

**EXPERTISE AND SERVICE PROVISION  
QUALITY OF LABORATORIES**

**CLINICAL BIOLOGIE COMMISSION  
COMITEE OF EXPERTS**

**EXTERNAL QUALITY ASSESSMENT  
IN CLINICAL BIOLOGIE**

**DEFINITIVE GLOBAL REPORT**

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**Sciensano/Molecular microbiology-Bordetella/1-E**

Expertise and service provision  
Quality of laboratories  
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**Authorization to release the report:** By Bernard China, scheme coordinator, on 23/11/2021.

*Bernard China*

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# TABLE OF CONTENTS

## Contents

.....	3
<b>THE SAMPLES</b> .....	4
<b>THE PARTICIPANTS</b> .....	4
<b>THE RESULTS</b> .....	5
RESULTS PER SAMPLE .....	5
RESULTS PER METHOD .....	5
RESULTS PER LABORATORY .....	6
<b>CONCLUSION</b> .....	6

## **The samples**

The samples were produced from a *Bordetella pertussis* strain originating from the NRC (UZ Brussels).

Bacteria were used to spike expectoration fluid. A panel of 5 samples was prepared.

The homogeneity and the target values were determined by the NRC. The results are summarized in table 1.

Table 1. The samples

Sample ID	content	Target value
BP2001	<i>B. pertussis</i> (2x10 <sup>6</sup> CFUs/mL)	Positive
BP2002	<i>B. pertussis</i> (2x10 <sup>5</sup> CFUs/mL)	Positive
BP2003	No <i>B. pertussis</i>	Negative
BP2004	<i>B. pertussis</i> (7x10 <sup>3</sup> CFUs/mL)	Positive
BP2005	No <i>B. pertussis</i>	Negative

The samples were considered stable (under the classical shipment conditions and beyond the duration of the survey) since the results before and during the surveys were identical.

## **The participants**

22 laboratories were registered. 17 laboratories encoded results (77.3%). One laboratory encoded 2 datasets. Therefore 18 datasets were encoded.

## The results

### Results per sample

Table 2. Results per sample

Sample ID	Expected result	Encoded results
BP2001	Positive	18 positive results
BP2002	Positive	18 positive results
BP2003	Negative	17 negative results 1 false positive result
BP2004	Positive	18 positive results
BP2005	Negative	17 negative results 1 false positive result

Out of 90 results, 88 (97.8%) were correct.

### Results per method

Table 3. Results per method

Method	Number of datasets	Number of results	Number of correct results	% correct results
In house RT-PCR	5	25	25	100
Aries Bordetella (Luminex)	2	10	10	100
Allplex RP4 (Seegene)	2	10	10	100
BioFire FilmArray RP 2.1 (bioMérieux)	3	15	15	100
Bordetella speciation plus toxin (BioGX)	1	5	5	100
R-DiaBorM (Diagenode)	2	10	8*	80
Alethia Pertussis (Meridian)	1	5	5	100
Bordetella R-gene (bioMérieux)	1	5	5	100
Simplexa bordetella (DiaSorin)	1	5	5	100
<b>Total</b>	<b>18</b>	<b>90</b>	<b>88</b>	<b>97.8</b>

\*: 2 false positive results

## Results per laboratory

Table 4. Results per laboratory

		The samples (ID and status)				
Lab	Method	BP2001	BP2002	BP2003	BP2004	BP2005
		Positive (1)	Positive (1)	Negative (0)	Positive (1)	Negative (0)
L1	In house RT-PCR	1	1	0	1	0
L2	In house RT-PCR	1	1	0	1	0
L3	In house RT-PCR	1	1	0	1	0
L9	In house RT-PCR	1	1	0	1	0
L5	In house RT-PCR	1	1	0	1	0
L6	Aries Bordetella (Luminex)	1	1	0	1	0
L4	Aries Bordetella (Luminex)	1	1	0	1	0
L8	Biofire FilmArray RP 2.1 (bioMérieux)	1	1	0	1	0
L10	Biofire FilmArray RP 2.1 (bioMérieux)	1	1	0	1	0
L13	Biofire FilmArray RP 2.1 (bioMérieux)	1	1	0	1	0
L11	Bordetella speciation plus toxin (BioGX)	1	1	0	1	0
L14	R-DiaBorM (Diagenode)	1	1	0	1	0
L16	R-DiaBorM (Diagenode)	1	1	1	1	1
L12	Allplex RP4 (Seegene)	1	1	0	1	0
L7	Allplex RP4 (Seegene)	1	1	0	1	0
L14	Simplexa bordetella (DiaSorin)	1	1	0	1	0
L15	Alethia Pertussis (Meridian)	1	1	0	1	0
L17	Bordetella R-gene (bioMérieux)	1	1	0	1	0

### Conclusion

All laboratories but one obtained 100% of correct responses. The lab (L14) encoding 2 datasets for 2 different methods obtained 100% of correct answers for both methods. Out of the two laboratories using the Diagenode (R-DiaBorM™) kit, one obtained 100% of correct result and the other only 60% of correct results. Maybe, a contamination problem occurred since all the results of this laboratory were positive.

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**END**

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