any procedure that will facilitate harmonisation of international regulations applicable to the main focus area for which you were designated

Proposal title	Scope/Content	Applicable Area
The use of single dose dependant evaluation of rabbit Pasteurellosis vaccines in comparison with booster dose evaluation assay in mice	Rabbit Pasteurellosis vaccine	Veterinary Products
Using PCR for detection of mycoplasma species contaminants in live attenuated poultry viral vaccines	All live attenuated poultry viral vaccines	Veterinary Products

3. In exercising your activities, have you identified any regulatory research needs* relevant for WOA?H?

Yes

Research need 1

Please type the Research need: Risk analysis for the impact of presence of endogenous avian leukosis virus as a contaminant in live attenuated poultry viral vaccines

Relevance for WOAH Extraneous virus contaminant detection,

Relevance for the Code or Manual Manual,

Field Vaccines,

Animal Category Terrestrial,

Disease:

Infectious bursal disease (Gumboro disease)

Marek's disease

Newcastle disease

Turkey rhinotracheitis

Kind of disease (Zoonosis, Transboundary diseases) Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer: Terrestrial Manual Chapter 1.1.9. Tests for sterility and freedom from contamination of biological materials intended for veterinary use

Notes:

Answer: Recent ELISA screenings of live attenuated IBDV and Marek's disease vaccines from US and European manufacturers revealed widespread contamination with avian leukosis virus (ALV). The detected ALV was primarily endogenous, as confirmed by PCR analysis, likely derived from the SPF eggs used in vaccine production. While endogenous ALV is typically considered permissible under the regulatory standards (CFR, European Pharmacopeia), its potential impact on vaccine efficacy and safety remains unclear. A collaborative research effort involving the World Organization for Animal Health (WOAH) and its collaborating centres are proposed to investigate the immunosuppressive potential of endogenous ALV and its potential role in the emergence of new ALV subgroups, such as the hypophysis ALV.

Research need 2

Please type the Research need: Establishment of a list for pathogenic bacteria and fungi that may be a contaminant for live attenuated poultry vaccines.

Relevance for WOAH Bacterial Sterility detection,

Relevance for the Code or Manual Manual,

Field Vaccines,

Animal Category Terrestrial,

Disease:

Avian mycoplasmosis (*Mycoplasma gallisepticum*)

Avian mycoplasmosis (*Mycoplasma gallisepticum*, *Mycoplasma synoviae*)

Avian mycoplasmosis (*Mycoplasma synoviae*)

Escherichia coli

Infectious bursal disease (Gumboro disease)

Marek's disease

Newcastle disease

Turkey rhinotracheitis

Kind of disease (Zoonosis, Transboundary diseases) Transboundary diseases,

If any, please specify relevance for Codes or Manual, chapter and title

(e.g. Terrestrial Manual Chapter 2.3.5 - Minimum requirements for aseptic production in vaccine manufacture)

Answer: Terrestrial Manual Chapter 1.1.9. Tests for sterility and freedom from contamination of biological materials intended for veterinary use

Notes:

Answer: At CLEVB, the Egyptian Standards Regulations for Evaluation of Veterinary Biologics is followed. Concerning the sterility test for live attenuated poultry viral vaccines, presence of one colony per dose of pathogenic bacteria or fungi led to rejection of the vaccine under test. There is a list for the most pathogenic bacterial for poultry and we need to share that list with WOA members for confirmation and assuring: * Staphylococcus aureus. * Pseudomonas aeruginosa. * Escherichia coli. * Salmonella sp. * Enterobacteriaceae family (Bile-tolerant) * Candida albicans * Clostridial strains. * Avibacterium paragallinarum * Bordetella avium * Borrelia anserina * Erysipelotrix insidiosa * Mycobacterium avium * Ornithobacterium rhinotracheale * Mycoplasmae * Listeria monocytogens * Yersinia pseudotuberculosis * Campylobacter species * Chlamydia psittaci * Pasteurella species * Streptococcus and Enterococcus species associated with poultry disease (Both of them are the most common contaminants detected in the CLEVB, so we need more investigations about the pathogenic subspecies of each)

4. Did your Collaborating Centre maintain a network with other WOA Collaborating Centres (CC), Reference Laboratories (RL), or organisations designated for the same specialty, to coordinate scientific and technical studies?

Yes

Name of WOA CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
Faculty of Veterinary Medicine, Cairo University	Egypt	Oriente Medio	Training, Master and PhD Supervision, Research Projects, Experience exchange
General Organization OF Veterinary Services (GOVS)	Egypt	Oriente Medio	License of Veterinary Biologics GOVS is liaison the between CLEVB and the vaccines manufacture/importers
FAO	Egypt	Oriente Medio	FAO supports CLEVB with the resources that facilitate the vaccine evaluation processes
GD Laboratories	Netherlands	Europa	Proficiency Test
			Training, Research Projects,

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FLI Laboratories	Germany	Europa	Experience Exchange, Internships. Biosafety and biosecurity, Diagnostics (There is a Memorandum of Cooperation)
Istituto Zooprofilattico Sperimentale	Italy	Europa	Proficiency Test for Avian Influenza vaccine and viruses including H5 and H9; besides Newcastle Disease vaccine and viruses

TOR 4 AND 5: NETWORKING AND COLLABORATION

5. Did your Collaborating Centre maintain a network with other WOAHA Collaborating Centres, Reference laboratories, or organisations in other disciplines, to coordinate scientific and technical studies?

Yes

Name of WOAHA CC/RL/other organisation(s)	Location	Region of networking Centre	Purpose
Animal Health Research Institute (AHRI)	Egypt	Middle East	Training, Interlab comparison, Research Projects, Experience exchange AHRI provides our lab with field strains of challenge viruses
GIBACHT	Germany	Europe	Training on biosafety and biosecurity
CDC	USA	Americas	Online training on biorisk management system
Sandia National Labs	USA	Americas	Training on Biosafety and biosecurity
Academy of Scientific Research and	Egypt	Middle East	Research Projects

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Technology (ASRT)			
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TOR 6: EXPERT CONSULTANTS

6. Did your Collaborating Centre place expert consultants at the disposal of WOA?H?

Yes

Name of expert	Kind of consultancy	Subject
Prof. Dr. Afaf A. Khedr	Alternative to antimicrobial resistance (AMR)	Write a reflection paper on Autogenous vaccines

TOR 7: SCIENTIFIC AND TECHNICAL TRAINING

7. Did your Collaborating Centre provide advice/services to requests from Members in your main focus area?

Yes

* Agreement for a request from Klybeck Life Science Factory, Saudi Arabia to evaluate the factory's Veterinary products (Sheep Pox, goat pox, lumpy skin disease, PPR vaccines)

* Initial agreement for a request from Libyan Veterinary Authority for training of some Libyan Veterinarians on Evaluation of Veterinary Vaccines during 2025.

8. Did your Collaborating Centre provide scientific and technical training, within the remit of the mandate given by WOA?H, to personnel from WOA?H Members?

No

TOR 8: SCIENTIFIC MEETINGS

9. Did your Collaborating Centre organise or participate in the organisation of scientific meetings related to your main focus area on behalf of WOA?H?

Yes

National/International	Title of event	Co-organiser	Date	Location	No. Participants
Internationally	Second World Veterinary Poultry Association Africa and Middle East Meeting	Central Laboratory for Evaluation of Veterinary Biologics (CLEVB)	2024-09-02	Cairo, Egypt	22
	Ninth International Scientific Conference of the Faculty of	Central Laboratory			

Internationally	Veterinary Medicine, Cairo University, (One World, One Health) a new era of veterinary medicine in sustainable development	for Evaluation of Veterinary Biologics (CLEVB)	2024-02-12	Ras Sidr, South Sinai, Egypt	10
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TOR 9: DATA AND INFORMATION DISSEMINATION

10. Publication and dissemination of any information within the remit of the mandate given by WOAHA that may be useful to Members of WOAHA

a) Articles published in peer-reviewed journals:

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b) International conferences:

1

Ninth International Scientific Conference of the Faculty of Veterinary Medicine, Cairo University, (One World, One Health) a new era of veterinary medicine in sustainable development (Prevalence, isolation, serodiagnosis and treatment of contagious pustular dermatitis in sheep and goat in Egypt 2023)

https://www.researchgate.net/publication/378299428_Prevalence_isolation_serodiagnosis_and_treatment_of_contagious_pustular_dermat

c) National conferences:

d) Other (Provide website address or link to appropriate information):

2

http://scielo.sld.cu/scielo.php?script=sci_abstract&pid=S1025-028X2024000100001&lng=es&nrm=iso&tlng=en

https://www.researchgate.net/publication/377526173_Protective_Efficacy_of_a_Locally_Prepared_Bivalent_Duck_Viral_Hepatitis_Serotypes

11. What have you done in the past year to advance your area of focus, e.g. updated technology?

1. Using of RT-PCR as an alternative method for qualification of live attenuated viral (RNA) vaccines.
2. Using of Lab Animals such as Guinea pigs as a model for evaluation of some large animal vaccines.
3. Using of lateral flow technique for evaluation of some pet animal vaccines

12. Additional comments regarding your report:

CLEVB BEGAN communication with WOAHA-ME regional manager to arrange for the first webinar to be held within the next month (February, 2025).

CLEVB website had already launched (www.clevb-arc.com)

CLEVB-ARC Facebook Page had already launched (<https://www.facebook.com/profile.php?id=61564524030699&mibextid=ZbWKwL>)

CLEVB participated in the 2nd World Veterinary Poultry Association (WVPA) Conference – Africa and Middle East, Cairo, Egypt that was held in Egypt during the period 3-6 September 2024. During this conference, a promotion video about the activities and services provided by CLEVB was shown on the main show screen in between the different seminars, besides a booth in the conference expo

