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STANDARDIZATION OF QUALITY CONTROL OF VETERINARY VACCINES PRODUCED IN THE NEAR EAST

by

Elham Ataa El-Ebiary

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Abstract

As a result of continuous encouragement of the Egyptian government, there is great development in poultry and animal industry. Accordingly, there is high demand of different varieties of efficient veterinary biologics to meet requirements needed to combat infections diseases affecting live stock and chicken. Some of these biologics are produced locally by veterinary serum and vaccine research institute (VSVRI), while others are imported. Evaluation of such products started early and up to 1996 in a specified department affiliated with VSVRI.

Recently a specified national laboratory for control of biologics was established under the name of " Central laboratory for evaluation of veterinary biologics "

The activities of this lab is achieved through

1. Testing and evaluation of veterinary biologics by applying standard regulations to assure that only pure, safe, potent and efficient biologics are marketed.

2. Issue of certificate for veterinary biologics before being permitted for use.

3. The lab is going to have a vital role in monitoring SPF eggs and chicken produced by SPF farm constructed at koom Oshim in Fayom governerate.

4. Establishment of a national bank strains and cell lines with special focus on the local field isolates.

The main future plan of our laboratory is to conduct researches to improve methods applied for evaluation by using techniques of vet. biotechnology and molecular biology aiming to develop more accurate and effective technique.

The function of the quality control (QC) provides testing that determines the appropriateness of a vaccinal batches for release. It is concerned with sampling, specifications mid testing, as well as with the organizational, documentation and relent procedures that ensure the necessary and relevant tests have been carried out and that materials are not released for use, or products not released for sale or supply, until their quality has been judged satisfactory. QC is not confined to the laboratory operations, but must be involved in all decision that may affect the quality of the product QC is standardized methologies to test the final product, the general instruction for these tests are outlined either in a country regulatory guidelines or in pharmacopoeias.

The documentation generated by quality control consists of bench record which provide the results from tests and should include the formulate used and the type of tests performed as well as referencing the established test methodology Other type of documentation generated by quality control are raw material assays, quality control sampling logs, certificate of analysis, equipment quality control laboratory instrumentation calibration programme data, log books and scheduling of animals headlong facility and the supporting documentation. Also the control documentation should contain confidential information concerning a company s process ,policies, ideas and methods.

The important aspect of quality control include :

* Control laboratories should apply good quality — control laboratory practice
* In- process controls play an especially important role.

Important control that cannot be carried out on the final product should be performed at an appropriate stage of production in case of locally produced vaccine Laboratory management is responsible for providing appropriate facilities, qualified and well trained personnel, good equipment's, reagents and materials and for maintaining personnel record and ensuring that written and approved standard operating procedures (SOPs), protocols and schedules are established and documented for all aspects of evaluation. The laboratory organization should include a persons responsible, for ensuring that good laboratory practices (GLP's) are in place - Control manger is responsible for all aspects affecting product quality, including maintenance, calibration, validation, monitoring of equipment's, instrument and testing of final product.

Harmonization and standardization of requirements for veterinary vaccines have two important goals:

- To keep the quality of the vaccines at a high level.
- To prevent or reduce potential trade herders.

Every new biological product developed in a country or imported front mother has to register according to die legalization and requirements in the country where the vaccine will be used. The registration file must report on the results of experiments directly related to the product itself and include :-

- An analytical section characterizing the different components and the substrate on which the antigens are produced.
- A toxico — pharmacological note, indicating the absence of remaining pathogenically or abnormal toxicity.
- A section on the product efficacy, describing with relation to immunity and protection (degree, duration, etc ...)

The analytical section should include:

1. The registration file should list the test that are cried out on the representative samples of each batch of final product The frequency of tests which are not routinely carried out on each batch should be tested and the expiry dates should be indicated.

2. Certain tests of general characteristic of the product should be included among the test of the final product, even if they are not carried out ii the course of the manufacturing process.

3. Description of techniques for assessing the final product should be set out in sufficiently precise detailed.

4. The quality and nature of the adjuvant and its constituents should be subjected to identification tests described in details in the file.

5. Sterility tests prior to the batch release have to be described in the registration file to demonstrate the absence of contamination by adventitious agents or other substances, and what applicable, a test of verify complete inactivation should be carried out on the product in its final container and results given.

6. Potency test also have to be described to ensure that efficacy of the product is reproducible from batch to batch as Is of acceptable minimum.

7. The registration file should include a description of all safety tests carried out on the target species.

8. Stability test A description should be given to support the shelf— life wider all likely storage condition should be given

9. Laboratory tests Trials should be undertaken in which the immunological veterinary products m administered at the recommended dose and by the recommended route of administration, to the animals of each species and category in which it is intended to use.

10. Inspection certificates provided by the authorities from the country of origin must be included in the registration file.

11. Field studies should include supported data to supplement the results of laboratory studies.

Bibliographical references should be given scientific data are required to explain some of forward by manufacture in support of the product.

The registration files are examined by experts appointed by the Ministry of Agriculture and particularly the General Organization for Veterinary Services.

In Egypt due to the recent development in poultry and anmal in dustry, there is a high demand of pest varieties of efficient veterinary biologics to meet the requirements needed for combating contagious and infectious diseases affecting live stock and chickens.

As about 5,000 million doses of different biologics are imported annually from different European and American countries and these quantity expected to be increased by full implementation of GATT agreement. Also around 155 million doses of Vet, Biologics are locally produced through Vet. Serum and Vaccine Res. Inst.

Therefore strict inspection and evaluation of these vaccines, is a vital process for protecting these animal industry (that represented 23.5% from agricultural income) from introducing and marketing of contaminated or impotent vaccines. For this reason the central laboratory for Control of Veterinary Biologics was established. Till 1996 the evaluation of Vet, biologics was applied in specified department affiliated with Vet. Ser. & Vac. Res. Inst. Recently, the independence of the quality control laboratory from the vaccine product units is considered fundamental to get satisfactory operation of quality control.

The CLCVB was officially opened in I6 of January 1999 by his excellency Dr. Ganzory, the prime minister as this lab is the only authorized laboratory in the Arab Republic of Egypt responsible for evaluation Veterinary biologics.

The Laboratory was funded by 10 million LE. Through EEC Food Aid counterpart Fund's Project mid 2tnillion L.E through National Agriculture Research Project (NARP) The building was constructed on about 3 lOOm2. The laboratory consists of three floors and a basement The first and the second floors include the quality control specified Laboratories and the isolated clean area. The third floor contains: library, conference room, staff offices, administration offices and isolators

The building was designed and constructed to prevent cross contamination during the process of evaluation. Halls, rooms and evaluation area are arranged to provide maximum biological security and minimal contamination of evaluation area. FWPA filters are used in conjunction with air conditioning system. Floors, walls, ceiling and doors are made of materials that prevent cross contamination and that can be easily cleaned and disinfected. The water supply is free from pollution and impurities and there adequate supply and distribution of cold and hot water. Thc sanitary system has necessary traps and vents and disposable method that minimize the pollution All the drainage of the building goes to a deep well fitted with an electric mixer which will be used for treatment of drainage with chemicals before going to the city council drainage system. All effort is made to minimize the fly and rodents population in the surrounding area

Engineering and maintenance are assisted in calibration and validation of various instruments in quality control. The laboratory is divided into 6 biological department which are:

1. Quality control Research department for poultry viral vaccines.
2. Quality control Research department for poultry bacterial vaccines.
3. Quality control Research department for large animal viral vaccines
4. Quality control Research department for large animal bacterial vaccines .
5. Quality control Research department for anti parasitic vaccines .
6. Sterility department for all biological products .

These are supported by other departments including :

1. Laboratory for Molecular biology Res.
2. National reference bank of bacterial and viral strains.
3. Laboratory for monitoring specific pathogen free eggs (SPF).
4. Clinical Pathology department.

Objectives

1. Testing and evaluation of imported and locally produced veterinary biologics by applying standard regulation to assure that only pure, safe, potent and effective biologics are marketed to live stock and poultry breeders.

2. Issue of certificates for veterinary biologics before being permitted for use.

3. Conducting and development protocols for evaluation to be suitable for Egyptian condition according to the standard protocols of regulation to be followed in the evaluation process.

4. The laboratory is going to have a vital role in monitoring SPF eggs, baby chicks and chicken that are intended to be produced by SPF farm at Koom Oshim in Fayom Governorate.

5. Research into standardization and control methods applying for evaluation of veterinary biologics to develop new, more accurate and effective methods.

6. Cooperating with different International and National organization to be aquatinted with up-dated standard method of evaluation.

Achievements

1- conducting protocols of testing and evaluation of veterinary biologics. A specialized groups consisting of central laboratory for cont. of Vet. Biologics, Vet. Serum and Vac. Res. Inst., animal Health Inst., General organization for Vet. Services and Faculty of Vet. Medicine have developed our own standard protocol based on the following documentation

- European pharmacopoeia.
- British Pharmacopoeia.
- USDA code of Federal Regulation.
- Office International De Epizootic (OIE).
- Food and Agriculture Organization of United Nation (FAO).

The main purpose of these working group would be to formulate legalization and requirements on the bases of the latest technology to ensure high quality and safety of the vaccines,

2- The central laboratory had an active training programs for the doctor staff on the techniques adopted in the field of evaluation steps, as outlined in the standard regulation.

3- with the support from National Agricultural Research project (NARP) there was a training project under the supervision of Prof. Dr. Ali Fadly the director of Avian disease and Oncology Laboratory, US. Department of Agriculture, Michigan. in the field of the use of biotechnology (PCR and probe) in detection of avian tumor viruses as extraneous viruses in poultry viral vaccine

4. The central laboratory is well equipped with all updated equipment through NARP project. EEC Food Aid Counterpart fund's project was the major support project assisting in establishment of CLCVB through three phases and also assisting the laboratory in upgrading its research capabilities and provided resources for establishing a machinery and development departments for upgrading testing center.

5- Constructed and upgrading of large animal facility to reach F, level in order to be suitable for animal challenge experiments, fitted With post mortum room and incinerator. The stable is constructed on about 1200m2, the area is designed to include isolators for calves, sheep, pet animals (dogs and cats), mice, rabbits, poultry, Ration store, quarantine, lab for collection of samples, staff room, labor room, and shower room. The stable is built away from the building of control laboratory as the recommended international regulation.

Activities

1- Testing and evaluation of all registered veterinary biologics also every new hatch of the registered vaccine must be controlled by the central laboratory.

For batch control, representative samples are collected by and under the responsibility of Veterinary quarantine (about 30 samples from live vaccines and six samples from inactivated one). The samples are examined for sterility to ascertain the absence of contaminating agents and to ensure the product's sterility as there is always awareness of the dangerous of the contaminating live poultry viral vaccines with agents present in seed culture of eggs used for production.

Safety and potency tests are carried out on target species. The potency test meet two requirements:

- It measures the immune response that is relevant to the efficiency of the vaccine
- Also provide assurance that size of that response is efficient to guarantee efficacy.

The challenge test has the advantage that it perceived to demonstrate efficacy directly. Unlike the inactivated vaccine which require an in-vivo potency test, the PD50 of live vaccine is assessed only once on the registered vaccine. The potency of the subsequent batches prepared from the registered one can be based on the virus titration on the organism in-vitro. Also, the identity test should be performed to ensure the type of the organism. Special chemical tests is applied on the diagnostic products

Determination of hydrogen ion concentration.
Total nitrogen determination
Trichloroacetic acid determination.

- Preservation requirement phenol, formalin determination, and the type of adjuvants also be determined specially in case of inactivated vaccines.

2- Issue of certificates for veterinary biologics before being permitted for use.

3- Identification and characterization of local field isolates using the biotechnology in order to establish the National Bank of strains and cell lines.

4- Preparation and characterization of monoclonal antibody and diagnostic kits to help in the accuracy of evaluation steps of identity and potency test.

5- Planning and conducting research project collaboration with producing department of VSVRI and Animal heath Research Institute and Faculty of Veterinary Medicine.

6- Publishing of research articles in national and international journals and participating in national and international vet. Conferences.

7- Sharing in supervision of number of Master Degree (25) and Ph.D. Degree. (11) registered by staff members in different faculties of veterinary medicine.

8- Training veterinarians from Arab, African and Asian countries on the evaluation methods of veterinary biologics.

Future Direction

1- Standardization of Biologicals including preparation and assessment of International standards by using biotechnology techniques

2- Issue international certificates.

3- Applying the GMP and QA on different locally producing companies.

4- Cooperate with international organization as FAO, OIE, etc to be acquainted with the latest techniques of evaluation.

POULTRY VACCINES

IMPORTE[illegible]AL BATCHES FROM 1/1[illegible]12/1999

	Vaccine	Local Vaccine		Imported Vaccine	
		No of batches	Doses	No of batches	Doses
1.	Lasota	2	21.090.000	89	1929.000.000
2.	Hitchner B1	6	23.550.000	58	1008.000.000
3.	Clone 30	0	0	30	495.000.000
4.	Live Gumboro	3	9.300.000	70	1628.000.000
5.	Komarov	7	37.224.000	0	0
6.	Inactivated ND	6	1.672.000	52	222.500.000
7.	Inactivated IBD	0	0	13	30.130.000
8.	Reo	2	350.000	19	10.420.000
9.	Maredk's d.	0	0	48	222.000.000
10.	ILT	0	0	26	45.760.000
11.	AE	0	0	14	16.500.000
12.	Fowl Pox	2	5.550.000	16	89.300.000
13.	DVH	1	935.000	2	500.000
14.	Duck Plaque	2	430.000	0	0
15.	Inact. ND+IBD	0	0	23	21.300.000
16.	Inact ND+EDS	0	0	10	3.400.000
17.	Inact. ND+IB+R+EDS	0	0	7	2.900.000
18.	Live IB	0	0	32	267.000.000
19.	Inact IB	0	0	0	0
20.	Chick Coccidiosis	0	0	16	12.475.000
21.	Fowl Cholera	9	20.000.000	11	10.750.000
22.	Coryza	7	4.117.000	20	16.000.000
23.	Form. Rab.Sept	1	837.800	0	0
24.	Oil Rab. Sept	4	644.100	0	0
25.	Avian Tuberclin	1	3000	0	0
26.	Mycoplasma	0	0	2	2.300.000
27.	ND + IB	0	0	17	7.530.000
28.	ND + G + IB	0	0	9	3.380.000
29.	Combined vaccine	0	0	27	124.220.000
30.	IB + EDS	0	0	1	1.000.000
31.	ND + IB + EDS	0	0	3	3.500.000
32.	Salmo	2	18.000	1	1.000.000
33.	Paramyxo	5	41.000	0	0
34.	Viral Haemo.Sept.	7	76.990	0	0

FARM ANIMAL VACCINES

IMPORTED AND LOCALLY PREPARED VACCINES FROM 1/1/1999 TO 31/12/1999

Vaccine		Local Vaccine		Imported Vaccine	
		No of batches	Doses	No of batches	Doses
1.	Sheep Pox	6	5.550.000	0	0
2.	Rinder Pest	15	425.000	0	0
3.	FMD	4	12000.000	0	0
4.	Inact. RVF	8	5.600.000	0	0
5.	Live RVF	3	4.500.000	0	0
6.	Combined vaccine for cattle	1	2000	1	47.000
7.	Live AHS	3	5580	0	0
8.	Inact. Rabies	3	1700	1	3.964
9.	Pentadog	0	0	1	2.000
10.	Bovine septi caemia	1	575.400	0	0
11.	Poly valent anaerobic vacc.	2	18.540	0	0
12.	Black leg & gas gang	1	38.040	0	0
13.	Brucella	0	0	2	3.000
14.	Rose bengal antigen	5	125.600	0	0
15.	Balanced PH	7	6000	0	0
16.	Brucella antigen	5	1520	0	0
17.	Rivanol brucella antigen	3	520	0	0
18.	Antitetanic serum	11	8500	0	0
19.	Bovine tubercline	5	150.000	0	0
20.	Colored salmonello antigen	1	115.000	0	0
21.	Non Colored salm. antigen	1	4000	0	0
22.	Camel Pox	2	300	0	0
23.	Scourgaurd	0	0	2	20.000
24.	Polyvalent vaccine for sheep	1	24.000	0	0

Kinds of vaccines evaluated by CLEVB

(I) Imported Vaccines

Live Viral Poultry Vaccines :

Vaccines
(A) Monovalent Vaccines :
LaSota
Hitchner B1
Clone – 30 or 58
Infectious Bronchitis
Infectious Laryngeotracheitis
Fowl Pox
Avian Encephalomyelitis
Gumboro
Marek's disease
Reo
Duck virus Hepatitis
Duck Plague
(B) Bivalent Vaccines :
Infectious Bronchitis + LaSota
Infectious Bronchitis + Hitchner B1
Avian Encephalomyelitis + Pox

Inactivated Viral Poultry Vaccines :

Vaccines
(A) Monovalent Vaccines :
Newcastle Disease
Gumboro
Infectious Bronchitis
Avian Encephalomyelitis
Rabbit viral haemorrhagic disease
EDS
REO
(B) Bivalent Vaccines :
Infectious Bronchitis + Newcastle Disease
Gumboro + Newcastle Disease
EDS + Newcastle Disease
(C) Trivalent Vaccines :
Newcastle Disease + Infectious Bronchitis + EDS
Newcastle Disease + Gumboro + Infectious Bronchitis
Newcastle Disease + REO + Infectious Bronchitis
(D) Tetravalent Vaccines :
Newcastle Disease + Gumboro + Infectious Bronchitis + EDS
ND + IB + TRT

poultry bacterial inactivated vaccines :

Vaccines
Fowl Cholera
Fowl Coryza
Mycoplasma

Poultry Bacterial living attenuated Vaccines :

Vaccines
Fowl Cholera
Mycoplasma

Farm Animal Viral Inactivated Vaccines :

Vaccines
Foot and Mouth Disease
Cattle tetravalent Vaccine (IBR + BVD + PI_3 + RSV

Polyvallent Anaerobic Bacterial Vaccine :

Vaccines
Ultrabac - 8
Clostridium bac
Covaxin

Farm animal live bacterial vaccines :

Vaccines
Brucella S_{19}
Brucella $^{45}/_{20}$
Brucella melitensis RIV

Farm animal inactivated bacterial vaccines :

Vaccines
Brucella $^{45}/_{20}$
Bovine Enteritis (E coli)

Pet Animal Vaccines :

Vaccines
(A) Monovalent Vaccines :
Inactivated Rabies Vaccine
Live Parvo Vaccine
Feline distemper
Canine Hepatitis
(B) Canine Pentavalent Vaccines :
Hepatitis + Parvo + Distemper + Liptospira + Rabies
(C) Feline Trivalent Vaccines :
PanLeucopenia , rhinotracheitis and calicivirus infections

Parasitic vaccines :

Vaccines
Chicken Coccidiosis

II LocaI Vaccines

Live Viral Poultry Vaccines :

Vaccines
(A) Monovalent Vaccines :
LaSota
Hitchner B1
Komarov
Infectious Bronchitis
Fowl Pox
Gumboro
Pigeon Pox

Inactivated Viral Poultry Vaccines :

Vaccines
Monovalent Vaccines :
Newcastle Disease
Rabbit viral haemorrhagic disease
Pigeon paramyxo

poultry bacterial inactivated vaccines :

Vaccines
Fowl Cholera
Fowl Coryza
Oily & Formalinized Rabbit Haemorrhagic septicaemia

Farm Animal Viral Inactivated Vaccines :

Vaccines
Rift Valley Fever
Foot and Mouth Disease
African horse sickness

Farm Animal Viral Live Vaccines :

Vaccines
Sheep Pox
Lumby Skin
Cattle Plague
African Horse Sickness
Rift Valley Fever

Pet Animal Vaccines :

Vaccines
(A) Monovalent Vaccines :
Live Rabies Vaccine

Farm animal inactivated anaerobic bacterial vaccines :

(a) bivalent vaccines :

Vaccines
Lamb Dysentry & Pulby Kidney
Black Quarter & Gas gangarene

(b) polyvalent vaccine

Vaccines
Black Leg & Gas gangrene & Lamb Dysentry & Pulby Kidney & Black Disease & Tetanus

Farm animal live bacterial vaccines :

Vaccines
BCG

Farm animal inactivated bacterial vaccines :

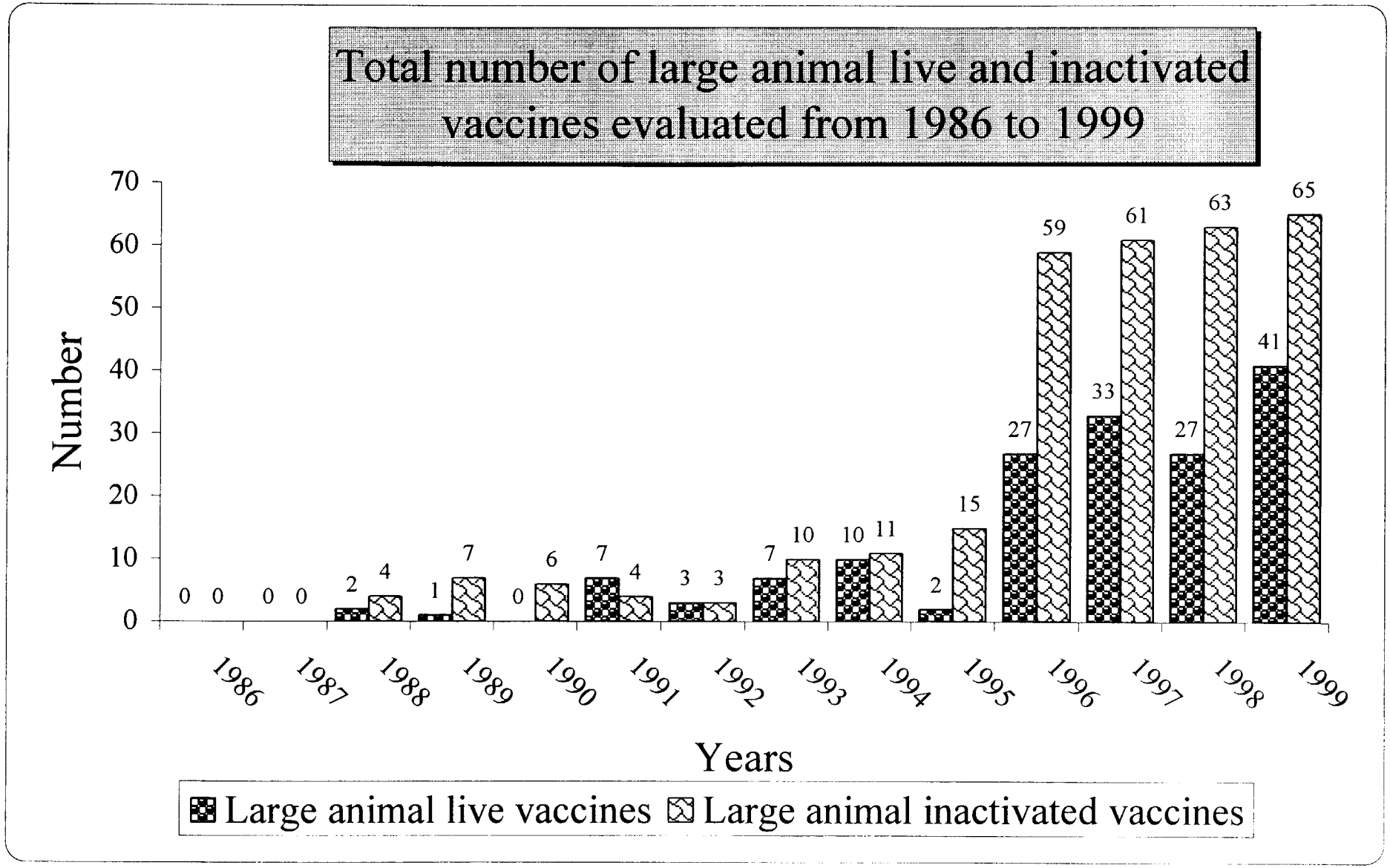
Vaccines
Haemorrhagic Septicaemia

Parasitic vaccines :

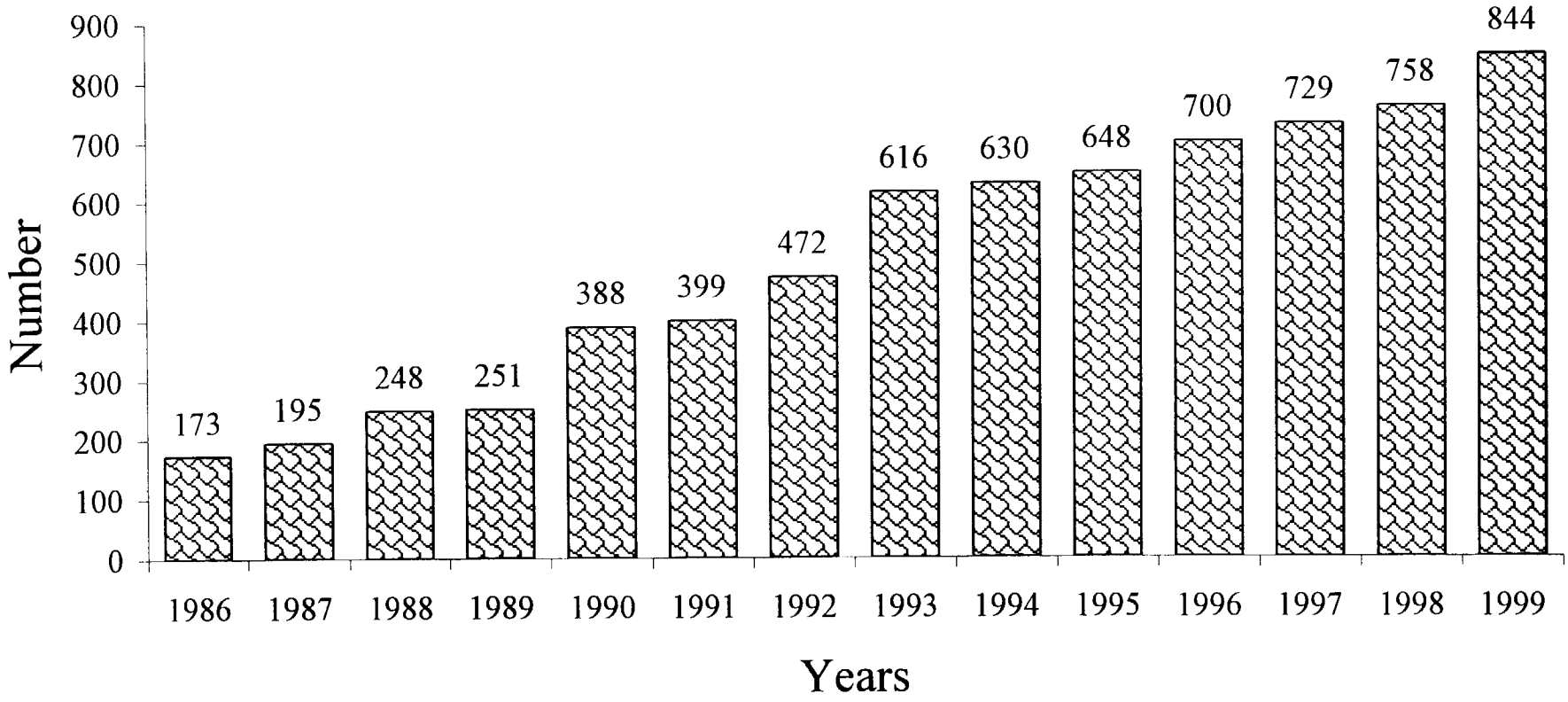
Vaccines
Fowl Spirochetosis

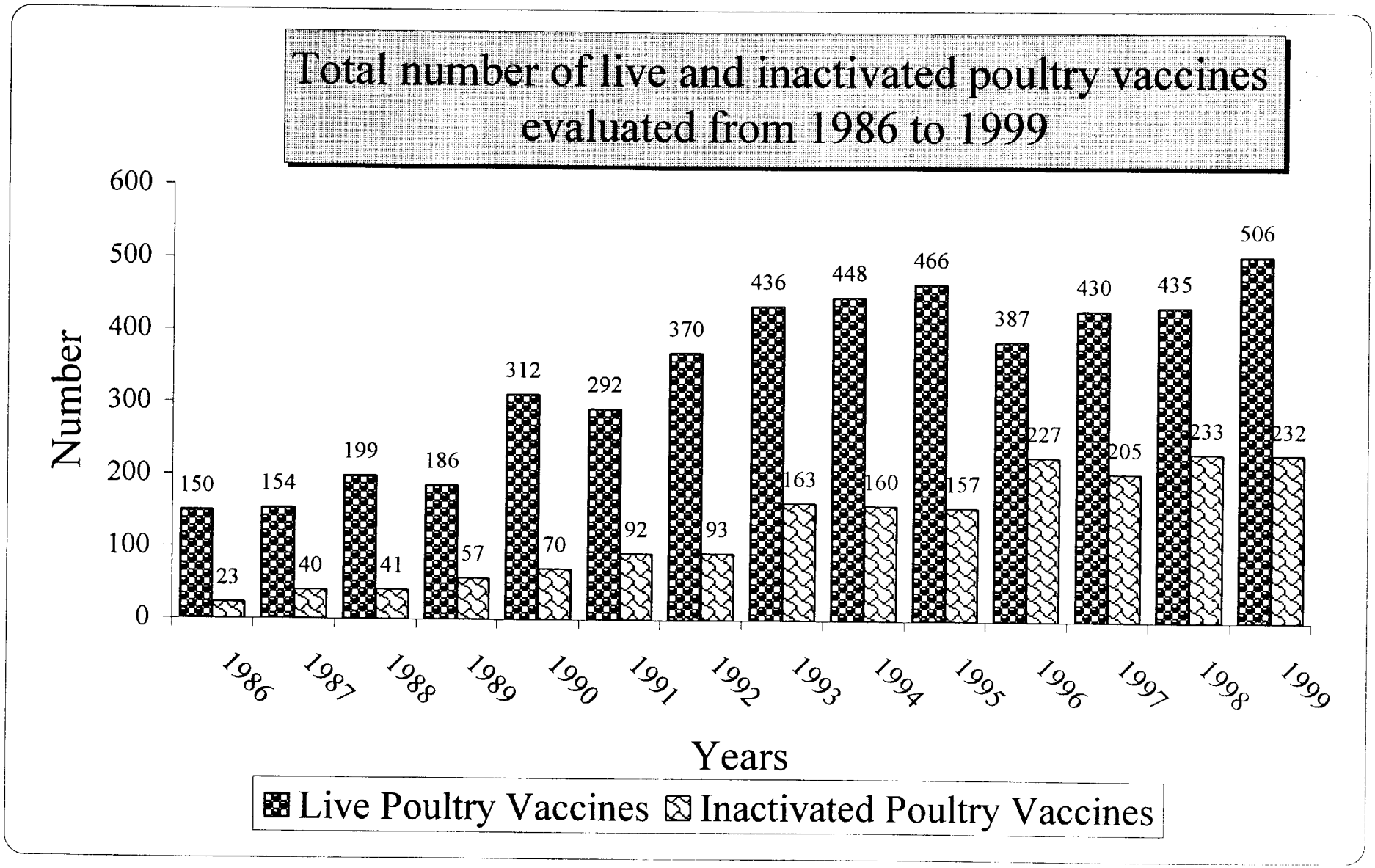
Antigen and antisera :

Vaccines
Brucella antigen (TAT,RBpT,BAPA,MRT,RIV)
Tuberculin antigen (mammalian & Avian)
Salmonella antigen


Total number of large animal live and inactivated vaccines evaluated from 1986 to 1999
Number
70
60
50
40
30
20
10
0
0 0 0 0 2 4 1 7 0 6 7 4 3 3 7 10 10 11 2 15 27 59 33 61 27 63 41 65
1986 1987 1988 1989 1990 1991 1992 1993 1994 1995 1996 1997 1998 1999
Years
Large animal live vaccines
Large animal inactivated vaccines

Total number of vaccine samples evaluated from 1986 to 1999




Total number of live and inactivated poultry vaccines evaluated from 1986 to 1999
Number
600
500
400
300
200
100
0
150
23
154
40
199
41
186
57
312
70
292
92
370
93
436
163
448
160
466
157
387
227
430
205
435
233
506
232
1986
1987
1988
1989
1990
1991
1992
1993
1994
1995
1996
1997
1998
1999
Years
Live Poultry Vaccines
Inactivated Poultry Vaccines

وزارة الزراعة
مركز البحوث الزراعية
المعمل المركزي للرقابة على المستحضرات
الحيوية البيطرية

السيد الأستاذ الدكتور /

تحية طيبه .. وبعد

أتشرف بأن أرفق طيه شهادة رقم ..... بفحص وصلاحية المستحضر البيطرى (المستورد / المحلى) ، دفعة رقم (.....) الوارد للمعمل المركزى بالخطاب رقم (.....) بتاريخ / / ١٩

برجاء الإحاطة والتفضل باتخاذ اللازم نحو الإفراج عن هذا المستحضر.

وتفضلوا سيادتكم بقبول فائق الاحترام ،،

مدير المعمل المركزى
ورئيس مجلس إدارة الوحدة

{ أ.د/ إلهام عطا الأبيارى }

تحريرا فى / / ١٩

وزارة الزراعة
مركز البحوث الزراعية
المعمل المركزي للرقابة على المستحضرات
الحيوية البيطرية

CLEVB 1996 CAIRO
المعمل المركزي للرقابة على
المستحضرات الحيوية البيطرية

شهادة

صلاحية مستحضرات حيوية بيطرية

/ / / ٢٠٠٠

نوع اللقاح : ..... اسم المستحضر : .....

رقم الدفعة : ..... الجهة المنتجـــة : .....

الجهة المستوردة :.....

الجهة الراسلـــه :.....

يشهد المعمل المركزى للرقابة على المستحضرات الحيوية البيطرية بالعباسية أنه قد تم فحص واختبار العينات المرسلة من دفعات المستحضرات (المستوردة – المحلية) والموضحة عالية وثبت أنها صالحة ومطابقة للمواصفات القياسية لبروتوكولات المعايرة .

وبـــناء على ذلك يصرح باستعمالها بجمهورية مصر العربية شريطة أن تكون محفوظة بدرجة الحرارة المناسبة طوال فترة التخزين .

وهذه شهادة منا بذلك .

مدير المعمل المركزى للرقابة
ورئيس مجلس إدارة الوحدة

(أ.د/ إلهام عطا الإبيارى)

تحريرا فى : / /

Arab Republic Of Egypt
Ministry Of Agriculture
Agricultural research center
Central Laboratory For Evaluation
Of Veterinary Biologics

جمهورية مصر العربية
وزارة الزراعة
مركز البحوث الزراعية
المعمل المركزى للرقابة على
المستحضرات الحيوية البيطرية

QUALITY CONTROL CERTIFICATE

Name & Mailing address of licensee : Central Laboratory For Evaluation Of Veterinary Biologics
P.O. Box. 131 Abbasia – Cairo **Tel. No.** : 4849204 **Fax No.** : 4849204

1. Product Name : TAD Reo vac I	2. License No. /	3. Product Code No. /	4. Serial or batch No. 9096911
5. True name of the product: Reo Vaccine	6. No. of Bottle: 30	7. No. of doses /Bottle 1000	8. Packing Vials.
	9. Date of manufacture:	10. Date of Expiry 11/2001	11. Date of Release 19/12/2000

TEST DATA

Test Performed	Test Dates		Result			
	Started	Conducted				
Sterility test			Extraneous viruses contamination			
			Bacterial Contamination	Aerobic	Anaerobic	
			Fungal contamination			
			Mycoplasma			
Safety test	.....	.....	Mice safety	Suckling mice	Adult mice	
			Guinea pigs safety			
			Specific host safety test			
Virus titration	.....	.....	Virus content	..... Log_{10} EID_{50} /dose		
Potency test	.....	.....	**Conduct in a**	**Serological test**		**Challenge test**
			Specific host	SNT FA ELISA	Pre-vaccinal Titer = Pre-vaccinal = titer	Protection 100%
Identity test	.....	.....	AGPT SNT FA*			

The Vaccine is Valid

Date : / / 2000

Director