Brucellosis EU Proficiency Ring-Trial

Bovine serum

2014

EU Reference Laboratory for Brucellosis
ANSES – Maisons-Alfort, France

EU Brucellosis Ring-Trials organised (past & present)

- 2007/2008: 1st EU Bovine Brucellosis Serum Proficiency Ring-Trial
- 2008/2009: 1st EU Bovine Brucellosis Milk iELISA Proficiency Ring-Trial
- 2009: 2nd EU Bovine Brucellosis Milk iELISA Proficiency Ring-Trial
- 2009/2010: EU Bovine Brucellosis Serum Collaborative Ring-trial for CFT harmonisation *(+ proficiency for the RBT)*
- 2009/2010: EU Ovine/Caprine Brucellosis serum iELISA Collaborative Ring-trial *(EU Sheep & Goat BSS)*
- 2010/2011: EU Collaborative Ring-Trial CFT Harmonisation (*EUPigBSS, EUSBSS & EUGBSS)*
- *2012 : EU Bovine Brucellosis Serum Proficiency Ring-Trial*
- 2013 : EU Bovine Brucellosis Milk iELISA Proficiency Ring-Trial
- 2013 : EU Ovine/Porcine Brucellosis serum Collaborative Ring-trial *(EU Sheep & Goat BSS)*
- *2014 : EU Bovine Brucellosis Serum Proficiency Ring-Trial*
  - *covering all serological methods, allowing a large overview*
  - *further assessment of analyses consistency performed throughout the EU*
  - *improvement of the support provided by the EURL to the NRL network*
  - *improvement of quality control of the reagents*

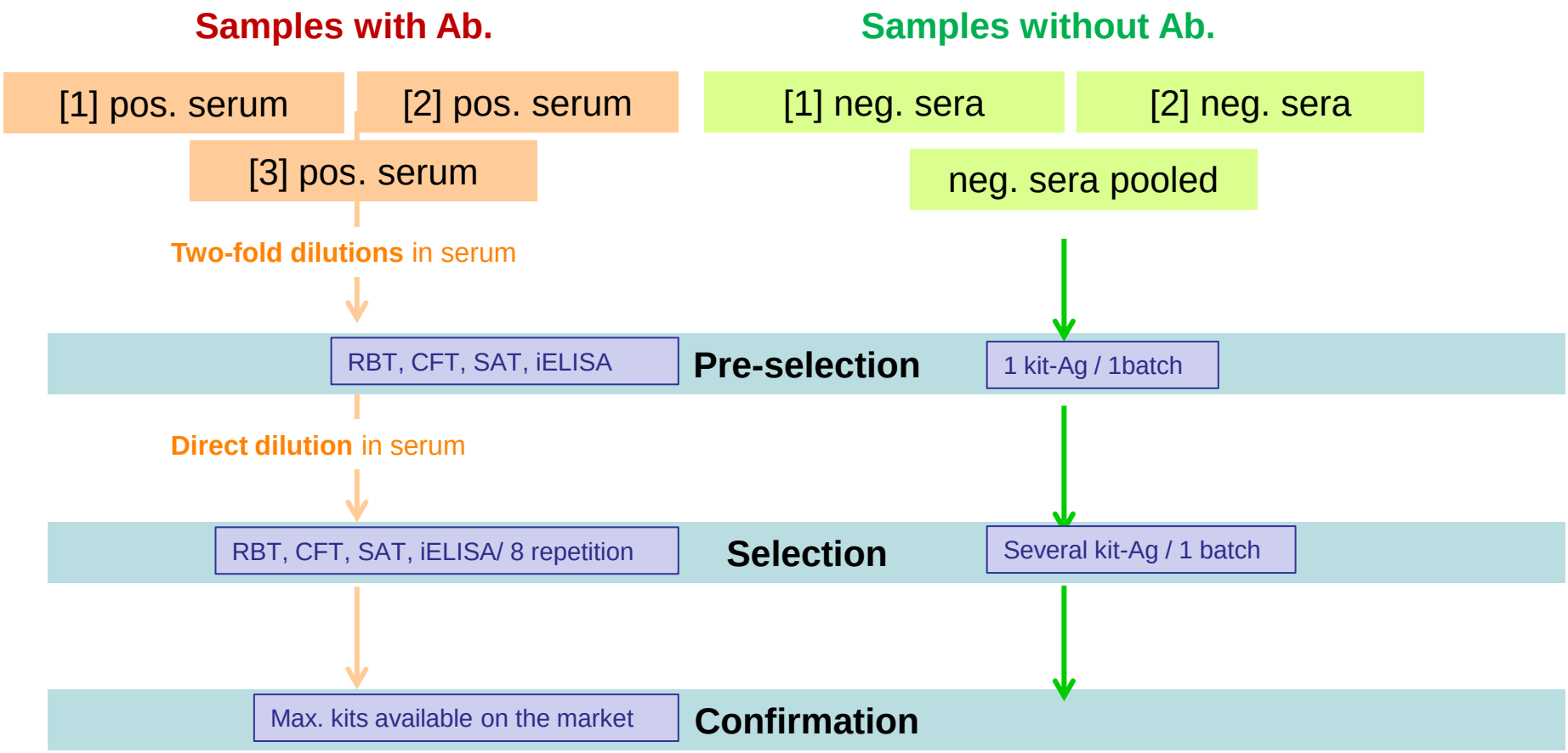
Participation

- Participants :
  - **27 EU MS NRLs + EURL (France)**
  - **EFTA (Switzerland, Norway)**
  - **EU candidate countries (Albania, FYROM, Montenegro, Turkey, Serbia)**
  - **Balkans Countries (Bosnia & Herzegovina, Kosovo)**
- 6 kit suppliers
- Method: EU approved serum tests in cattle = **RBT, CFT, SAT, I-ELISA, C-ELISA**

Ag/kits that should have been approved by a European NRL according to the Annex C of the 64/432 EC Directive.

RT led simultaneously at French level (84 labs)

Panel preparation (August-sept. 2013)



Panel preparation (January 2014)

Samples with Ab. :

- **2 different bovine pos. sera** (from infected animals) diluted in pooled neg. sera (4) were used in order to get different levels of antibodies:

Samples without Ab. :

- 2 neg. sera → *For the dilution : pooled neg. sera*

Sample	Serum (internal number)	Dilution	Obtained results (1 Ag-Kit /1 batch)				Level	Rep.
			Qualitative	Semi-quantitative		Quantitative		
			RBT	CFT	SAT	iELISA		
pos. serum diluted in neg. pooled sera	Batch 49	1/4	Strong pos.	Strong pos.	Strong pos.	Strong pos.	**8**	2
		1/10	pos.	pos.	neg. (with traces)	pos.	**7**	3
		1/20	Weak pos.	pos. (~cut-off)	neg. (with traces)	pos.	**6**	3
		1/150	neg.	neg.	neg.	neg. (with traces)	**5**	2
	Batch 50	1/8	Weak pos.	pos. (~cut-off)	neg. (with traces)	pos.	**4**	2
		1/32	neg.	neg.	neg.	pos. (close to cut-off)	**3**	2
neg. serum	N2	-	neg.	neg.	neg.	neg. (with traces)	**2**	2
	N1	-	neg.	neg.	neg.	neg.	**1**	2

Panels preparation (January 2014)

- Test with all the kits received from the suppliers → validated

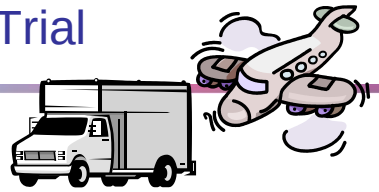
☞ **8 levels of samples**

- Samples were in duplicate or in triplicate → **repeatability**
  - Samples without Ab. and with Ab. / **duplicates** : 2 * Level 1, 2, 3, 4, 5, 8
  - Samples with Ab. / **triplicates** : 3 * Level 6 + 3 * Level 7

☞ **Panel of 18 sera**

- Results of preliminary testing = complement for participants' results evaluation
- Preparation of the bulk; distribution in tubes (storage -20° C); codification
- Homogeneity challenge: 10 samples; 2 technicians; 1 Kit

  → validated (RBT: <+, CFT/SAT: <1 dilution, ELISA: CV<10%)
- Instructions:
  - Test the samples in **their usual working conditions**
  - 8 days after reception



Organization

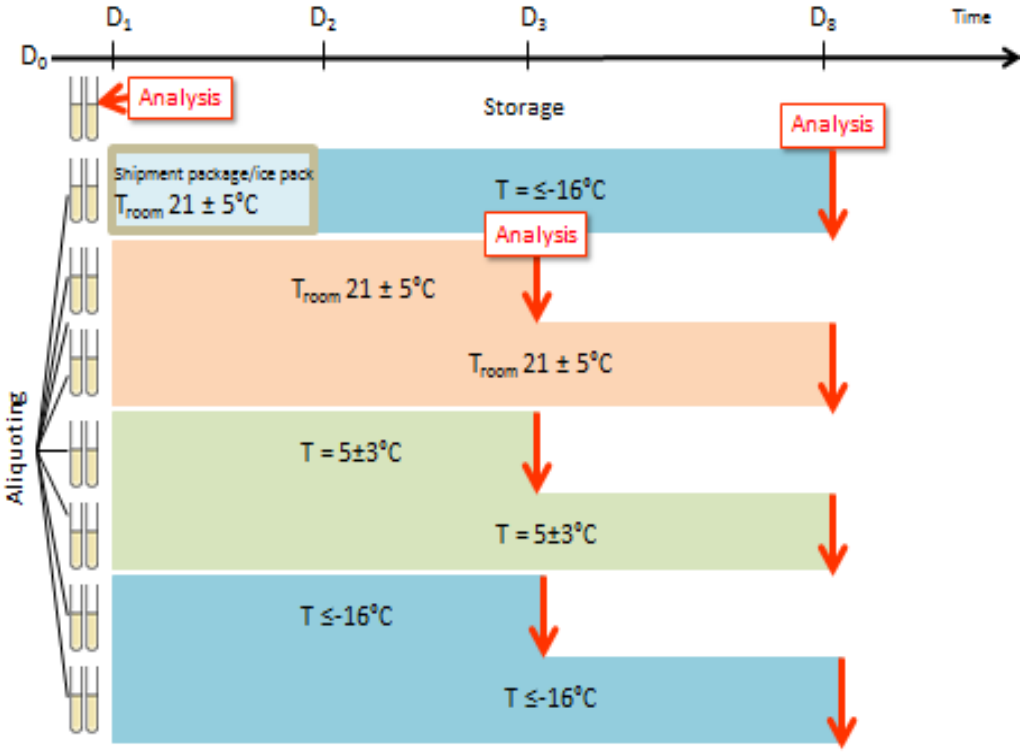
- Announcement and information : **January 2014** (EU, EEA, EU candidate & West-Balkan countries)
- Shipment of samples : **March 25, 2014**; time of shipment 1 or 2 days (6 days for FYROM & Serbia; 8 days for Montenegro), room T + ice pack

- **No problems were reported during the shipment**
- Results returned in due time

→ instructions followed by all participants ☺

→ *In parallel : stability challenge*

3 samples/ level in 8 ≠ conditions



Analysis

- Expected / accepted results :
  - ☞ according to results of EURL & participants (French, European labs and others);
  - ☞ Expectations especially adjusted for samples close to the threshold

- Analysis:
  - **qualitative and quantitative results**
    - ☞ **Sensitivity, specificity and repeatability, coherence between dilutions of the same serum**
    - ☞ **Consistency qualitative/quantitative (interpretation)**
  - **traceability (sample codes) → 1 lab. (70) for 1 sample**
  - Information about reagents? Controls?...

- Assessment of the proficiency compared to the previous ring trials

Analysis

- Nb. EU participants:

	RBT	CFT	SAW	iELISA	cELISA
2014	27	26	15	23	7
2012	26	25	15	22	8

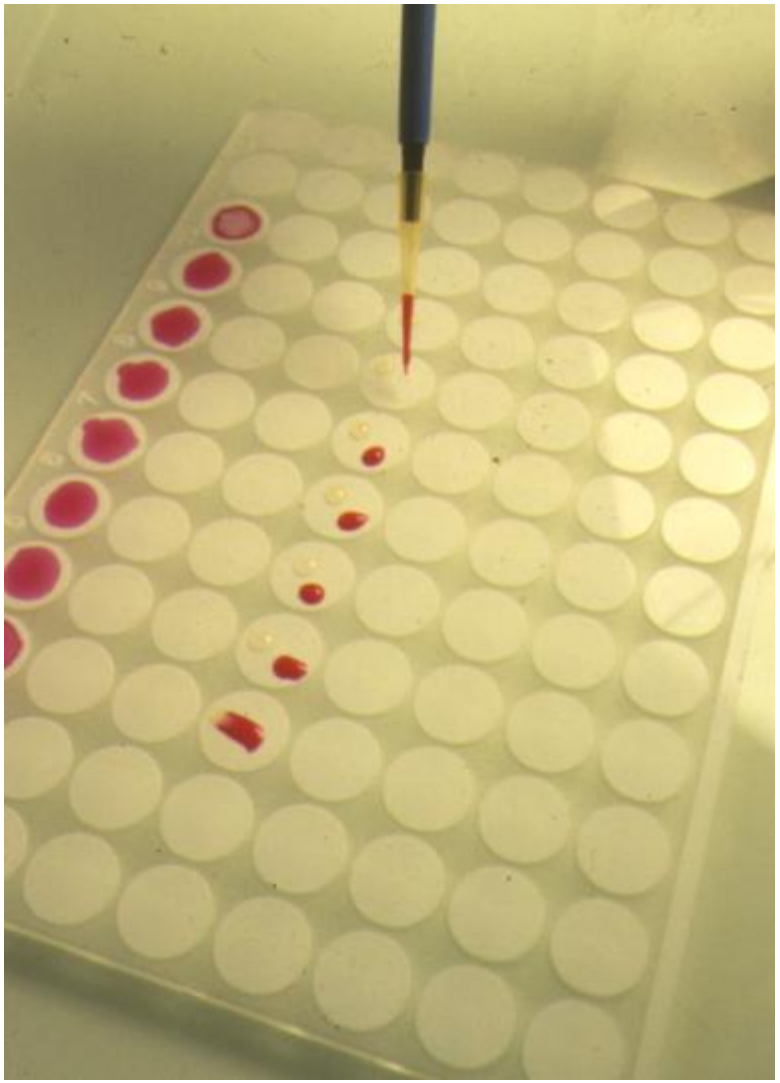
- Nb. non EU:

	RBT	CFT	SAW	iELISA	cELISA
2014	7	6	2	8	3
2012	8	8	2	8	0

Reagents used

Suppliers	RBT	CFT	SAT	i-ELISA	c-ELISA
AHVLA	x	x	x	x	x
Biopharmingenering Ltd	x	x			
BioRad	x				
Biowet Pulawy Sp. z o.o.	x	x	x		
CLV		x			
CVI		x	x		
CZV	x				
DaesungMicrobiol.Labs	x				
Idexx / Bommeli				x	
Idexx / Pourquier	x	x	x	x	
ID-VET	x	x		x	
Ingenasa				x	x
IZSAM	x	x		x	
NRL Spain	x	x			
Prionics AG	x			x	
PVCI	x				
Svanova				x	x
Synbiotics	x	x	x	x	
Vircell	x				
virion/serion		x			

RBT



RBT (qualitative)

Expected results definition (Occurrence N/P French/EURL/ European)

	L1	L2	L3	L4	L5	L6	L7	L8
Obtained results	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive
French labs.	168/0	165/2	166/2	43/124	167/0	225/26	6/246	0/168
EURL	12/0	12/0	12/0	0/12	12/0	1/17	0/18	0/12
European labs.	67/1	67/0	66/2	3/64	65/0	36/64	0/102	0/68
	No Ab.						**High level of Ab.**	

- **L3** : vast majority of N (P=1.6%; 4) → P = slight excess of Se, not critical (Ab.)
- **L4** : majority of P (N=19%) → N accepted (close to cut-off; + to ++)
- **L5**: only N
- **L6** : majority of N (P=29%) → P accepted (close to cut-off; w+ to +)

Compared to French results : Se > on level 6 (more pos. results)

	Level							
	1	2	3	4	5	6	7	8
Expected	N	N	N	P	N	N	P	P
Accepted	N	N	N (P)	N	N	P	P	P

RBT (qualitative)

	Level							
	1	2	3	4	5	6	7	8
Expected	N	N	N	P	N	N	P	P
Accepted	N	N	N	N	N	P	P	P

Sp

Se exc.

Lab. code	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
3	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
4	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
21	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
29	N	N	N	N	N	N	P	P	N	N	N	P	N	P	P	P	P	P
31	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
32	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
45	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
46	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
47	N	N	N	N	N	P	p	P	N	N	p	P	P	P	P	P	P	P
50	N	N	N	N	N	N	P	P	N	N	P	P	N	P	P	P	P	P
55	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
57	N	N	N	N	N	N	P	P	N	N	N	P	N	P	P	P	P	P
60	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
67	P	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
72	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	p	P	P
73	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
82	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
84	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
86	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
98	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
100	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
102	N	N	N	N	N	N	N	P	N	N	N	P	N	P	P	P	P	P
104	N	N	QI	N	N	N	P	N	N	N	QI	N	N	P	P	P	P	P
112	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
118	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
123	N	N	N	N	N	N	P	N	N	N	N	N	N	P	P	P	P	P

RBT

Investigation of the causes?

			Level																	
Lab.	Ag	Batch	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
2	Ag B	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
32	Ag B	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
29	Ag B	3	N	N	N	N	N	N	P	P	N	N	N	P	N	P	P	P	P	P
60	Ag B	3	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
73	Ag B	3	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
104	Ag B	4	N	N	QI	N	N	N	P	N	N	N	QI	N	N	P	P	P	P	P
123	Ag B	5	N	N	N	N	N	N	P	N	N	N	N	N	N	P	P	P	P	P
21	Ag B	6	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
98	Ag B	7	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
57	Ag B	8	N	N	N	N	N	N	P	P	N	N	N	P	N	P	P	P	P	P
112	Ag B	8	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
84	Ag B	9	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
102	Ag B	9	N	N	N	N	N	N	N	P	N	N	N	P	N	P	P	P	P	P
50	Ag B	10	N	N	N	N	N	N	P	P	N	N	P	P	N	P	P	P	P	P
55	Ag B	10	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
67	Ag B	10	P	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
3	Ag B	11	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
82	Ag C	5	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
47	Ag D	1	N	N	N	N	N	P	P	P	N	N	p	P	P	P	P	P	P	P
45	Ag D	2	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
100	Ag E	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
72	Ag F	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	p	P	P
86	Ag G	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
46	Ag H	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
118	Ag J	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
4	Ag K	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
31	Ag N	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P

Method?

Method or Ag?

RBT (qualitative)

Ext. EU

	Level							
	1	2	3	4	5	6	7	8
Expected	N	N	N	P	N	N	P	P
Accepted	N	N	N	N	N	P	P	P

← **Se exc.** →

Lab. code	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
6	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
23	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
37	N	N	N	N	N	P	P	P	N	N	P	P	P	P	P	P	P	P
66	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
70	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
80	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
115	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P

Investigation of the causes?

Lab.	Ag	Batch	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
6	Ag A	-	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
37	Ag B	Batch 3	N	N	N	N	N	P			N	N	P	P	P	P	P	P	P	P
66	Ag B	Batch 3	N	N	N	N	N	N			N	N	N	N	N	P	P	P	P	P
70	Ag B	Batch 3	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
23	Ag B	Batch 8	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
115	Ag L	Batch 1	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
80	Ag M	Batch 1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P

Method?

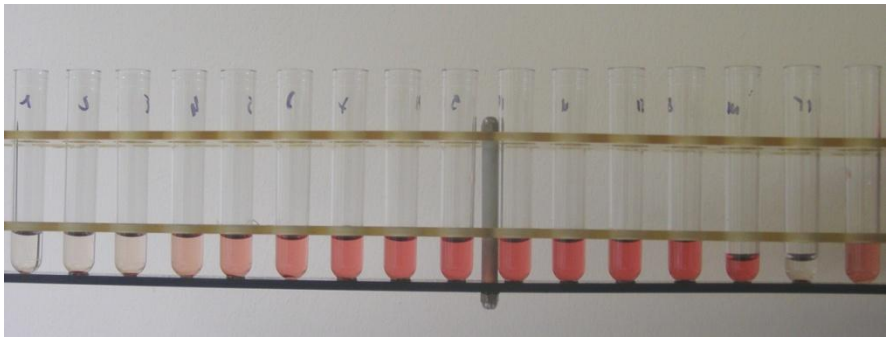
RBT (qualitative)

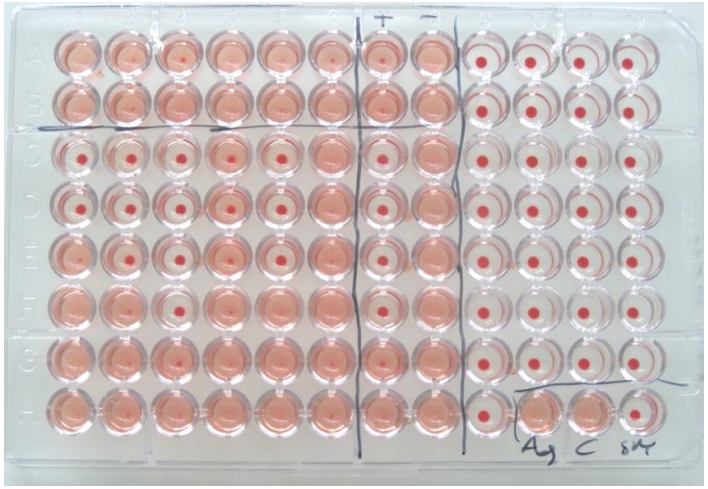
- Overall results are very satisfactory **(compared to 2012)**

- Various antigens used (13 different antigens)
- EU:
  - **1 lab. / 27** : problem of Se (**excess**) and repeatability on level 3; not critical
    (7/26 excess or lack on several levels)
  - **1 lab.** with a specificity lapse ☞ Critical **(1/26)**
- Ext. EU:
  - **1 lab./ 7** : problems of Se (**excess**) and repeatability on level 3; not critical
    (3/8 excess or lack on several levels)

☞ Investigation of the origin :
- ☞ Critical points in the **method** ? Antigen homogenisation ? Pipettes control? Temperature conditions? Equal volumes used? Simultaneous mixing? Internal controls?
- ☞ **Antigen** standardisation?

CFT





CFT

Expected results definition (Occurrence N/P French/EURL/ European)

	L1	L2	L3	L4	L5	L6	L7	L8
Obtained results	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive
French labs.	152/0	151/0	144/8	3/147	151/0	8/220	0/228	0/152
EURL	8/0	8/0	8/0	0/8	8/0	0/12	0/12	0/8
European labs.	66/0	66/0	60/6	1/65	66/0	6/93	0/99	0/65

No Ab.

High level of Ab.

- **L3** : majority of N (P=6%) → P accepted (titer close to cut-off)
- **L4** : majority of P (N=2%) → N accepted (titer close to cut-off)
- **L5:** Totality of N
- **L6** : majority of P (N=4%) → N accepted (titer close to cut-off)

	Level							
	1	2	3	4	5	6	7	8
Expected	N	N	N	P	N	P	P	P
Accepted	N	N	P (cut-off)	N (cut-off)	N	N (cut-off)	P	P

CFT (qualitative)

	1	2	3	4	5	6	7	8
Expected	N	N	N	P	N	P	P	P
Accepted	N	N	P (cut-off)	N (cut-off)	N	N(ut-off)	P	P

Lab.	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
3	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
4	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
21	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
29	N	N	N	N	23,3	23,3	P	P	N	N	P	P	P	P	P	P	P	P
31	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
32	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
45	N	N	N	N	N	N	P	P	N	N	16,6	P	P	P	P	P	P	P
46	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
47	N	N	N	N	23	20	p	P	N	N	P	P	P	P	P	P	P	P
50	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
55	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
57	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
60	N	N	N	N	N	N	P	P	N	N	P	19	P	P	P	P	P	P
67	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
72	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
73	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
82	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
84	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
86	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
98	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
100	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
102	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
104	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	QI
112	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
118	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P

No troubles except non critical qualitative repeatability lapse

CFT (qualitative)

- No visible influence of the Ag

Lab.	Ag	Batch	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
2	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
29	Ag A	1	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
32	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
46	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
55	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
57	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
72	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
73	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
82	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
84	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
98	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
102	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
104	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	QI
112	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
60	Ag A	3	N	N	N	N	N	N	P	P	N	N	P	N	P	P	P	P	P	P
60-2	Ag A	3	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
67	Ag A	3	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
21	Ag D	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
31	Ag D	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
45	Ag D	1	N	N	N	N	N	N	P	P	N	N	N	P	P	P	P	P	P	P
100	Ag E	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
86	Ag F	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
3	Ag H	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
50	Ag I	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
47	Ag I	1	N	N	N	N	P	P	p	P	N	N	P	P	P	P	P	P	P	P
118	Ag K	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
4	Ag L	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P

CFT (qualitative)

Ext. EU

	1	2	3	4	5	6	7	8
Expected	N	N	N	P	N	P	P	P
Accepted	N	N	P (cut-off)	N (cut-off)	N	N(ut-off)	P	P

Lab.	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
6	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
23	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
37	N	N	N	N	N	N	N	P	N	N	N	N	N	P	P	P	P	P
70	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
80	N	N	N	N	N	N	P	P	N	N	N	P	P	P	P	P	P	P
121	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P

No troubles

except non critical qualitative repeatability lapse

Lab.	Ag	Batch	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
23	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
70	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
6	Ag B	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
121	Ag I	1	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
37	Ag N	1	N	N	N	N	N	N	N	P	N	N	N	N	N	P	P	P	P	P
80	Ag N	1	N	N	N	N	N	N	P	P	N	N	N	P	P	P	P	P	P	P

CFT (semi-quantitative)

- **Heterogeneity** in units interpretation
- "Quantitative" repeatability : on replicates of 1 level 3 labs obtained titers exceeding 1 dilution → not critical
- 1 lab (titers ↔dilutions)
- Narrower titre ranges compared to last RT

Lab.	Ag	Batch	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
2	Ag A	1	<16,6	< 16,6	<16,6	<16,6	<16,6	<16,6	53,3	53,3	<16,6	<16,6	53,3	53,3	53,3	107	107	107	213	213
29	Ag A	1	<16,6	<16,6	<16,6	<16,6	23,3	23,3	46,6	46,6	<16,6	<16,6	46,6	46,6	46,6	93,3	93,3	66,6	747	320
32	Ag A	1	0	0	0	0	10	10	40	66,6	0	0	40	40	40	80	133	133	373	373
46	Ag A	1	0	0	0	0	13	13	67	67	0	0	53	53	53	107	107	107	267	267
55	Ag A	1	<8,3	<8,3	<8,3	<8,3	11,6	11,6	53,3	53,3	<8,3	<8,3	53,3	46,6	46,6	107	107	107	213	213
57	Ag A	1	<8,3	<8,3	<8,3	<8,3	<8,3	<8,3	33,3	40	<8,3	<8,3	26,6	26,6	26,6	53,3	53,3	53,3	187	213
72	Ag A	1	0	0	0	0	16,6	11,6	46,6	46,6	0	0	53,3	46,6	33,3	93,3	93,3	66,6	373	320
73	Ag A	1	0	0	0	0	0	0	40	40	0	0	33,33	40	66,67	93,33	93,33	93,33	320	373,33
82	Ag A	1	0	0	0	0	8,3	8,3	33,3	33,3	0	0	26,6	26,6	26,6	53,3	53,3	53,3	133	133
84	Ag A	1	0	0	0	0	16,6	16,6	80	40	0	0	33,3	33,3	33,3	80	80	80	266	266
98	Ag A	1	0	0	0	0	0	0	50	50	0	0	30	25	25	60	60	60	220	200
102	Ag A	1	0	0	0	0	0	0	26	26	0	0	26	26	26	52	52	52	105	132
104	Ag A	1	<8,3	<8,3	<8,3	<8,3	<8,3	8,3	40	46,6	<8,3	<8,3	26,6	66,6	33,3	46,6	46,6	33,3	93,3	QI
112	Ag A	1	0	0	0	0	8,3	8,3	46,6	26,6	0	0	46,6	40	26,6	107	80	80	213	213
23	Ag A	1	0	0	0	0	8	8	80	80	0	0	40	40	40	80	80	80	160	320
70	Ag A	1	0	0	0	0	0	0	62,5	62,5	0	0	31,25	62,5	62,5	62,5	125	62,5	250	250
60	Ag A	3	<9	<9	<9	<9	<9	<9	26	31	<9	<9	22	19	26	26	63	31	63	125
60-2	Ag A	3	<20	<20	<20	<20	<20	<20	40	40	<20	<20	33	33	20	33	67	40	80	47
67	Ag A	3	0	0	10	0	11,67	8,33	46,67	66,67	0	0	40	40	33,33	80	93,33	93,33	266,67	266,67
6	Ag B	1	0	0	0	0	0	0	35,15	35,15	0	0	35,15	29,3	29,3	70,31	70,31	70,31	187,5	187,5
21	Ag D	1	0	0	0	0	0	0	50	50	0	0	50	50	50	100	100	100	400	400
31	Ag D	1	0	0	0	0	0	0	40	33,3	0	0	26,6	23,3	26,6	46,6 ,	46,6	66,6	133	267
45	Ag D	1	<8,3	<8,3	<8,3	<8,3	<8,3	<8,3	66,6	106,4	<8,3	<8,3	16,6	40	20	53,2	53,2	46,6	160	160
100	Ag E	1	0	0	0	0	8,3	8,3	40	40	0	0	23,3	23,3	23,3	46,6	40	46,6	133	93,3
86	Ag F	1	0	0	0	0	0	0	23,3	46,5	0	0	23,3	23,3	23,3	46,5	53	53	160	160
50	Ag G	1	0	0	0	0	0	0	66,6	66,6	0	0	46,6	46,6	46,6	93,2	93,2	93,2	320	320
3	Ag H	1	<20	<20	<20	<20	<20	<20	40	40	<20	<20	40	40	40	>=80	>=80	>=80	>=80	>=80
47	Ag I	1	0	0	0	0	23	20	80	80	0	0	47	47	47	93	133	107	320	320
121	Ag I	1	0	0	0	0	4	4	16	32	0	0	16	16	16	32	32	32	32	32
118	Ag K	1	0	0	0	0	0	0	26,6	23,2	0	0	20	20	20	53,2	53,2	53,2	106,4	106,4
4	Ag L	1	<8,3	<8,3	<8,3	<8,3	8,3	<8,3	53,2	53,2	<8,3	<8,3	33,2	46,4	46,4	92,8	106,4	106,4	212,8	265,6
80	Ag N	1	0	0	0	0	9,3	9,3	22,1	22,1	0	0	18,6	22,1	22,1	44,2	31,25	44,2	125	125
37	Ag N	1	<20	<20	<20	<20	<20	<20	<20	37	<20	<20	<20	<20	<20	37	37	37	74	74

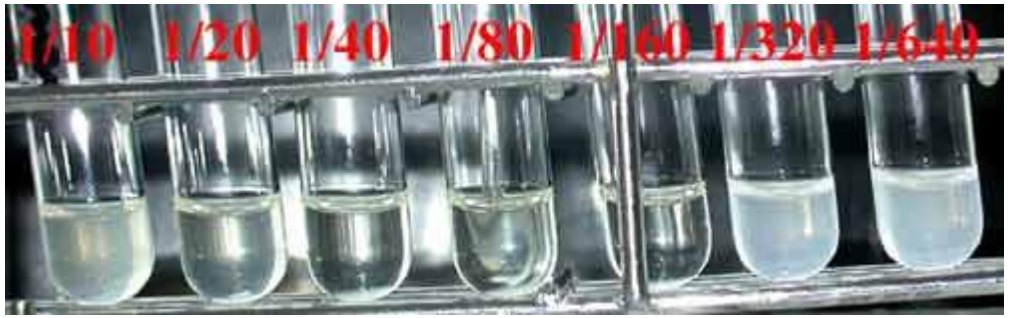
CFT

Qualitative results

- All results are satisfactory **(compared to 2012)**
- Various antigens used (11 different antigens)
- Heterogeneity in titers (IUCFT/ml) → conversion table?
- EU:
  - 0 lab. / 26 : problems of Se (excess or lack) **(5/25 exc./lack on several levels)**
  - 0 lab. with a specificity lapse **(1/25)**
  - Non critical repeatability lack on qualitative results for 2 labs. on levels close to cut-off
- Ext. EU:
  - 0 lab./ 6 participants : critical problems of sensitivity (excess or lack) **(0/7)**
  - Non critical repeatability lack on qualitative results for 2 labs. on levels close to cut-off

☞Improvement compared to last ring-trial

☞ Despite the panel was more “difficult”



SAT

SAT

Ext. EU +

	L1	L2	L3	L4	L5	L6	L7	L8
Obtained results	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive	Negative/positive
French labs.	12/0	12/0	12/0	12/0	10/0	17/1	5/13	0/12
EURL	4/0	4/0	4/0	4/0	4/0	6/0	3/3	0/4
European labs.	34/0	34/0	34/0	19/15	34/0	28/23	8/43	0/34
	neg.				neg.			pos.

- **L4** : majority of N → P accepted (titer close to cut-off)

→*Higher Se at EU level*

- **L6** : majority of N → P accepted (titer close to cut-off)
- **L7** : majority of P → N accepted if consistent with result of level 6 & close to cut-off

Expected	N	N	N	N	N	N	P	P
Accepted	N	N	N	P (cut-off)	N	P (cut-off)	N (cut-off)	P

SAT (qualitative)

Ext. EU +

Expected	N		N		N		N		N		N			P		P			
Accepted	N		N		N		P (cut-off)		N		P (cut-off)			N (cut-off)		P			

Lab.	Ag	Batch	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
21	Ag A	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	P	P	P	P
31	Ag A	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	P	P
72	Ag A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
45	Ag A	3	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	P	P
86	Ag B	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
3	Ag C	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
29	Ag D	1	N	N	N	N	N	N	N	N	N	N	N	N	N	P	P	P	P	P
47	Ag D	1	N	N	N	N	N	N	N	N	N	N	N	N	N	P	P	P	P	P
57	Ag D	1	N	N	N	N	N	N	N	N	N	N	N	N	N	P	P	N	P	P
60	Ag D	1	N	N	N	N	N	N	N	P	N	N	N	P	P	P	P	P	P	P
73	Ag D	1	N	N	N	N	N	N	N	N	N	N	N	N	N	P	P	P	P	P
104	Ag D	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
2	Ag D	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
82	Ag D	2	N	N	N	N	N	N	N	N	N	N	N	N	N	P	P	P	P	P
23	Ag D	3	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
6	Ag F	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
98	Ag F	2	N	N	N	N	N	N	N	N	N	N	N	N	N	P	P	P	P	P

- Qualitative : All the lab. (15/15) got satisfactory results, Ext. EU : 2/2
  - Minor troubles qualitative repeatability (cut-off)

SAT (semi-quantitative)

Ext. EU +

Lab.	Ag	Batch	1	1	2	2	3	3	4			5	6	6	6	7	7	7	8	8
21	Ag A	1	0	0	0	0	0	0	0			0	0	0	0	0	31	31	61,5	61,5
31	Ag A	1	0	0	0	0	0	0	0			0	0	0	0	23,25	20	0	33,5	33,5
72	Ag A	1	0	0	0	13	13	13	100	50	13	0	50	50	30	100	50	50	120	120
45	Ag A	3	<13	<13	<13	<13	<13	<13	15,5	15	<13	<13	<13	<13	<13	18	18	18	51,5	41
86	Ag B	1	0	0	13	13	15,5	15,5	36	36			36	36	36	61,5	61,5	61,5	123	123
3	Ag C	1	<15	<15	<15	<15	<15	<15	15	15			15	15	15	30	30	30	60	60
29	Ag D	1	<15	<15	<15	<15	<15	<15	15	15			15	15	15	30	30	30	30	30
57	Ag D	1	<13	<13	<13	<13	<13	<13	18	18	<13	<13	15,5	18	18	31	31	25,5	61,5	72
60	Ag D	1	<16	<16	<16	<16	<16	<16	26	31	<16	<16	26	31	31	53	53	53	105	105
73	Ag D	1	0	0	0	0	0	0	20	20	0	0	20	15	0	35	35	35	100	60
104	Ag D	1	0	0	0	0	0	0	30	30	0	0	30	50	30	60	35	30	80	70
47	Ag D	1	0	0	0	0	0	0	20,5	25,6	0	0	20,5	20,5	20,5	41	41	41	82	82
2	Ag D	2	<13	<13	13	13	13	13	50	50	13	13	50	50	50	100	100	100	200	200
82	Ag D	2	0	0	0	0	0	0	20,5	20,5	0	0	20,5	20,5	20,5	30	30	30	82	82
23	Ag D	3	0	0	0	0	0	0	40	40	0	0	40	40	40	40	40	40	80	80
6	Ag F	1	0	0	0	0	0	0	35,15	35,15	0	0	35,15	35,15	35,15	70,31	70,31	70,31	281,5	281,5
98	Ag F	2	0	0	0	0	0	0	20	0	0	0	15	0	15	40	30	40	100	100
Expected			N		N		N		N		N		N			P			P	
Accepted			N		N		N		P (cut-off)		N		P (cut-off)			N (cut-off)			P	

Rp/Se

Interpr.

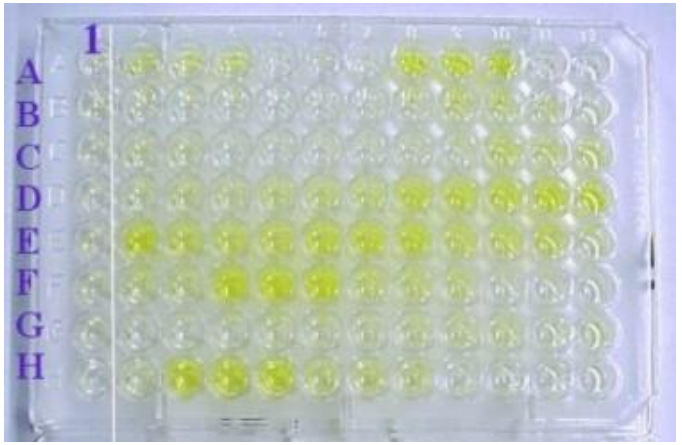
Background

- Quantitative : satisfactory, on level 4, 6 & 7 : all results accepted are close to the cut-off
  - Minor troubles

Qualitative results

- Various antigens used (5 different antigens)

☞All the participant got satisfactory results **(as in 2012)**

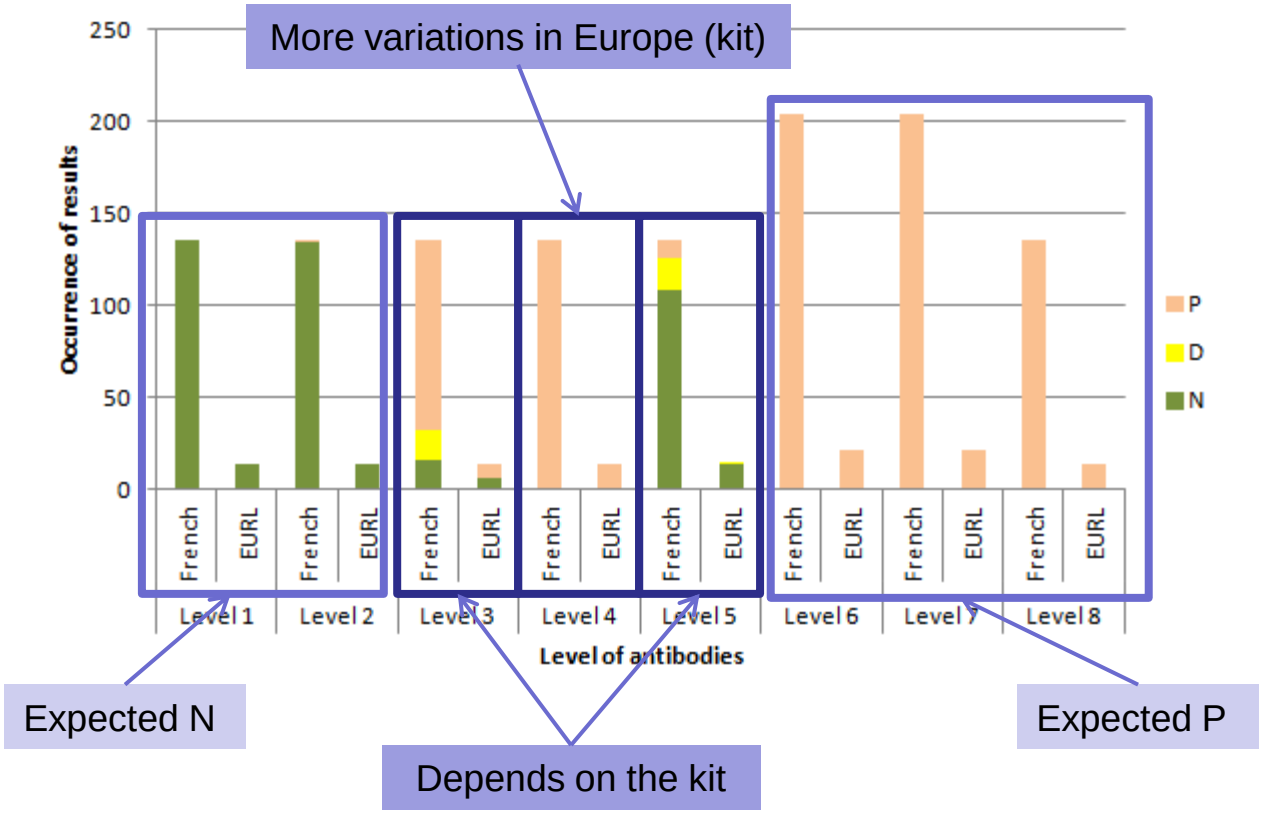


I-ELISA

i-ELISA

Qualitative

Results obtained by French laboratories and EURL (2 kits, C and D):



i-ELISA (qualitative)

Ext. EU +

All results consistent with expected results on levels 1, 2, 6, 7 & 8

Lab.	Kit	Batch	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
2	Kit C	2	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
3	Kit G	1	N	N	N	N	N	N	N	N	N	N	P	P	P	P	P	P	P	P
4	Kit B	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
6	Kit B	2	N	N	N	N	P	P	P	P	N	P	P	P	P	P	P	P	P	P
23	Kit C	-	N	N	N	N	D	D	P	P	N	N	P	P	P	P	P	P	P	P
29	Kit C	1	N	N	N	N	P	P	P	P	D	D	P	P	P	P	P	P	P	P
31	Kit H	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
32	Kit H	2	N	N	N	N	D	D	P	P	N	N	P	P	P	P	P	P	P	P
37	Kit B	1	N	N	N	N	N	P	P	P	N	N	P	P	P	P	P	P	P	P
45	Kit A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
46	Kit C	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
47	Kit G	2	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
57	Kit C	3	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
60	Kit B	3	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
66	Kit B	1	N	N	N	N	P	P	P	P	P	P	P	P	P	P	P	P	P	P
67	Kit D	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
68			N	N	N	N	P	N	P	P	N	N	P	P	P	P	P	P	P	P
72	Kit H	4	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
73	Kit C	2	N	N	N	N	D	P	P	P	N	N	P	P	P	P	P	P	P	P
80	Kit G	3	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
84	Kit H	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
86	Kit C	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
98	Home made	/	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
100	Kit H	3	N	N	N	N	D	D	P	P	D	P	P	P	P	P	P	P	P	P
102	Kit C	2	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
104	Kit C	2	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
112	Kit B	2	N	N	N	N	P	P	P	P	P	P	P	P	P	P	P	P	P	P
115	Kit G	4	N	N	N	N	N	N	N	N	N	N	P	P	P	P	P	P	P	P
118	Kit F	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
121	Kit H	1	N	N	N	N	P	P	P	P	P	P/D	P	P	P	P	P	P	P	P

i-ELISA (qualitative)

Ext. EU +

Influence of the kit? All the kits tested by the EURL (excepted home-made, A, F, G)

Lab.	Kit	Batch	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
98	Home made	/	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
45	Kit A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
37	Kit B	1	N	N	N	N	N	P	P	P	N	N	P	P	P	P	P	P	P	P
66	Kit B	1	N	N	N	N	P	P	P	P	P	P	P	P	P	P	P	P	P	P
4	Kit B	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
6	Kit B	2	N	N	N	N	P	P	P	P	N	P	P	P	P	P	P	P	P	P
112	Kit B	2	N	N	N	N	P	P	P	P	P	P	P	P	P	P	P	P	P	P
60	Kit B	3	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
29	Kit C	1	N	N	N	N	P	P	P	P	D	D	P	P	P	P	P	P	P	P
2	Kit C	2	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
46	Kit C	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
86	Kit C	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
102	Kit C	2	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
104	Kit C	2	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
57	Kit C	3	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
23	Kit C	-	N	N	N	N	D	D	P	P	N	N	P	P	P	P	P	P	P	P
73	Kit C	2	N	N	N	N	D	P	P	P	N	N	P	P	P	P	P	P	P	P
67	Kit D	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
118	Kit F	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
3	Kit G	1	N	N	N	N	N	N	N	N	N	N	P	P	P	P	P	P	P	P
47	Kit G	2	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
80	Kit G	3	N	N	N	N	P	P	P	P	N	N	P	P	P	P	P	P	P	P
115	Kit G	4	N	N	N	N	N	N	N	N	N	N	P	P	P	P	P	P	P	P
121	Kit H	1	N	N	N	N	P	P	P	P	P	P/D	P	P	P	P	P	P	P	P
31	Kit H	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
32	Kit H	2	N	N	N	N	D	D	P	P	N	N	P	P	P	P	P	P	P	P
84	Kit H	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
100	Kit H	3	N	N	N	N	D	D	P	P	D	P	P	P	P	P	P	P	P	P
72	Kit H	4	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
68			N	N	N	N	P	N	P	P	N	N	P	P	P	P	P	P	P	P

i-ELISA (qualitative)

Ext. EU +

Lab.	Kit	Batch	3	3	4	4	5	5
98	Home made	/	P	P	P	P	N	N
45	Kit A	1	N	N	P	P	N	N
37	Kit B	1	N	P	P	P	N	N
66	Kit B	1	P	P	P	P	P	P
4	Kit B	2	N	N	P	P	N	N
6	Kit B	2	P	P	P	P	N	P
112	Kit B	2	P	P	P	P	P	P
60	Kit B	3	N	N	P	P	N	N
29	Kit C	1	P	P	P	P	D	D
2	Kit C	2	P	P	P	P	N	N
46	Kit C	2	N	N	P	P	N	N
86	Kit C	2	N	N	P	P	N	N
102	Kit C	2	P	P	P	P	N	N
104	Kit C	2	P	P	P	P	N	N
57	Kit C	3	P	P	P	P	N	N
23	Kit C	-	D	D	P	P	N	N
73	Kit C	2	D	P	P	P	N	N
67	Kit D	1	N	N	P	P	N	N
118	Kit F	1	N	N	P	P	N	N
3	Kit G	1	N	N	N	N	N	N
47	Kit G	2	P	P	P	P	N	N
80	Kit G	3	P	P	P	P	N	N
115	Kit G	4	N	N	N	N	N	N
121	Kit H	1	P	P	P	P	P	P/D
31	Kit H	2	N	N	P	P	N	N
32	Kit H	2	D	D	P	P	N	N
84	Kit H	2	N	N	P	P	N	N
100	Kit H	3	D	D	P	P	D	P
72	Kit H	4	N	N	P	P	N	N
68			P	N	P	P	N	N

Expected results

Overall quantitative results, whatever the kit used :

- Level 3 : P/D/N
- Level 4 : P; few N
- Level 5 : N, few P/D

i-ELISA (qualitative)

Ext. EU +

Lab.	Kit	Batch	3	3	4	4	5	5
98	Home made	/	P	P	P	P	N	N
45	Kit A	1	N	N	P	P	N	N
37	Kit B	1	N	P	P	P	N	N
66	Kit B	1	P	P	P	P	P	P
4	Kit B	2	N	N	P	P	N	N
6	Kit B	2	P	P	P	P	N	P
112	Kit B	2	P	P	P	P	P	P
60	Kit B	3	N	N	P	P	N	N
29	Kit C	1	P	P	P	P	D	D
2	Kit C	2	P	P	P	P	N	N
46	Kit C	2	N	N	P	P	N	N
86	Kit C	2	N	N	P	P	N	N
102	Kit C	2	P	P	P	P	N	N
104	Kit C	2	P	P	P	P	N	N
57	Kit C	3	P	P	P	P	N	N
23	Kit C	-	D	D	P	P	N	N
73	Kit C	2	D	P	P	P	N	N
67	Kit D	1	N	N	P	P	N	N
118	Kit F	1	N	N	P	P	N	N
3	Kit G	1	N	N	N	N	N	N
47	Kit G	2	P	P	P	P	N	N
80	Kit G	3	P	P	P	P	N	N
115	Kit G	4	N	N	N	N	N	N
121	Kit H	1	P	P	P	P	P	P/D
31	Kit H	2	N	N	P	P	N	N
32	Kit H	2	D	D	P	P	N	N
84	Kit H	2	N	N	P	P	N	N
100	Kit H	3	D	D	P	P	D	P
72	Kit H	4	N	N	P	P	N	N
68			P	N	P	P	N	N

Expected results

Kit B (not tested by EURL):

- Level 3 : P/N
- Level 4 : P
- Level 5 : N/P

Qualitative Rp (minor)

i-ELISA (qualitative)

Ext. EU +

Lab.	Kit	Batch	3	3	4	4	5	5
98	Home made	/	P	P	P	P	N	N
45	Kit A	1	N	N	P	P	N	N
37	Kit B	1	N	P	P	P	N	N
66	Kit B	1	P	P	P	P	P	P
4	Kit B	2	N	N	P	P	N	N
6	Kit B	2	P	P	P	P	N	P
112	Kit B	2	P	P	P	P	P	P
60	Kit B	3	N	N	P	P	N	N
29	Kit C	1	P	P	P	P	D	D
2	Kit C	2	P	P	P	P	N	N
46	Kit C	2	N	N	P	P	N	N
86	Kit C	2	N	N	P	P	N	N
102	Kit C	2	P	P	P	P	N	N
104	Kit C	2	P	P	P	P	N	N
57	Kit C	3	P	P	P	P	N	N
23	Kit C	-	D	D	P	P	N	N
73	Kit C	2	D	P	P	P	N	N
67	Kit D	1	N	N	P	P	N	N
118	Kit F	1	N	N	P	P	N	N
3	Kit G	1	N	N	N	N	N	N
47	Kit G	2	P	P	P	P	N	N
80	Kit G	3	P	P	P	P	N	N
115	Kit G	4	N	N	N	N	N	N
121	Kit H	1	P	P	P	P	P	P/D
31	Kit H	2	N	N	P	P	N	N
32	Kit H	2	D	D	P	P	N	N
84	Kit H	2	N	N	P	P	N	N
100	Kit H	3	D	D	P	P	D	P
72	Kit H	4	N	N	P	P	N	N
68			P	N	P	P	N	N

Expected results

Kit C (tested by EURL and used by French labs.):

- Level 3 : P/D/N (maj. P)
- Level 4 : P
- Level 5 : N/D (maj. N)

Qualitative Rp (minor)

EURL

Homogeneity								
H	Kit C	3	P	P	P	P	N	D
Stability								
S1	Kit C	3	P	P	P	P	N	N
S7	Kit C	3	P	P	P	P	N	N

anses

i-ELISA (qualitative)

Lab.	Kit	Batch	3	3	4	4	5	5
98	Home made	/	P	P	P	P	N	N
45	Kit A	1	N	N	P	P	N	N
37	Kit B	1	N	P	P	P	N	N
66	Kit B	1	P	P	P	P	P	P
4	Kit B	2	N	N	P	P	N	N
6	Kit B	2	P	P	P	P	N	P
112	Kit B	2	P	P	P	P	P	P
60	Kit B	3	N	N	P	P	N	N
29	Kit C	1	P	P	P	P	D	D
2	Kit C	2	P	P	P	P	N	N
46	Kit C	2	N	N	P	P	N	N
86	Kit C	2	N	N	P	P	N	N
102	Kit C	2	P	P	P	P	N	N
104	Kit C	2	P	P	P	P	N	N
57	Kit C	3	P	P	P	P	N	N
23	Kit C	-	D	D	P	P	N	N
73	Kit C	2	D	P	P	P	N	N
67	Kit D	1	N	N	P	P	N	N
118	Kit F	1	N	N	P	P	N	N
3	Kit G	1	N	N	N	N	N	N
47	Kit G	2	P	P	P	P	N	N
80	Kit G	3	P	P	P	P	N	N
115	Kit G	4	N	N	N	N	N	N
121	Kit H	1	P	P	P	P	P	P/D
31	Kit H	2	N	N	P	P	N	N
32	Kit H	2	D	D	P	P	N	N
84	Kit H	2	N	N	P	P	N	N
100	Kit H	3	D	D	P	P	D	P
72	Kit H	4	N	N	P	P	N	N
68			P	N	P	P	N	N

Expected results

Kit G (not tested by EURL):

- Level 3 : P/N
- Level 4 : P/N
- Level 5 : N

Lower Se for 2 labs

→ Different cut-off used (40 ou 45%)

→Qualitative Se variations

→ Consistent quantitative results

→ Minor trouble

Qualitative lack of Se on level 4 (not critical)

i-ELISA (qualitative)

Ext. EU +

Lab.	Kit	Batch	3	3	4	4	5	5
98	Home made	/	P	P	P	P	N	N
45	Kit A	1	N	N	P	P	N	N
37	Kit B	1	N	P	P	P	N	N
66	Kit B	1	P	P	P	P	P	P
4	Kit B	2	N	N	P	P	N	N
6	Kit B	2	P	P	P	P	N	P
112	Kit B	2	P	P	P	P	P	P
60	Kit B	3	N	N	P	P	N	N
29	Kit C	1	P	P	P	P	D	D
2	Kit C	2	P	P	P	P	N	N
46	Kit C	2	N	N	P	P	N	N
86	Kit C	2	N	N	P	P	N	N
102	Kit C	2	P	P	P	P	N	N
104	Kit C	2	P	P	P	P	N	N
57	Kit C	3	P	P	P	P	N	N
23	Kit C	-	D	D	P	P	N	N
73	Kit C	2	D	P	P	P	N	N
67	Kit D	1	N	N	P	P	N	N
118	Kit F	1	N	N	P	P	N	N
3	Kit G	1	N	N	N	N	N	N
47	Kit G	2	P	P	P	P	N	N
80	Kit G	3	P	P	P	P	N	N
115	Kit G	4	N	N	N	N	N	N
121	Kit H	1	P	P	P	P	P	P/D
31	Kit H	2	N	N	P	P	N	N
32	Kit H	2	D	D	P	P	N	N
84	Kit H	2	N	N	P	P	N	N
100	Kit H	3	D	D	P	P	D	P
72	Kit H	4	N	N	P	P	N	N
68			P	N	P	P	N	N

Expected results

Kit H (tested by EURL):

- Level 3 : D/N
- Level 4 : P
- Level 5 : N/D

Interpretation :

- ≠ cut-offs used 40%; 40-60%; 25%
- ≠ protocols (serum dilution)

→Qualitative Se variation

→Consistent quantitative results

→ Minor trouble

Qualitative excess of Se on level 3 & 5 (not critical) – Rp

EURL

S1	Kit H	4	N	D	P	D	D	N
S7	Kit H	4	D	D	P	P	D	D
S7	Kit H	4	N	N	P	P	N	N

i-ELISA (qualitative)

Lab.	Kit	Batch	3	3	4	4	5	5
98	Home made	/	P	P	P	P	N	N
45	Kit A	1	N	N	P	P	N	N
37	Kit B	1	N	P	P	P	N	N
66	Kit B	1	P	P	P	P	P	P
4	Kit B	2	N	N	P	P	N	N
6	Kit B	2	P	P	P	P	N	P
112	Kit B	2	P	P	P	P	P	P
60	Kit B	3	N	N	P	P	N	N
29	Kit C	1	P	P	P	P	D	D
2	Kit C	2	P	P	P	P	N	N
46	Kit C	2	N	N	P	P	N	N
86	Kit C	2	N	N	P	P	N	N
102	Kit C	2	P	P	P	P	N	N
104	Kit C	2	P	P	P	P	N	N
57	Kit C	3	P	P	P	P	N	N
23	Kit C	-	D	D	P	P	N	N
73	Kit C	2	D	P	P	P	N	N
67	Kit D	1	N	N	P	P	N	N
118	Kit F	1	N	N	P	P	N	N
3	Kit G	1	N	N	N	N	N	N
47	Kit G	2	P	P	P	P	N	N
80	Kit G	3	P	P	P	P	N	N
115	Kit G	4	N	N	N	N	N	N
121	Kit H	1	P	P	P	P	P	P/D
31	Kit H	2	N	N	P	P	N	N
32	Kit H	2	D	D	P	P	N	N
84	Kit H	2	N	N	P	P	N	N
100	Kit H	3	D	D	P	P	D	P
72	Kit H	4	N	N	P	P	N	N
68			P	N	P	P	N	N

Expected results

Kit D (tested by EURL and by French labs.):

- Level 3 : N
- Level 4 : P
- Level 5 : N

EURL

S1	Kit D	1	N	N	P	P	N	N
S7	Kit D	1	N	N	P	P	N	N

i-ELISA (qualitative)

Ext. EU +

Lab.	Kit	Batch	3	3	4	4	5	5
98	Home made	/	P	P	P	P	N	N
45	Kit A	1	N	N	P	P	N	N
37	Kit B	1	N	P	P	P	N	N
66	Kit B	1	P	P	P	P	P	P
4	Kit B	2	N	N	P	P	N	N
6	Kit B	2	P	P	P	P	N	P
112	Kit B	2	P	P	P	P	P	P
60	Kit B	3	N	N	P	P	N	N
29	Kit C	1	P	P	P	P	D	D
2	Kit C	2	P	P	P	P	N	N
46	Kit C	2	N	N	P	P	N	N
86	Kit C	2	N	N	P	P	N	N
102	Kit C	2	P	P	P	P	N	N
104	Kit C	2	P	P	P	P	N	N
57	Kit C	3	P	P	P	P	N	N
23	Kit C	-	D	D	P	P	N	N
73	Kit C	2	D	P	P	P	N	N
67	Kit D	1	N	N	P	P	N	N
118	Kit F	1	N	N	P	P	N	N
3	Kit G	1	N	N	N	N	N	N
47	Kit G	2	P	P	P	P	N	N
80	Kit G	3	P	P	P	P	N	N
115	Kit G	4	N	N	N	N	N	N
121	Kit H	1	P	P	P	P	P	P/D
31	Kit H	2	N	N	P	P	N	N
32	Kit H	2	D	D	P	P	N	N
84	Kit H	2	N	N	P	P	N	N
100	Kit H	3	D	D	P	P	D	P
72	Kit H	4	N	N	P	P	N	N
68			P	N	P	P	N	N

Expected results

Kit A, F, home-made (not tested by EURL):

- Level 3 : P/D/N
- Level 4 : P; few N
- Level 5 : N, few P/D

i-ELISA (quantitative)

- Minor troubles :
  - ponctual repeatability problems for 7 labs. (CV > 20%)
  - Interpretation (quali. quanti.) 1 lab (121)

Lab.	Kit	Batch	cut-off P	cut-off D	cut-off N	3	3	CV%	4	4	CV%	5	5	CV%
98	HM	/	>=2	-	<2	3	3	0,00	11	10	6,73	0	0	
45	Kit A	1	>=90	-	<90	74,44	76,6	2,02	150,45	127,73	11,55	72,7	67,92	4,81
37	Kit B	1	>80%		<80%	70,7	80,85	9,47	100,15	97,35	2,00	77,75	79,05	1,17
66	Kit B	1	>=80		<80	81,9	83,84	1,66	93,25	94,38	0,85	82,87	84,76	1,59
4	Kit B	2	>=80	-	<80	75	79	3,67	97	97	0,00	76	71	4,81
112	Kit B	2	>=80	-	<80	84	91	5,66	108	100	5,44	86	93	5,53
6	Kit B	2	>80		<=80	81,1	87,3	5,21	85,1	96,7	9,02	72,2	89,6	15,21
60	Kit B	3	>=80	-	<80	78,3	75,2	2,86	82,1	84,5	2,04	71,8	72,3	0,49
29	Kit C	1	>=120	110-120	<=110	141	138,1	1,47	185,1	191,8	2,51	119,5	117,7	1,07
46	Kit C	2	>=120	110-120	<=110	102,325	105,515	2,17	197,675	201,686	1,42	80,538	69,417	10,49
73	Kit C	2	>=120	110-120	<=110	115,528	134,952	10,97	199,322	197,854	0,52	85,263	77,019	7,18
102	Kit C	2	>=120	110-120	<=110	174,61	162,88	4,92	299,55	288,27	2,71	100,37	94,54	4,23
104	Kit C	2	>=120	110-120	<=110	142,5	154,4	5,67	258,9	250	2,47	86,51	86,91	0,33
2	Kit C	2	>=120	110-120	<=110	167	160	3,03	226	230	1,24	94	94	0,00
86	Kit C	2	>=120	110-120	<=110	47,25	48,85	2,35	136	142,15	3,13	49,65	57,8	10,73
23	Kit C		<110	<110,>120	>110	121	111	6,10	202	220	6,03	66	68	2,11
57	Kit C	3	>=120	110-120	<=110	137,957	134,184	1,96	195,769	181,516	5,34	95,579	98,589	2,19
67	Kit D	1	>=120	110-120	<=110	98	79	15,18	152,8	173,6	9,01	82,9	60,2	22,43
118	Kit F	1	>=25	-	<25	18,2	19,4	4,51	50,1	47,8	3,32	7,7	7,9	1,81
3	Kit G	1	>=45	-	<45	33,1	33,2	0,21	42,9	43,6	1,14	28,2	34,8	14,82
47	Kit G	2	>= 40	-	<40	55,7	48,7	9,48	104,6	114,6	6,45	17,9	17,7	0,79
80	Kit G	3	PP>40		PP<40	90	76,85	11,15	149,43	151,09	0,78	37,47	25,43	26,94
115	Kit G	4	> 45	/	< 45	31	34,06	6,65	40,15	44,14	6,69	36,93	33,56	6,76
121	Kit H	1	>25		<25	38,1	38,5	0,74	63,3	64,5	1,33	33,1	28,3	11,06
31	Kit H	2	>= 40	-	<40	29,662	27,972	4,15	46,445	51,515	7,32	28,089	25,991	5,49
32	Kit H	2	>=60	40-59	<40	48,6	47,4	1,77	61,2	61,6	0,46	16,1	22,3	22,83
84	Kit H	2	>=40	-	<40	33,93	36,4	4,97	50,19	64,27	17,40	2,51	36,33	123,14
100	Kit H	3	>=60	40-59	<40	52,01	55,01	3,96	75,86	71,51	4,17	56,85	66,27	10,82
72	Kit H	4	>=40	-	<40	33,7	24,3	22,92	57,4	57,9	0,61	25,4	26,9	4,06
68			>=80 %		<80	94,87	75,89	15,72	87,95	103,74		77,08	78,77	1,53

i-ELISA (quantitative)

- ponctual repeatability problems for 7 labs. (CV > 20%)

Lab.	Kit	Batch	cut-off P	cut-off D	cut-off N	6	6	6	CV%	7	7	7	CV%	8	8	CV%
98	HM	/	>=2	-	<2	11	10	11	5,41	19	20	21	5,00	39	54	22,81
45	Kit A	1	>=90	-	<90	160,85	184,41	117,7	21,92	178,97	202,54	171	8,91	177,04	209,79	11,97
37	Kit B	1	>80%		<80%	113,85	116,3	83,4	17,54	86,6	114,95	120,8	17,02	119,1	118,6	0,30
66	Kit B	1	>=80		<80	96,47	93,51	95,5	1,59	99,34	100,72	99,37	0,79	100,61	100,46	0,11
4	Kit B	2	>=80	-	<80	106	95	112	8,26	112	120	109	5,00	120	119	0,59
112	Kit B	2	>=80	-	<80	116	114	120	2,62	120	120	118	0,97	117	128	6,35
6	Kit B	2	>80		<=80	101,3	102,1	106,8	2,87	107,7	105,9	110	1,91	111,9	114,6	1,69
60	Kit B	3	>=80	-	<80	94,7	90,3	91	2,57	97,3	95,1	95,3	1,27	100,85	102	0,80
29	Kit C	1	>=120	110-120	<=110	208,3	219,3	216,1	2,64	238,5	245,9	246,7	1,86	264,2	221,7	12,37
46	Kit C	2	>=120	110-120	<=110	215,816	195,761	195,305	5,79	242,89	230,036	235,232	2,74	250,547	256,199	1,58
73	Kit C	2	>=120	110-120	<=110	225,296	232,185	228,346	1,51	271,937	252,626	252,964	4,26	249,975	290,796	10,68
102	Kit C	2	>=120	110-120	<=110	304,77	313,96	318,82	2,28	385,51	376,7	377,58	1,28	405,97	417,77	2,03
104	Kit C	2	>=120	110-120	<=110	277,9	330,1	270,9	11,04	333,1	371	253,1	18,86	417,4	365,4	9,39
2	Kit C	2	>=120	110-120	<=110	218	291	271	14,51	297	301	303	1,02	319	319	0,00
86	Kit C	2	>=120	110-120	<=110	179,9	131,3	129,1	19,57	193,9	193,3	156,6	11,79	261,8	239,8	6,20
23	Kit C		<110	<110,>120	>110	218	209	206	2,96	260	245	268	4,53	284	284	0,00
57	Kit C	3	>=120	110-120	<=110	195,274	193,635	208,955	4,22	223,932	217,987	211,852	2,77	222,942	220,617	0,74
67	Kit D	1	>=120	110-120	<=110	193,3	189,1	186,4	1,83	196,3	208	195	3,58	189,1	188,3	0,30
118	Kit F	1	>=25	-	<25	50,1	49,4	49,3	0,88	72	72,6	72,2	0,42	90,6	91	0,31
3	Kit G	1	>=45	-	<45	64,8	60,8	67,2	5,03	77,9	80,4	86,5	5,42	94,4	104	6,84
47	Kit G	2	>= 40	-	<40	104,3	90,07	88,6	9,19	119,2	115,39	127,2	5,00	136,9	140,6	1,89
80	Kit G	3	PP>40		PP<40	151,09	143,49	151,09	2,95	151,09	151,09	151,09	0,00	151,09	151,09	0,00
115	Kit G	4	> 45	/	< 45	64,86	63,37	68,08	3,68	76,51	75,98	74,52	1,36	89,16	91,57	1,89
121	Kit H	1	>25		<25	89,6	77,8	80,1	7,58	86,3	89,6	90,2	2,37	96,4	95,9	0,37
31	Kit H	2	>= 40	-	<40	68,415	67,483	77,156	7,51	82,576	86,538	82,226	2,86	90,326	85,431	3,94
32	Kit H	2	>=60	40-59	<40	75,8	60,3	82,9	15,83	77,7	91,8	64	17,86	94,9	94,9	0,00
84	Kit H	2	>=40	-	<40	82,85	73,03	71,69	8,03	71,6	80,3	86,44	9,39	93,63	96,85	2,39
100	Kit H	3	>=60	40-59	<40	83,53	83,56	89,5	4,02	103,2	87,16	95,69	8,42	97,41	98,68	0,92
72	Kit H	4	>=40	-	<40	57,9	74	67,7	12,19	86,6	77,4	66,4	13,17	91,4	91,8	0,31
68			>=80 %		<80	111,94	92,48	102,01	9,53	102,64	113,62	116,69	6,66	108,62	110,73	1,36

iELISA

- Very good results **(compared to 2012)**
- EU:
  - Various kits used (8 different kits)
  - 0/ 23 participants : sensitivity (lack or excess) : **5 labs / 22**
  - Se variations due to choice of cut-off→ investigation
  - 6 laboratories / 23 participants: problems of repeatability
- Ext. EU:
  - Various kits used (7 different kits)
  - 1 lab with discrepancies between qualitative and quantitative results
  - 1 lab : problems of repeatability

☞ Compared to last RT: same variety of kits, less sensitivity problems...

→ Better standardization?

☞ Investigation of the origin :

☞ Repeatability (critical points : washing, pipeting, etc.)

cELISA

cELISA

Expected results of iELISA

- Se < iELISA (level 3, 5 & 6) as shown in bovine specific studies (Kit C)

			N	N	N	N	P/N/D	P/N/D	P>N,D	P>N,D	N>P,D	N>P,D	P	P	P	P	P	P	P	P
Lab.	Kit	Batch	1	1	2	2	3	3	4	4	5	5	6	6	6	7	7	7	8	8
2	Kit A	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
45	Kit A	2	N	N	N	N	D	D	P	P	N	N	P	P	P	P	P	P	P	P
4	Kit B	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
32	Kit B	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
47	Kit C	1	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
66	Kit C	1	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
80	Kit C	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
82	Kit C	2	N	N	N	N	N	N	P	P	N	N	P	P	P	P	P	P	P	P
102	Kit C	3	N	N	N	N	N	N	P	P	N	N	N	N	N	P	P	P	P	P
115	Kit C	3	N	N	N	N	N	N	P	P	N	N	N	N	P	P	P	P	P	P

- Satisfactory, improved results compared to previous ILPT (no critical Se problems)
- 3 different kits used

Conclusion

- Overall excellent results
  - **Very good in CFT, SAT, iELISA, cELISA**
  - 1 critical problem in RBT (method? antigen?)

☞ Investigation of the causes ?

Notification will be made to the corresponding laboratories about the weak failures evidenced, so that they investigate whether it is appropriate to address these issues to identify the source of the problem

☞ For the next serology training, focus change to biological control ?

☞ Final report planned for end of 2014


Thanks for your attention!!!