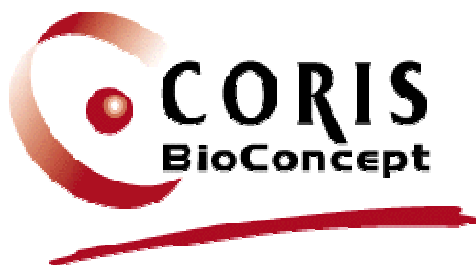


Evaluation of the Coris  
Influ A+B K-SeT (type Influenza A)

In comparison with  
cell culture and PCR

24/05/2012

Coris BioConcept



## Report of Clinical Performance Study of

Influenza Coris BioConcept test  
in comparison with cell culture and PCR

### Truthful and Accurate Statement

I, Dr Laurent Busson certify that, in my capacity as microbiologist, I believe to the best of my knowledge, that all data and information submitted in the above referenced "Report of Clinical Performance Study of Coris Influenza test are truthful and accurate and that no material fact has been omitted.

These data belong to Coris BioConcept, therefore they can be used for any commercial purpose.

Signature:

A handwritten signature in black ink, appearing to read 'L. Busson', with a long horizontal flourish extending to the right.

Date: 24/05/2012

Report of Clinical Performance Study of  
Influenza Coris BioConcept test in comparison with culture and PCR

Place where test was performed: information about the trial Site

CHU St-Pierre

Laboratoire de la Porte de Hal Microbiologie

Rue Haute, 322 1000 Bruxelles

Lead Investigator, Responsible Person of the investigation:

Dr Laurent Busson

Dect : 0032 2 535 31 07

Investigator :

Marc De Foor

Period of Testing (including the estimated end date ) :

January - February 2012

Product evaluated:

Coris BioConcept kit : 2 envois (2 x 40)

Batch Number of sticks stick AB111101 exp 2013/10

Batch Number of extraction batch 111101 exp 2013/10

provided: tubes,  $\mu$ pipettes of 100 $\mu$ l + 3 vials of 16-ml buffer (lot 111101)

Binax kit

Espline kit

Comparator(s) Method(s) :

Cell culture and Influenza PCR

Espline et binax avec PCR (discordants)

Batch Number of kit

Brief description of that reference methods used :

Study Objective:

Evaluate the performance of type A component of cassettes Influenza A+B K-SeT kit

Sample type tested and collection method:

77 naso-pharyngeal aspirates, 15 naso-pharyngeal swabs, 8 throat swabs

Study Population

Nd; Patient specimens collected in routine in hospital

Samples collected (number of samplings to test):

N= 100

Methods employed:

See notice

Trials findings summary (at the end of study):

Calculation with raw data:

Type A		CULT/PCR		total
		POS	NEG	
Coris Test	POS	39	1*	39
	NEG	4	53	57
total		43	54	97

The sample labeled with \* correspond to a true positive with PCR testing.

Calculation of CHU:

Type A		CULT/PCR		total
		POS	NEG	
Coris Test	POS	40	0	40
	NEG	4	53	57
total		44	53	97

Sensitivity : 90,9 % (TP/ (TP+FN))

Specificity : 100 % (TN/ (TN+FP))

Reliability : 95.9% (TN+TP)/Total

Positive Predictive Value 100% (TP/(TP+FP))

Negative Predictive Value 93% (TN/ (TN+ FN))

4 False-negative Coris but Culture + and PCR+:

1393 PCR+	C†20.82	ANP
1442 PCR+	C†29.7	ANP
1462 PCR+	C†27.98	FNASO
1544 PCR+	C†18.82	ANP

Additional tests were not done with these 4 false-negative results. We don't have access to results with Espline and Binax tests.

Conclusion:

- The performance of this prototype cassette is quite interesting. There are no false-positive diagnoses and we have a sensitivity of 90.9% which is better than competitor kits.

- The 4 false-negative Coris (# 1393, # 1442, # 1462 and # 1544) were positive by culture and confirmed by PCR.
- To explain the non-detection of these 4FN by our test, three hypothesis:
  - a. we do not have enough virus in the samples,
  - b. we have a subtype H3N2 not recognized by the antibody test.
  - c. we are within the limits of performance of the kit

Hypothesis a.

For two of the four discordant (# 1393 and # 1544), Ct values suggest that the virus concentration is rather high.

Hypothesis b.

Unlikely because we have the same result with our current kit

-> Hypothesis c. is the one that we favour

- The data are not available with other competitors Espline and Binax test.

Table 1. Results for Each Specimen (No. 1)

A/ The status of samples is defined by the reference method used and should be notified as: N: Negative, P: Positive, TN: True Negative, TP: True Positive, FN: False Negative, FP: False Positive

B/ Legend of the here-under table:

N° 20/....	Prélèv	Coris K7	MRC5	Vero	LLC	PCR
1354	ANP	A	N	N	A	
1355	ANP	N	IN	N	N	
1356	ANP	N	N	N	N	
1357	ANP	A	N	N	A	
1358	ANP	N	RSV	RSV	RSV	
1359	ANP	N	N	N	N	
1360	ANP	A	N	N	A	
1361	ANP	A	N	N	A	
1362	ANP	A	N	N	A	H3N2
1363	FNASO	N	RHINO	N	N	
1364	FNASO	N	N	N	N	
1365	FNASO	N	X	X	X	RSV B
1383	ANP	N	N	N	N	
1384	ANP	N	N	N	N	
1385	ANP	N	RHINO	N	N	
1386	ANP	N	N	N	N	
1387	ANP	A	N	N	A	
1388	ANP	A	N	N	A	
1389	ANP	A	N	N	A	
1390	ANP	A	N	N	A	
1391	ANP	N	N	N	N	
1392	GORGE	traces A	N	N	A	H3N2
1393	ANP	N	N	N	A	H3N2
1394	GORGE	N	N	N	N	
1405	ANP	N	N	N	N	
1406	ANP	A	IN	N	A	
1407	ANP	N	IN	N	N	
1408	ANP	N	RHINO	N	N	
1409	ANP	A	IN	N	A	
1410	ANP	A	N	N	A	
1411	FNASO	N	X	X	X	N
1413	GORGE	N	N	N	N	
1414	GORGE	N	N	N	N	
1421	ANP	N	N	N	N	
1422	ANP	N	N	N	N	
1423	ANP	A	N	N	A	
1427	FNASO	N	N	N	N	
1428	ANP	N	N	N	N	
1429	ANP	N	RHINO	N	N	
1430	ANP	N	N	N	N	
1431	ANP	A	N	N	A	
1434	ANP	A	N	N	A	
1435	ANP	N	N	RSV	RSV	
1436	FNASO	A	N	N	A	
1437	ANP	A	N	N	A	
1438	ANP	A	N	N	A	

1439	ANP	(N)	RHINO	N	N	
1440	ANP	N	ENTERO	N	ENTERO	
1441	ANP	A	N	N	A	
1442	ANP	N	N	N	A	H3N2
1443	ANP	N	N	N	N	
1444	ANP	N	N	N	N	
1445	FNASO	A	N	N	N	H3N2
1456	ANP	N	N	N	N	
1458	ANP	A	N	N	A	
1459	ANP	N	N	N	N	
1461	FNASO	N	N	N	N	
1462	FNASO	N	N	N	A	H3N2
1463	ANP	A	N	N	A	
1499	ANP	N	N	N	N	
1500	ANP	N	N	N	META	
1501	ANP	(N)	N	N	N	
1502	ANP	(N)	RHINO	N	N	
1503	ANP	A	N	N	A	
1504	FNASO	A	N	N	A	
1522	ANP	A	N	N	A	
1523	ANP	N	IN	N	N	
1524	ANP	N	ADENO	ADENO	ADENO	
1525	ANP	A	N	N	A	
1526	ANP	N	CMV	N	N	
1539	ANP	N		N	N	
1540	ANP	N	N	N	N	
1541	ANP	A	N	N	A	H3N2
1542	ANP	N	N	N	N	
1544	ANP	N	N	N	A	H3N2
1545	ANP	A	N	N	A	
1546	FNASO	A	N	N	A	
1547	GORGE	N	N	N	N	
1565	ANP	A	N	N	A	
1566	GORGE	N	N	N	N	
1567	GORGE	N	N	N	N	
1569	ANP	A	IN	N	A	
1570	GORGE	N	N	N	N	
1704	ANP	N	ADENO	ADENO	N	
1705	ANP	N	N	N	N	
1706	ANP	traces A	CMV	N	A	
1707	FNASO	N	N	N	N	
1708	FNASO	A	N	N	A	
1709	FNASO	N	X	X	X	N
1710	ANP	N	N	N	N	
1711	ANP	A	N	N	A	
1712	ANP	A	N	N	A	
1713	ANP	N	N	N	N	
1725	ANP	N	RHINO	N	N	
1726	ANP	A	IN	N	A	
1727	ANP	A	N	N	A	
1728	ANP	N	RSV	RSV	RSV	
1729	ANP	A	N	N	A	
1730	ANP	N	N	N	N	
1740	FNASO	A	N	N	A	

FNASO (1462) is nasopharyngeal smear (type "flocked swab")