

External Quality Assessment Scheme

## ***Bordetella pertussis* antibodies** **Round 1, 2023**

### **Specimens**

Please find enclosed 2 human serum samples S001 and S002, each 0.3 mL.

### **Caution**

Quality control specimens derived from human blood must be handled with the same care as patient samples, i.e. as potential transmitters of serious diseases. The specimens are found to be HBsAg, HCVAb and HIVAgAb negative when tested with licensed reagents, but no known test method can offer complete assurance that the specimens will not transmit these or other infectious diseases.

### **Examinations**

BopeAbA

BopeAbG

BopeAbM

Clinical interpretation

### **Storage and use**

The specimens should be stored at 2 ... 8 °C and analysed as soon as possible, preferably within a week. Analyse as adult patient samples.

### **Result reporting**

Please enter the results and methods via LabScala. If you can't find your method from the registry, please contact the EQA Coordinator.

S001:



S002:



2023-01-16

### **INSTRUCTIONS**

Product no. 5950

LQ757223011-012/FI

If the kit is incomplete or contains damaged specimens, please report immediately to [info@labquality.fi](mailto:info@labquality.fi).

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The results should be reported no later than **February 7, 2023**.

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The expected results of the round are published in LabScala in the View Reports section by February 13, 2023.

### **Inquiries**

EQA Coordinator

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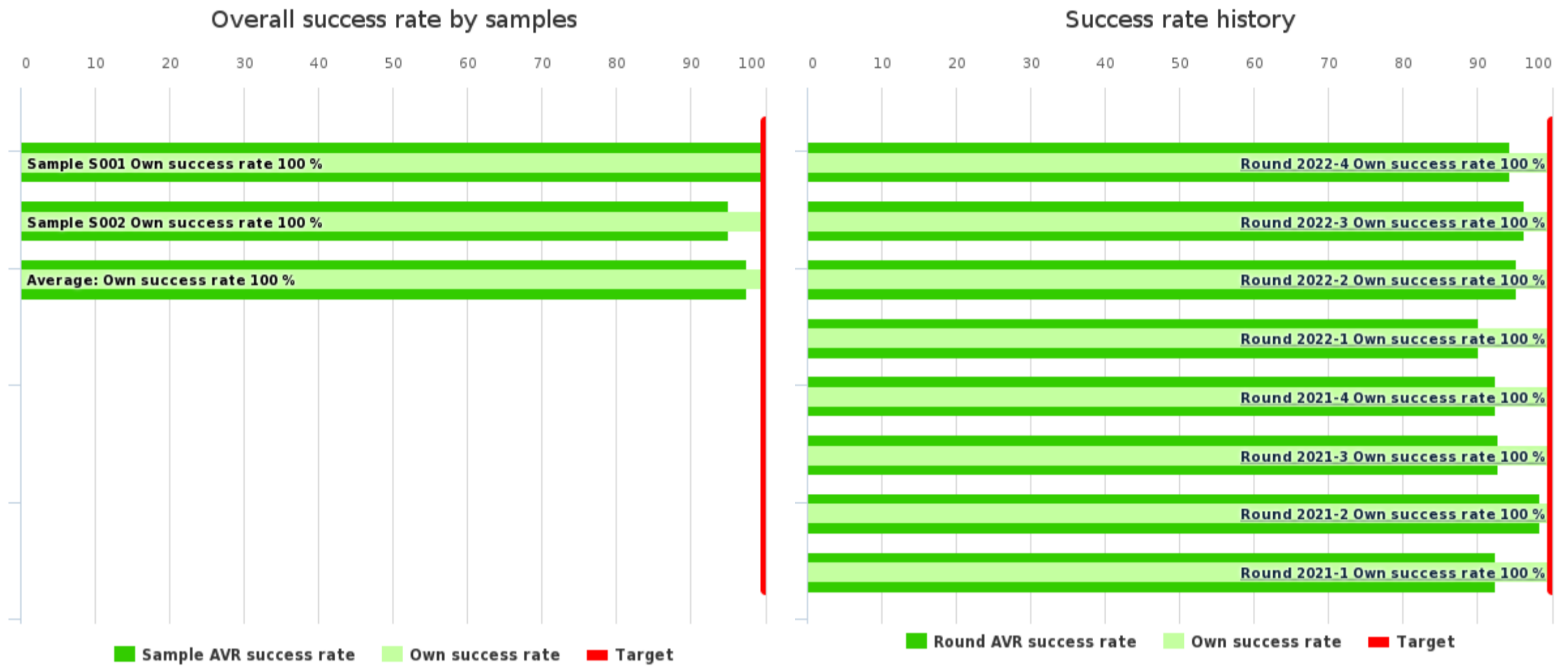
[www.labquality.fi](http://www.labquality.fi)



Client report

	No of participants	No of responded participants	Response percentage
Bordetella pertussis, antibodies, January, 1-2023	44	41	93.2 %

Summary

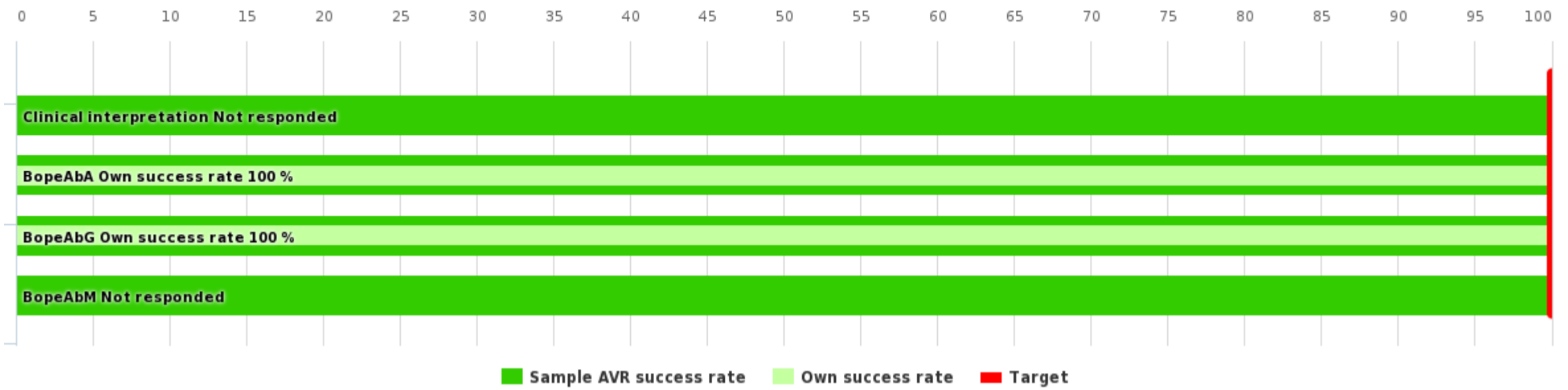


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	4	4	100 %	0 %	100 %
Sample S002	4	4	100 %	4.9 %	95.1 %
Average:			100 %	2.4 %	97.6 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-4	1-1	100 %	5.6 %	94.4 %
Round 2022-3	1-1	100 %	3.7 %	96.3 %
Round 2022-2	1-1	100 %	4.7 %	95.3 %
Round 2022-1	1-1	100 %	9.9 %	90.1 %
Round 2021-4	1-1	100 %	7.6 %	92.4 %
Round 2021-3	1-1	100 %	7.2 %	92.8 %
Round 2021-2	1-1	100 %	1.5 %	98.5 %
Round 2021-1	1-1	100 %	7.5 %	92.5 %

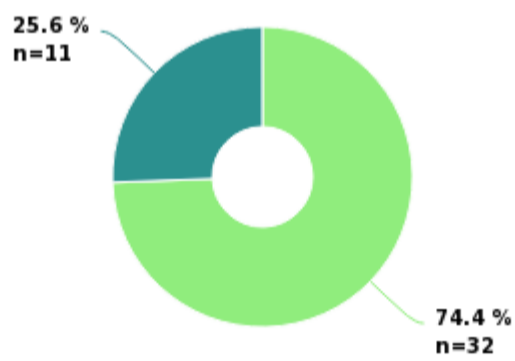
Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	-	-	-	-	100 %	43
	BopeAbA	2	2	100 %	0 %	100 %	27
	BopeAbG	2	2	100 %	0 %	100 %	43
	BopeAbM	-	-	-	-	100 %	9
	Total:	4	4	100 %	0 %	100 %	122

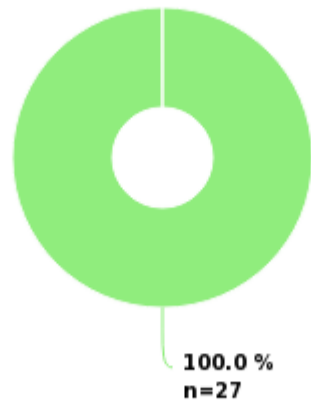
Sample S001 Clinical interpretation



■ Positive, sign of infection  
■ Laboratory does not give clinical interpretations

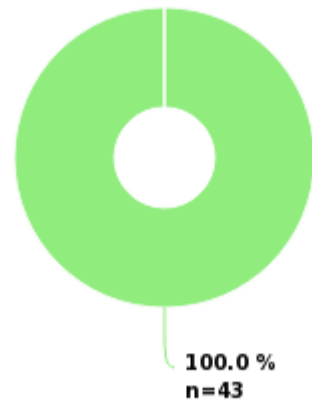
Clinical interpretation	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive, sign of infection	32	-	-	-	-	100 %
	<input checked="" type="radio"/> Laboratory does not give clinical interpretations	11	-	-	-	-	-
	Total:	43	-	-	-	-	100 %

Sample S001 BopeAbA



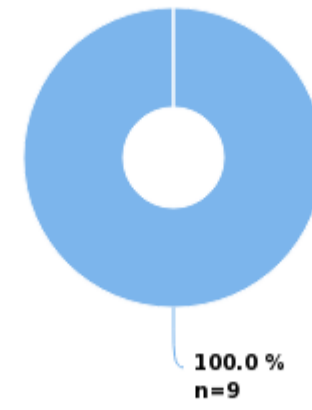
Positive

Sample S001 BopeAbG



Positive

Sample S001 BopeAbM



Negative

BopeAbA	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		27		2	2	100 %	0 %	100 %
		Diasorin LIAISON® Bordetella pertussis Toxin IgA		7					
		Euroimmun Anti- B. pertussis Toxin ELISA IgA		7					
		Euroimmun Anti-Bordetella FHA ELISA IgA		2					
		Euroimmun Euroline Bordetella pertussis IgA		1					
		Novatec NovaLisa B. pertussis IgA ELISA		2					
		<input checked="" type="radio"/> Orgentec B. pertussis TOXIN IgA ELISA		5					
		Siemens Novagnost B. pertussis IgA		1					
		TestLine SmartEIA Bordetella pertussis Toxin IgA		1					
		Virotech Pertussis Toxin ELISA		1					
	Total:		27		2	2	100 %	0 %	100 %

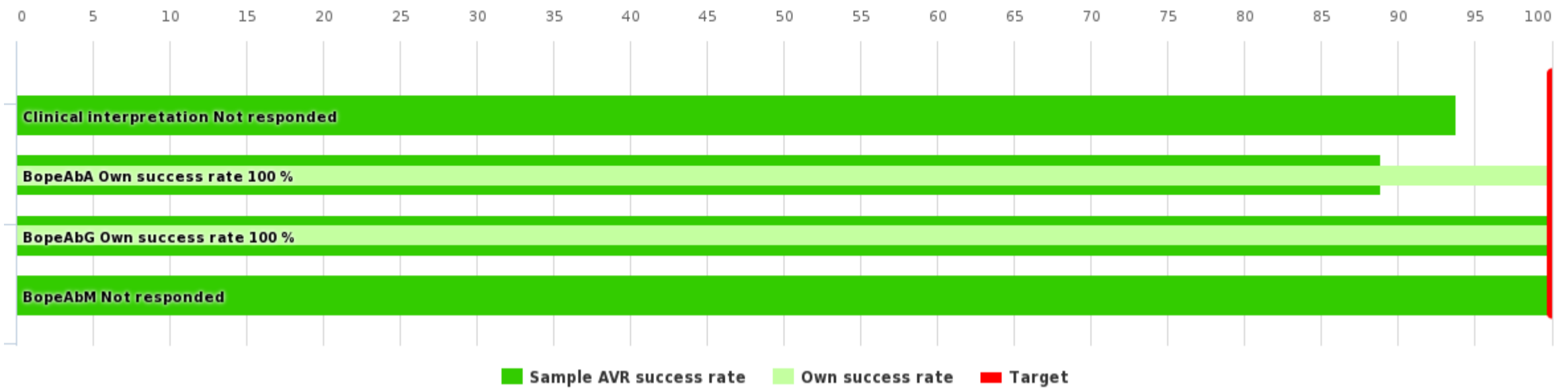
BopeAbG	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		43		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Diasorin LIAISON® Bordetella pertussis Toxin IgG		17					
		Euroimmun Anti-B. pertussis Toxin ELISA IgG		9					
		Euroimmun Anti-Bordetella FHA ELISA IgG		3					
		Euroimmun Euroline Bordetella pertussis IgG		1					
		Novatec NovaLisa B. pertussis IgG ELISA		2					
		Orgentec B. pertussis TOXIN IgG ELISA		4					
		Siemens Novagnost B. pertussis IgG		1					
		TestLine EIA Bordetella pertussis Toxin IgG		1					
		Vircell VIRCLIA Monotest Bordetella Pertussis Toxin IgG		1					
		Virion/Serion B. pertussis IgG		2					
		Virion/Serion B. pertussis Toxin IgG		1					
		Virotech Pertussis Toxin ELISA		1					
	Total:		43		2	2	100 %	0 %	100 %

BopeAbM	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		9		-				100 %
		Euroimmun Anti-B. pertussis ELISA IgM		5					

		Novatec NovaLisa B. pertussis IgM ELISA		1					
		Siemens Novagnost B. pertussis IgM		1					
		TestLine SmartEIA Bordetella pertussis Toxin IgM		1					
		Virotech Pertussis Toxin ELISA		1					
	Total:		9		-	-	-	-	100 %

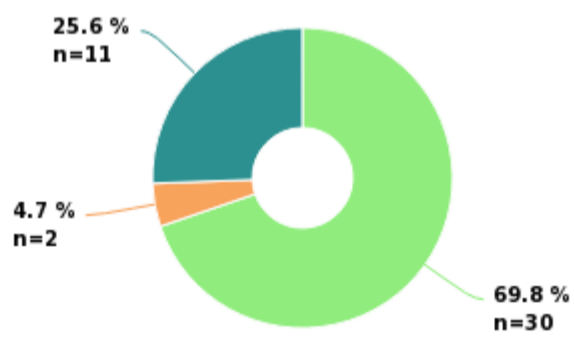
Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	-	-	-	-	93.8 %	43
	BopeAbA	2	2	100 %	11.1 %	88.9 %	27
	BopeAbG	2	2	100 %	0 %	100 %	43
	BopeAbM	-	-	-	-	100 %	9
	Total:	4	4	100 %	4.9 %	95.1 %	122

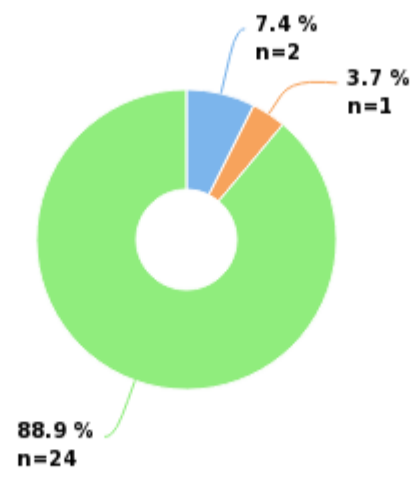
Sample S002 Clinical interpretation



- Positive, sign of infection
- Longstanding infection, serological scar
- Laboratory does not give clinical interpretations

Clinical interpretation	Interpretation	Interpretation count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive, sign of infection	30	-	-	-	-	100 %
	Longstanding infection, serological scar	2	-	-	-	-	0 %
	Laboratory does not give clinical interpretations	11	-	-	-	-	-
	Total:	43	-	-	-	-	93.8 %

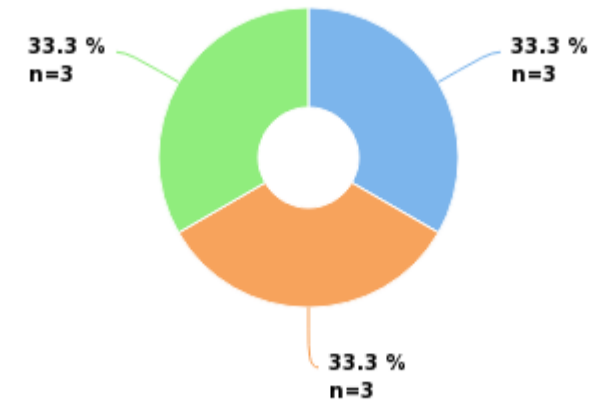
Sample S002 BopeAbA



Sample S002 BopeAbG



Sample S002 BopeAbM



■ Negative ■ Borderline ■ Positive

■ Positive

■ Negative ■ Borderline ■ Positive

BopeAbA	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		Euroimmun Anti-Bordetella FHA ELISA IgA		1					
		Novatec NovaLisa B. pertussis IgA ELISA		1					
	Borderline		1		-				0 %
		Euroimmun Euroline Bordetella pertussis IgA		1					
	<input checked="" type="radio"/> Positive		24		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Diasorin LIAISON® Bordetella pertussis Toxin IgA		8					
		Euroimmun Anti- B. pertussis Toxin ELISA IgA		7					
		Euroimmun Anti-Bordetella FHA ELISA IgA		1					
		Novatec NovaLisa B. pertussis IgA ELISA		1					
		Orgentec B. pertussis TOXIN IgA ELISA		4					
		Siemens Novagnost B. pertussis IgA		1					
		TestLine SmartEIA Bordetella pertussis Toxin IgA		1					
		Virotech Pertussis Toxin ELISA		1					
	Total:		27		2	2	100 %	11.1 %	88.9 %

BopeAbG	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		43		2	2	100 %	0 %	100 %
		<input checked="" type="radio"/> Diasorin LIAISON® Bordetella pertussis Toxin IgG		17					
		Euroimmun Anti-B. pertussis Toxin ELISA IgG		9					
		Euroimmun Anti-Bordetella FHA ELISA IgG		3					
		Euroimmun Euroline Bordetella pertussis IgG		1					
		Novatec NovaLisa B. pertussis IgG ELISA		2					
		Orgentec B. pertussis TOXIN IgG ELISA		4					
		Siemens Novagnost B. pertussis IgG		1					
		TestLine SmartEIA Bordetella pertussis Toxin IgG		1					
		Viricell VIRCLIA Monotest Bordetella Pertussis Toxin IgG		1					
		Virion/Serion B. pertussis Toxin IgG		3					
		Virotech Pertussis Toxin ELISA		1					
	Total:		43		2	2	100 %	0 %	100 %

BopeAbM	Interpretation	Method	Interpretation count	Method count	Own score	Max score	Own success rate	Difference	AVR success rate
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Negative			3		-				100 %
		Euroimmun Anti-B. pertussis ELISA IgM		1					
		Novatec NovaLisa B. pertussis IgM ELISA		1					
		Virotech Pertussis Toxin ELISA		1					
Borderline			3		-				100 %
		Euroimmun Anti-B. pertussis ELISA IgM		2					
		TestLine SmartEIA Bordetella pertussis Toxin IgM		1					
Positive			3		-				100 %
		Euroimmun Anti-B. pertussis ELISA IgM		2					
		Siemens Novagnost B. pertussis IgM		1					
Total:			9		-	-	-	-	100 %



## Report Info

### PARTICIPANTS

Altogether 44 laboratories from 16 countries participated in this EQA round.

### REPORT INFO

The results are divided into groups according to the method stated by the laboratory and presented in laboratory-specific tables. Accepted results are marked with green color and laboratory's own result with a black radio button . In the scoring report you will find summaries of overall success rate and sample specific success rates (%). Sample specific interpretations are shown in pie diagrams as percentages and the total interpretation and methodic counts in the tables. If you have not reported any results you will get a note: "You have not responded in time, only global report is available."

For information on report interpretation and performance evaluation, please see the "EQAS Interpretation guidelines" in LabScala User instructions. In case you have any questions regarding the reports, please contact the EQA Coordinator.

### SCORING

The round is scored based on test results and clinical interpretations when 60% or more of the participants report the expected result and when at least three results are reported.

The following general rules are applied:

Correct/expected test result 2/2 points  
False/deviating test result 0/2 points  
Correct/expected clinical interpretation 4/4 points  
False/deviating clinical interpretation 0/4 points

The performance of the laboratory is assessed by the Own success rate (%). The target is 100%. The examination-specific scores obtained by the laboratory in the round are converted to Own success rate per sample (scores/maximum scores\*100). The Laboratory's Own success rate is the average of the sample success rates.

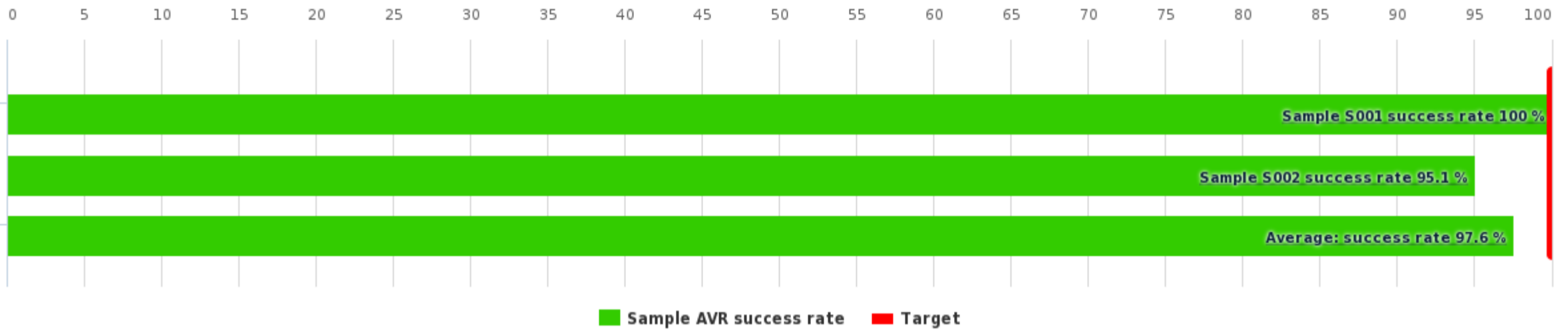
The success rate for the entire round (AVR success rate) is calculated from the total number of scores given to the results per sample (all scores/maximum scores\*100). The AVG success rate of the entire round is the average of the sample success rates. The difference in the Laboratory's Own success rate (%) to the corresponding numbers for the entire round is shown in the table.

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Bordetella pertussis, antibodies, January, 1-2023	44	41	93.2 %

Summary

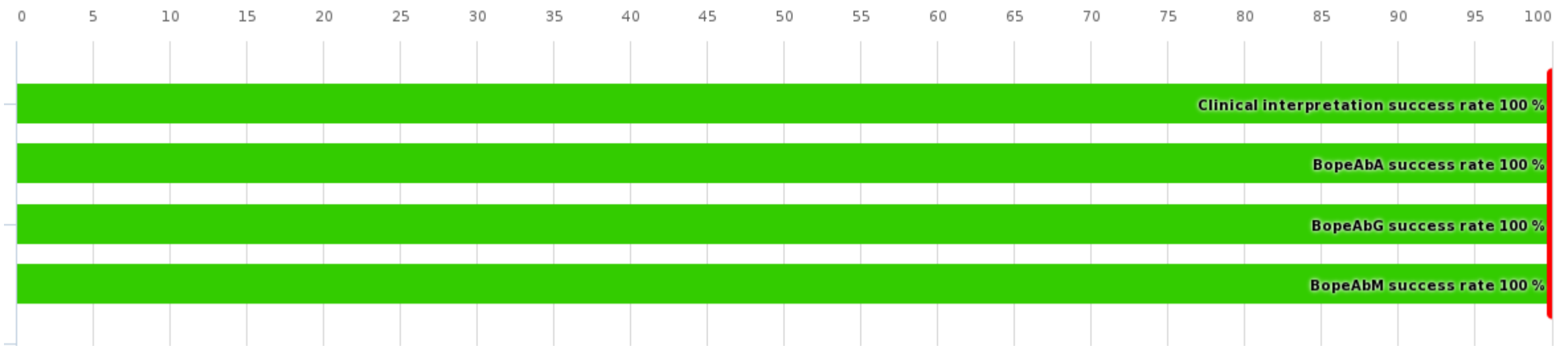
Overall success rate by samples



Summary	AVR success rate
Sample S001	100 %
Sample S002	95.1 %
Average:	97.6 %

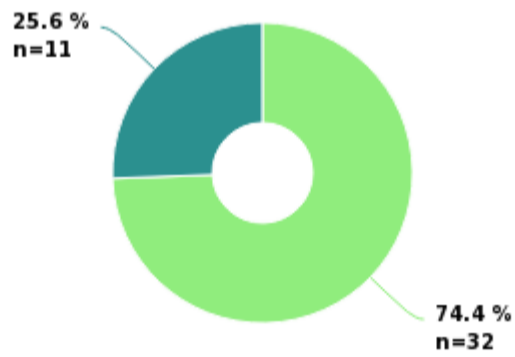
Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	43
	BopeAbA	100 %	27
	BopeAbG	100 %	43
	BopeAbM	100 %	9
	Total:	100 %	122

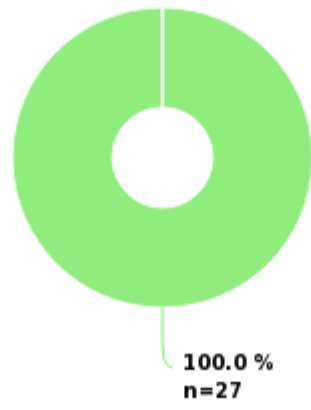
Sample S001 Clinical interpretation



■ Positive, sign of infection  
■ Laboratory does not give clinical interpretations

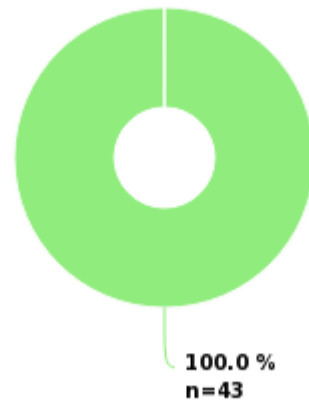
Clinical interpretation	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	Positive, sign of infection	32	100 %	4
	Laboratory does not give clinical interpretations	11	-	-
	Total:	43	100 %	

Sample S001 BopeAbA



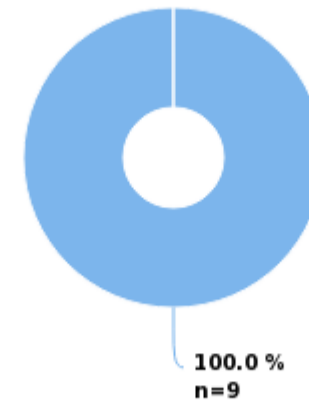
Positive

Sample S001 BopeAbG



Positive

Sample S001 BopeAbM



Negative

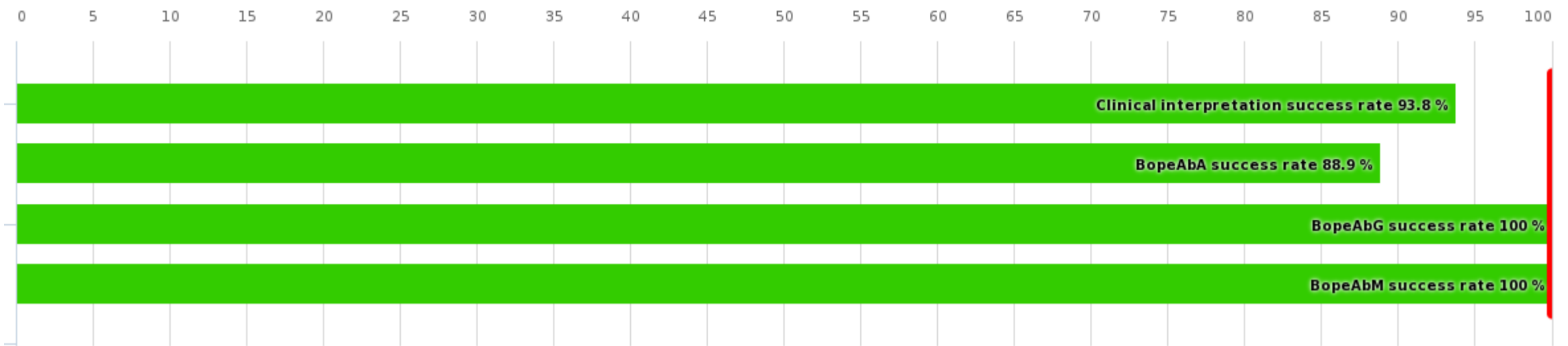
BopeAbA	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		27		100 %	2
		Diasorin LIAISON® Bordetella pertussis Toxin IgA		7		
		Euroimmun Anti- B. pertussis Toxin ELISA IgA		7		
		Euroimmun Anti-Bordetella FHA ELISA IgA		2		
		Euroimmun Euroline Bordetella pertussis IgA		1		
		Novatec NovaLisa B. pertussis IgA ELISA		2		
		Orgentec B. pertussis TOXIN IgA ELISA		5		
		Siemens Novagnost B. pertussis IgA		1		
		TestLine SmartEIA Bordetella pertussis Toxin IgA		1		
		Virotech Pertussis Toxin ELISA		1		
	Total:		27		100 %	

BopeAbG	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		43		100 %	2
		Diasorin LIAISON® Bordetella pertussis Toxin IgG		17		
		Euroimmun Anti-B. pertussis Toxin ELISA IgG		9		
		Euroimmun Anti-Bordetella FHA ELISA IgG		3		
		Euroimmun Euroline Bordetella pertussis IgG		1		
		Novatec NovaLisa B. pertussis IgG ELISA		2		
		Orgentec B. pertussis TOXIN IgG ELISA		4		
		Siemens Novagnost B. pertussis IgG		1		
		TestLine EIA Bordetella pertussis Toxin IgG		1		
		Viricell VIRCLIA Monotest Bordetella Pertussis Toxin IgG		1		
		Virion/Serion B. pertussis IgG		2		
		Virion/Serion B. pertussis Toxin IgG		1		
		Virotech Pertussis Toxin ELISA		1		
	Total:		43		100 %	

BopeAbM	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		9		100 %	2
		Euroimmun Anti-B. pertussis ELISA IgM		5		
		Novatec NovaLisa B. pertussis IgM ELISA		1		
		Siemens Novagnost B. pertussis IgM		1		
		TestLine SmartEIA Bordetella pertussis Toxin IgM		1		
		Virotech Pertussis Toxin ELISA		1		
	Total:		9		100 %	

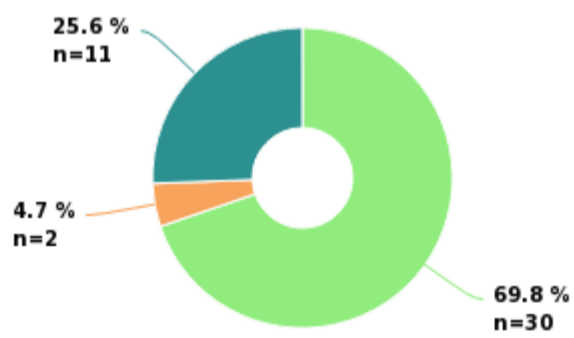
Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Clinical interpretation	93.8 %	43
	BopeAbA	88.9 %	27
	BopeAbG	100 %	43
	BopeAbM	100 %	9
	Total:	95.1 %	122

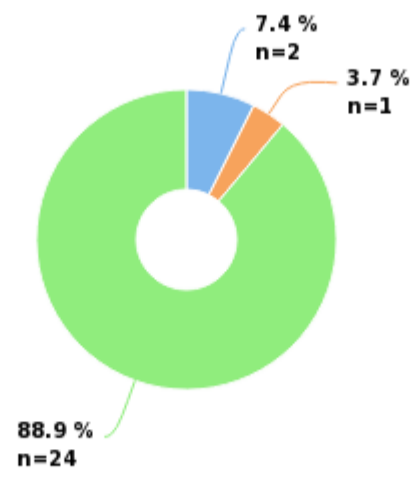
Sample S002 Clinical interpretation



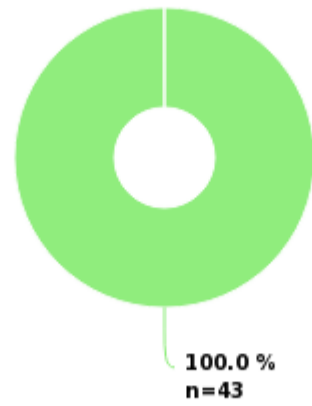
- Positive, sign of infection
- Longstanding infection, serological scar
- Laboratory does not give clinical interpretations

Clinical interpretation	Interpretation	Interpretation count	AVR success rate	Interpretation Score
	Positive, sign of infection	30	100 %	4
	Longstanding infection, serological scar	2	0 %	0
	Laboratory does not give clinical interpretations	11	-	-
	Total:	43	93.8 %	

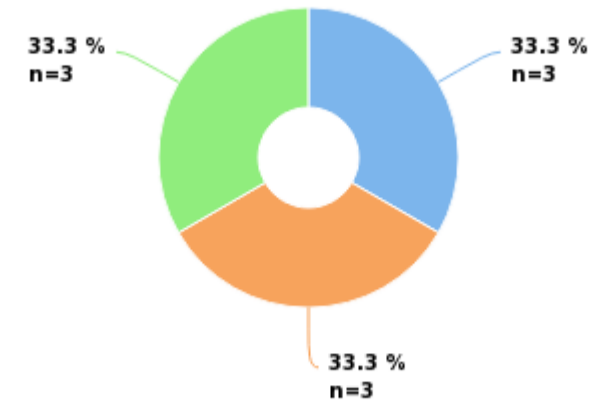
Sample S002 BopeAbA



Sample S002 BopeAbG



Sample S002 BopeAbM



■ Negative ■ Borderline ■ Positive

■ Positive

■ Negative ■ Borderline ■ Positive

BopeAbA	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		2		0 %	0
		Euroimmun Anti-Bordetella FHA ELISA IgA		1		
		Novatec NovaLisa B. pertussis IgA ELISA		1		
	Borderline		1		0 %	0
		Euroimmun Euroline Bordetella pertussis IgA		1		
	Positive		24		100 %	2
		Diasorin LIAISON® Bordetella pertussis Toxin IgA		8		
		Euroimmun Anti- B. pertussis Toxin ELISA IgA		7		
		Euroimmun Anti-Bordetella FHA ELISA IgA		1		
		Novatec NovaLisa B. pertussis IgA ELISA		1		
		Orgentec B. pertussis TOXIN IgA ELISA		4		
		Siemens Novagnost B. pertussis IgA		1		
		TestLine SmartEIA Bordetella pertussis Toxin IgA		1		
		Virotech Pertussis Toxin ELISA		1		
	Total:		27		88.9 %	

BopeAbG	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Positive		43		100 %	2
		Diasorin LIAISON® Bordetella pertussis Toxin IgG		17		
		Euroimmun Anti-B. pertussis Toxin ELISA IgG		9		
		Euroimmun Anti-Bordetella FHA ELISA IgG		3		
		Euroimmun Euroline Bordetella pertussis IgG		1		
		Novatec NovaLisa B. pertussis IgG ELISA		2		
		Orgentec B. pertussis TOXIN IgG ELISA		4		
		Siemens Novagnost B. pertussis IgG		1		
		TestLine SmartEIA Bordetella pertussis Toxin IgG		1		
		Viricell VIRCLIA Monotest Bordetella Pertussis Toxin IgG		1		
		Virion/Serion B. pertussis Toxin IgG		3		
		Virotech Pertussis Toxin ELISA		1		
	Total:		43		100 %	

BopeAbM	Interpretation	Method	Interpretation count	Method count	AVR success rate	Interpretation Score
	Negative		3		100 %	2
		Euroimmun Anti-B. pertussis ELISA IgM		1		
		Novatec NovaLisa B. pertussis IgM ELISA		1		
		Virotech Pertussis Toxin ELISA		1		
	Borderline		3		100 %	2
		Euroimmun Anti-B. pertussis ELISA IgM		2		
		TestLine SmartEIA Bordetella pertussis Toxin IgM		1		

	Positive		3		100 %	2
		Euroimmun Anti-B. pertussis ELISA IgM		2		
		Siemens Novagnost B. pertussis IgM		1		
	Total:		9		100 %	

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External Quality Assessment Scheme

## ***Bordetella pertussis*, antibodies** **Round 1, 2023**

### **Specimens**

Samples of this EQA round were human plasma. The homogeneity of samples was ensured during the sample preparation. The antibodies are known to be stable and there are no special requirements for their handling or storage. The samples were suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

The accepted results were as follows:

#### Sample S001 (LQ757223011)

BopeAbA	Positive
BopeAbG	Positive
BopeAbM	Negative
Clinical interpretation	Positive, sign of infection

#### Sample S002 (LQ757223012)

BopeAbA	Positive
BopeAbG	Positive
BopeAbM	Negative/Borderline/Positive
Clinical interpretation	Positive, sign of infection

### **Report info**

It is important to read the Final report first, because it contains important information of the samples and results in each round.

### **Comments - Expert**

Both samples in this round were *B. pertussis* antibody positive.

In sample S001, IgA and IgG pertussis antibodies were positive and IgM antibodies negative in the analysis of the expert laboratory. These were also the results of all participating laboratories. IgG antibodies against pertussis toxin were highly elevated (>140 IU/mL) in the analysis of the expert laboratory. Based on positive IgA and IgG results, the expected clinical interpretation was "positive, sign of infection".

In sample S002, IgA and IgG pertussis antibodies were positive in the pretesting of the sample, and borderline reactivity was detected in IgM antibodies. IgG antibodies against pertussis toxin were highly elevated (>200 IU/mL in the pretesting). All participants reported positive IgG results, and IgA antibodies were positive in 24/27 laboratories. IgM results ranged from negative to positive and no consensus was achieved. Therefore, all IgM results were scored two points. As clinical interpretation, "positive, sign of infection" was the correct one.

### **End of report**

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2023-02-22

### **FINAL REPORT**

Product no. 5950

Subcontracting: Sample pretesting

Samples sent	2023-01-16
Round closed	2023-02-07
Final report	2023-02-22

### **Request for correction**

Typing errors in laboratory's result forms are on laboratory's responsibility. Labquality accepts responsibility only for result processing. Requests must be notified by writing within three weeks from the date of this letter.

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