

Outline of the 2nd Research Coordination Meeting (RCM) of the Coordinated Research Programme “The use of non-structural antigens of FMD virus to assess antibodies in vaccinated and infected livestock” (D3.20.20) to be held in Geelong, Australia, 4-8 March 2002

Agenda

Day	Time	Speaker	Country	
Mon 4th	08.30-09.00	Administrative matters with Technical Officer (TO)	IAEA	
	09.00-09.15	Opening of meeting. Geelong ‘officials’. TO Vienna	Australia CSIRO	
	09.15-09.45	Introduction of participants	Various	
	09.45-10.30	J. R. Crowther Aims of meeting, and overview of problems	IAEA	
	Coffee	10.30-11.00		
		11.00-11.45	W. Doughty Australian perspective on FMD diagnosis	Geelong
		11.45-12.45	I. Bergman. S. American overview. Test in practice	PANAFTOSA
	Lunch	12.45-13.45		
		13.45-15.15	UBI/INTERVET/PANAFTOSA Commercial kits	Various
	Tea	15.15-15.30		Austria
	15.30-16.15	H. Unger. ELISA development/ Vienna Vet. Univ/ Geelong/IAEA		
	16.15-17.00	R. Armstrong. Total antibodies measured by C-ELISA	UK	
	17.00-17.30	K. Sorensen Lindholm. Perspectives on assay development	Denmark	
	17.30-18.00	F. De Simone . Perspectives on assay development	Italy	
Tues 5th				
	09.00-10.00	N. Fondevila	Argentina	
	10.00-10.30	A. Braga	Brazil	
	10.30-11.00	E. Maradei	Argentina	
Coffee	11.00-11.15			
	11.15-12.00	C.Sánchez Martínez	Colombia	
	12.00-13.00	W. Linchongsubongkoch	Thailand	
Lunch	13.00-14.00			
	14.00-14.30	K. Dyrting	China	
	14.30-15.15	B. Verin	Philippines	
Tea	15.15-15.45			
	15.45-16.00	M. Espinoza	Peru	
	16.00-16.30	S. Khounsy	Lao P.D.R	
	16.30-17.00	U. Kyin	Myanmar	
Wed 6th				
	09.00-10.30	IQC, EQA, Accreditation Axel Colling, TO, IAEA.	IAEA	
	10.30-11.00	Charting methods TO’s IAEA	Various	
Coffee	11.00-11.15			
	11.15-12.45	Exercises in charting	Various	
Lunch	12.45-	Field trip/lab visit?/ Discussions	Various	
Thu 7th				
	09.00-10.00	M. N. Hussein NS report. and Experiences with Lab. Accreditation	Malaysia	
	10.00-10.30	Report by TO. On Africa perspective/problems	S. Africa	
Coffee	10.30-11.00			
	11.00-12.30	Slot for other presentations. e.g. Commercial participants arriving, input from observers.	Various	
	12.15-13.15	J. R. Crowther. Conclusions based on reports. IQC, EQA. Possibilities	IAEA	
Lunch	13.15-14.00			
	14.00-15.00	J. R. Crowther Ref. Sera, Harmonisation, Work plans, Reporting	IAEA	
	15.00-16.00	Discussion period.	Various	
Tea	16.00-16.20			
	16.20-17.20	Development of work plans to be completed over night	Various	
Fri 8th				
	09.00-09.30	TO receipt of work plans.	Various	
	09.30-11.00	Delivery of work plans from participants 10 mins each	Various	
Coffee	11.00-11.15			
	11.15-12.45	Summary and conclusions, formal thanks and end meeting	IAEA/others	
Lunch	12.45-14.00			
	14.00-16.00	TO to see individuals	IAEA	

Official Participants attending RCM

Country	Name	Status
Argentina (INTA, B. Aires)	N. Fondevila	Research Contract
Argentina (Geelab, B. Aires)	E. Maradei	Research Contract
Australia (CSIRO-Geelong)	W. Doughty	Technical contract
Austria (Vet Univ. Vienna)	H. Unger.	Technical contract
Brazil (CPVDF, Rio G)	A Braga	Research Contract
Brazil (PANAFTOSA)	I. Bergman	Agreement Holder
China (Castle Peak, Hong Kong)	K. Dyrting	Research Contract
Colombia (ICAS, Bogata)	C. Sánchez Martínez	Research Contract
Denmark (Lindolm)	K. Sorensen	Agreement Holder
Italy (Brescia)	F. De Simone	Agreement Holder
Lao P.D.R. (Min of Ag. Vientiane)	S. Khounsy	Research Contract
Malaysia (Kelantale Reg. Vet. Lab.)	M. Mohamed Hussein	Research Contract
Myanmar (Insein FMD lab, Yangon)	U. Kyin	Research Contract
Peru (NIH, Lima)	A. Espinoza	Research Contract
Philippines (Manilla)	B. Verin	Research Contract
Thailand (Pakchong)	W. Linchongsubongkoch	Research Contract
United Kingdom (WRL, Pirbright)	B. Armstrong	Agreement Holder

Representatives from INTERVET, UBI and EMBRABIO (PANAFTOSA kit) have been invited.

Outline

At the beginning of the CRP we had a variety of reagents and systems. Some conclusions can be made.

1. Reagents had been produced put together to form the basis of tests to differentiate vaccinated and infected animals.
2. Various systems have been examined then changed.
3. Some systems could be regarded as approaching kits, some not.
4. Data suggested that differentiation of vaccinated and infected livestock was possible when herds were examined, not individual animals.

Note: As from October 2001, there are only three viable “kits” available from the point of view of costings, sustainability and distribution, namely:

- The kit from S. America, PANAFTOSA,(bovine, caprine, ovine, pig?)
- The kits from UBI (bovine, caprine, ovine as well as porcine)
- The kit from Intervet (bovine, caprine, ovine as well as porcine).

This allows the CRP to concentrate on their harmonisation and it is here that we will concentrate in designing acceptable workplans for contract holders.

Note. A competitive ELISA is being developed using baculo expressed 3ABC (Denmark) for all species using chicken antibodies by Geelong and Vienna. This will be looked at in the CRP , hopefully this will be ready towards end of 2002.

5. The internal quality control (IQC) aspects have not been addressed too well.
6. Commercial considerations are important and complicating with regard to supply and cost for developing countries.
7. The purpose of the tests needs to be clearly defined and tests “fit for purpose” are needed with appropriate activities defined to arrive at the required test performance. This requires agreement on diagnostic sensitivity and specificity criteria.

8. Reference sera are badly needed.

A 'true' kit has to be/ must be?

- a. Available in bulk. (assessment of likely need worldwide are crucial to supply).
- b. Available and distributed on demand. (be available immediately)
- c. Costed - high costs will prohibit use in developing countries. Price needed by buyers.
- d. Quality controlled in terms of day to day running. (IQC and EQA needed).
- e. Robust (stable reagents with defined performances).
- f. Validated in terms of diagnostic sensitivity.
- g. Validated in terms of diagnostic specificity.
- h. Fit for purpose (linked to estimates of sens/spec and this defined by producer, or at least criteria of validation, so far, described in full)).
- i. Contain control sera and have agreed reference standards.
- j. Contain everything necessary to fully perform the assay. This includes plates, conjugates, tips, etc. etc.

Proposed scheme

3 sources kits to be examined

INTERVET bovine and pig

UBI bovine and pig

PANAFTOSA bovine (pig?)

- Kits will be supplied from each to perform 1000 tests (possibly 2000 better)
- Sera will be selected according to availability in labs
- A minimum of 200 sera will be examined per laboratory. As many as possible please. Sera already tested can be used and may offer choice of a better spectrum of results.
- Sera will be examined by all three assays and results reported in columns relating same serum result to test
- IQC charting of the control values will be made by all.
- **Great care is needed in protecting serum samples between tests!**
- It would be better to test a batch of serum by all three tests in one day, then next day process another batch. In this way the same serum conditions apply to all tests.
- Do not take all samples, examine against one kit, then repeat with another test on the same sera which have been stored.
- The serum controls for all the kits will be run on the other tests as extra controls.
- This control data should be clearly highlighted. This will allow some QA of the data.
- Where possible the sera should be examined by VNT and LPBE (note new assay here described by Bob Armstrong)
- As much information about the serum must be include in database.
- An Excel spread sheet will be provided for data capture.

Selection of sera

- Try and examine at least 100 negative sera.
- Try and examine at least 50 post vaccinated sera.
- Try and examine at least 50 positive sera.

Time line

It is hoped that all can report complete results by the end of September 2002.

Of course this does depend on receipt of kits and that the kits do perform as expected.

Data processing and access to data considerations

Software?

Who has raw data?
How do we reach agreement on conclusions?
Use of data before publication?
Further validation needs?
IQC considerations? Are they sufficient in existing kits?
Document preparation?
Publication and use of data from CRP?

Reference sera will be discussed

Identification of sera.

We need large volumes to meet possible (region of 500mL)
to meet possible "World demands".

Collection

Is it available already? Have we to produce it? Is it available in the field?
Technical contract with Onderstepoort to make anti SAT1, 2 and 3 sera.

Sending

We should receive sera in Seibersdorf for irradiation and storage.

Storage

Catalogued and stored in Seibersdorf laboratories.
Method and preservatives etc.

Can be sent as panels to other reference laboratories in Africa, UK, S.E. Asia,
Australia, USA, Middle East etc. Labs need defining and acceptance of status and
criteria for receipt.

Aliquots etc, exact scheme needs (details).

Data base needed.

OIE recognition with EU etc.

European input vital. Kris de Clerc is also interested here.

Characterisation

Hopefully when fully licensed in Seibersdorf. How? Sera must be routinely checked.
Agreement as to testing and where to confirm sensitivity/specificity is needed.

Access

Who can lay claim to being sent sera?

Costs involved, who pays for them?

Official status of serum bank needs agreement and ratification