# LABQUALITY

External Quality Assessment Scheme

# Tick-borne encephalitis virus, antibodies Round 1, 2023

#### **Specimens**

Please find enclosed 3 human plasma or serum samples S001, S002 and S003, each  $0.5\ mL$ .

#### 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**

TBEV total antibodies
TBEV IgG antibodies
TBEV IgM antibodies + POCT
Clinical interpretation

#### Storage and use

After arrival, the samples should be stored at +2...8 °C, and used as soon as possible, preferably within a week. The samples are ready for use. Analyse as patient samples.

#### Result reporting

Please enter the results and methods via LabScala (www.labscala.com). If you cannot find your instrument or reagent from the registry, please contact the EQA Coordinator. All reported examinations will be scored.

S001



S002



S003



#### 2023-03-07

#### **INSTRUCTIONS**

Product no. 5099 LQ774123011-013/FI

Subcontracting: Sample pretesting

If the kit is incomplete or contains damaged specimens, please report immediately to info@labquality.fi.

The results should be reported no later than **March 30, 2023**.

The expected results of the round are published in LabScala in the View Reports section by April 4, 2023.

#### Inquiries

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#### **Labquality Oy**

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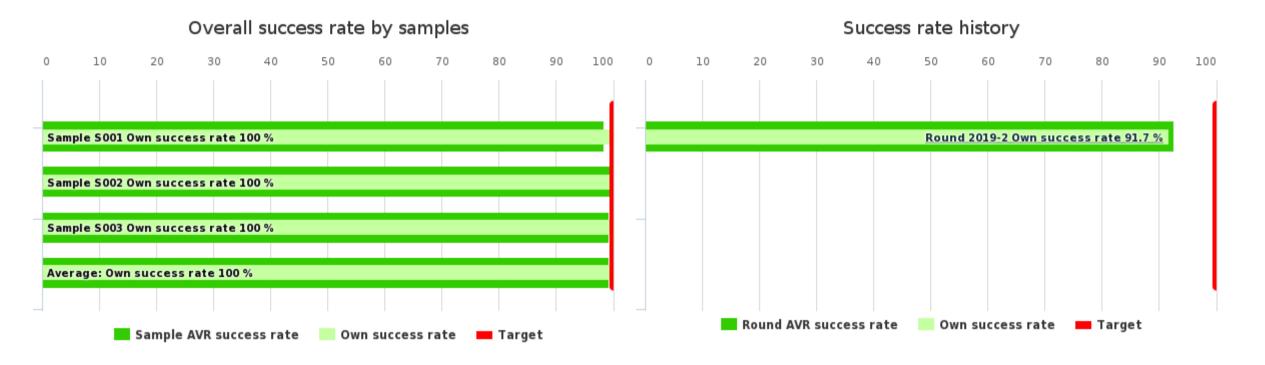




# **Client report**

	No of participants	No of responded participants	Response percentage
Tick-borne encephalitis virus, antibodies, March, 1-2023	43	41	95.3 %

# Summary

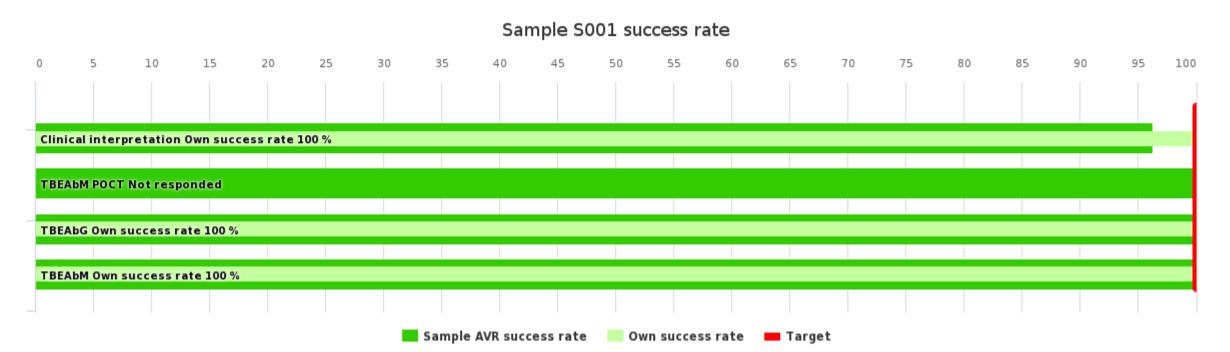


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	8	8	100 %	1.5 %	98.5 %
Sample S002	8	8	100 %	0 %	100 %
Sample S003	8	8	100 %	0.7 %	99.3 %
Average:			100 %	0.7 %	99.3 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2019-2	1-1	91.7 %	-0.9 %	92.6 %

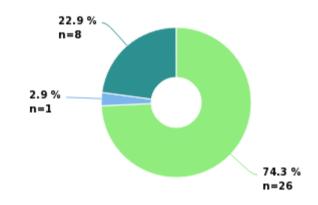






Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	4	4	100 %	3.7 %	96.3 %	35
	ТВЕАЬМ РОСТ	-	-	-	-	100 %	15
	TBEAbG	2	2	100 %	0 %	100 %	34
	TBEAbM	2	2	100 %	0 %	100 %	33
Total:		8	8	100 %	1.5 %	98.5 %	117

# Sample S001 Clinical interpretation



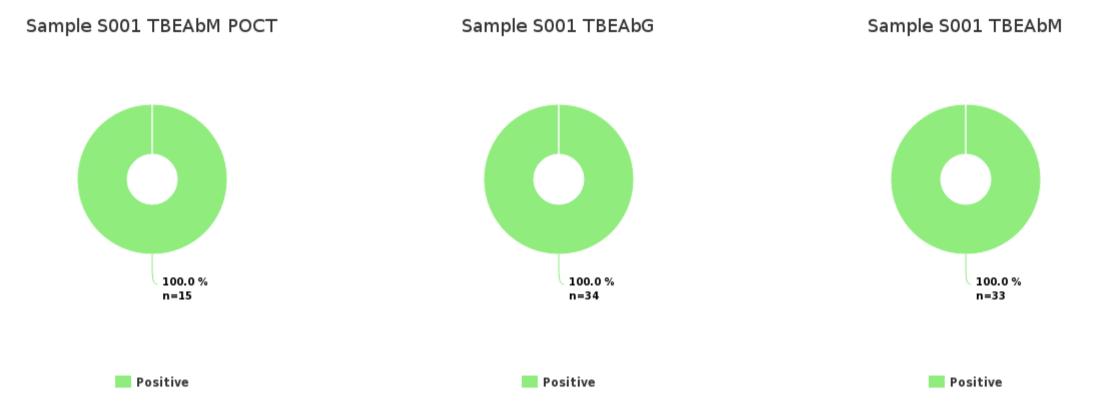


Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	<ul><li>Acute/recent infection</li></ul>		26		4	4	100 %	0 %	100 %
		<ul><li>A second sample is requested</li></ul>		4	-	-			
		Referred to confirmation		1	-	-			
	Old immunity/vaccinated		1		-				0 %
	Laboratory does not give clinical interpretation		8		-				-
	Total:		35		4	4	100 %	3.7 %	96.3 %

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TBEAbM POCT	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		15		-				100 %
		Reagena ReaScan TBE IgM		15					
	Total:		15		-	-	-	-	100 %

## **OWN DEVICE: VIROTECH REAGENTS**

TBEAbG	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<ul><li>Positive</li></ul>		34		2	2	100 %	0 %	100 %
		Diesse Chorus Tick-borne Encephalitis Virus IgG		1					
		Euroimmun Anti-TBE virus ELISA		13					
		Euroimmun TBE IFA		2					
		Euroimmun TBEV Vienna IgG		1					
		TestLine SmartEIA TBE Virus IgG		1					
		Vidia VIDITEST anti-TBEV IgG ELISA		1					
		Vircell TBE VirClia IgG		7					
		Virion/Serion SERION ELISA classic TBE Virus IgG		4					
		ViroTech FSME/TBE ELISA		4					
	Total:		34		2	2	100 %	0 %	100 %

# **OWN DEVICE: VIROTECH REAGENTS**

TBEAbM	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<ul><li>Positive</li></ul>		33		2	2	100 %	0 %	100 %
		Diesse Chorus Tick-borne Encephalitis Virus IgM		1					
		Euroimmun Anti-TBE virus ELISA		13					
		Euroimmun TBE IFA		3					
		TestLine SmartEIA TBE Virus IgM		1					
		Vidia VIDITEST anti-TBEV IgM ELISA		1					
		Vircell TBE VirClia IgM		7					
		Virion/Serion Virion/Serion SERION ELISA classic TBE Virus IgM		3					
		ViroTech FSME/TBE ELISA		4					
	Total:		33		2	2	100 %	0 %	100 %

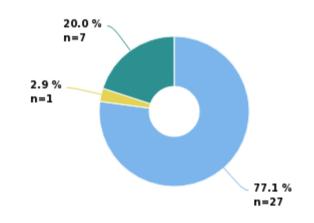


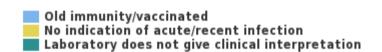




Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	4	4	100 %	0 %	100 %	35
	ТВЕАЬМ РОСТ	-	-	-	-	100 %	14
	TBEAbG	2	2	100 %	0 %	100 %	34
	TBEAbM	2	2	100 %	0 %	100 %	33
Total:		8	8	100 %	0 %	100 %	116

# Sample S002 Clinical interpretation





Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	<ul><li>Old immunity/vaccinated</li></ul>		27		4	4	100 %	0 %	100 %
		A second sample is requested		2	-	-			
	No indication of acute/recent infection		1		-				100 %
	Laboratory does not give clinical interpretation		7		-				-
	Total:		35		4	4	100 %	0 %	100 %

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Negative

XXXX





TBEAbM POCT	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		14		-				100 %
		Reagena ReaScan TBE IgM		14					
	Total:		14		-	-	-	-	100 %

Positive

## **OWN DEVICE: VIROTECH REAGENTS**

Negative

TBEAbG	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<ul><li>Positive</li></ul>		34		2	2	100 %	0 %	100 %
		Diesse Chorus Tick-borne Encephalitis Virus IgG		1					
		Euroimmun Anti-TBE virus ELISA		13					
		Euroimmun TBE IFA		2					
		Euroimmun TBEV Vienna IgG		1					
		TestLine SmartEIA TBE Virus IgG		1					
		Vidia VIDITEST anti-TBEV IgG ELISA		1					
		Vircell TBE VirClia IgG		7					
		Virion/Serion SERION ELISA classic TBE Virus IgG		4					
		ViroTech FSME/TBE ELISA		4					
	Total:		34		2	2	100 %	0 %	100 %

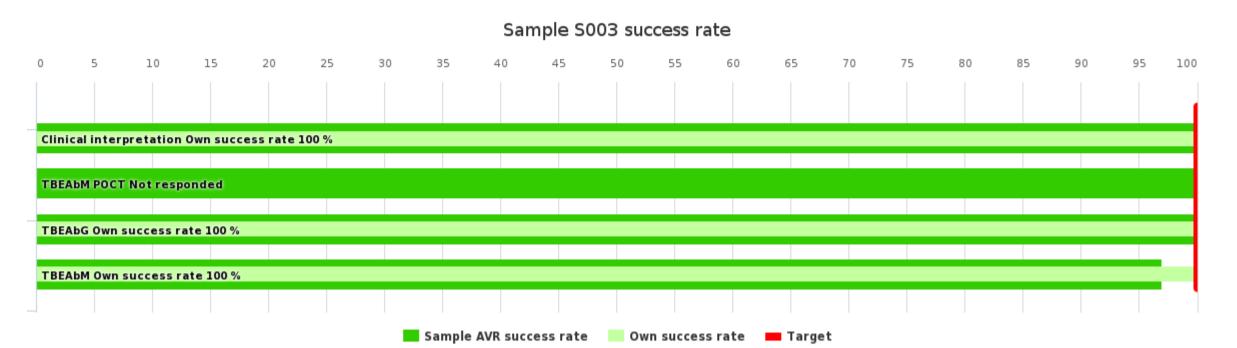
# **OWN DEVICE: VIROTECH REAGENTS**

TBEAbM	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<ul><li>Negative</li></ul>		33		2	2	100 %	0 %	100 %
		Diesse Chorus Tick-borne Encephalitis Virus IgM		1					
		Euroimmun Anti-TBE virus ELISA		13					
		Euroimmun TBE IFA		3					
		TestLine SmartEIA TBE Virus IgM		1					
		Vidia VIDITEST anti-TBEV IgM ELISA		1					
		Vircell TBE VirClia IgM		7					
		Virion/Serion Virion/Serion SERION ELISA classic TBE Virus IgM		3					
		ViroTech FSME/TBE ELISA		4					
	Total:		33		2	2	100 %	0 %	100 %

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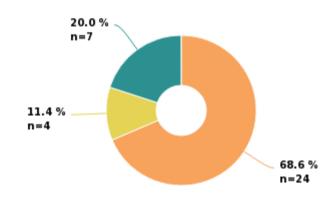


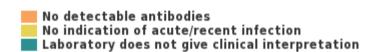




Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	4	4	100 %	0 %	100 %	35
	TBEAbM POCT	-	-	-	-	100 %	14
	TBEAbG	2	2	100 %	0 %	100 %	34
	TBEAbM	2	2	100 %	3 %	97 %	33
Total:		8	8	100 %	0.7 %	99.3 %	116

# Sample S003 Clinical interpretation



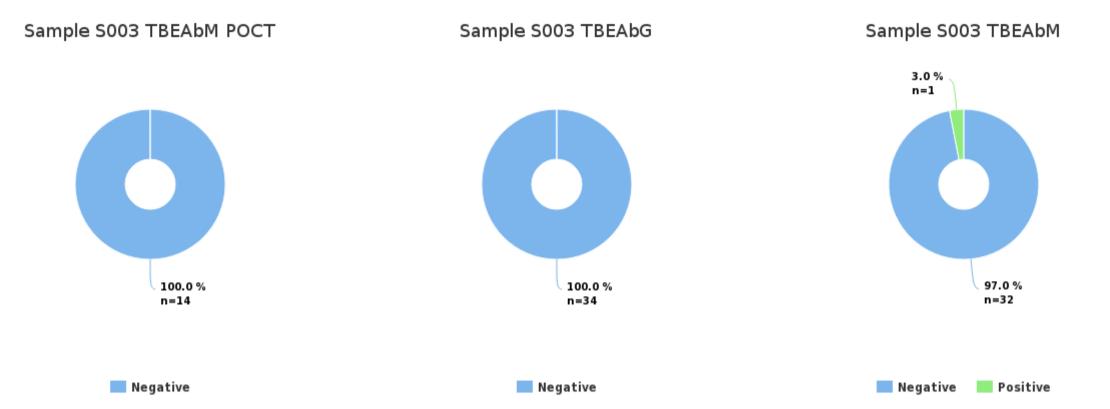


Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	<ul> <li>No detectable antibodies</li> </ul>		24		4	4	100 %	0 %	100 %
		A second sample is requested		4	-	-			
	No indication of acute/recent infection		4		-				100 %
	Laboratory does not give clinical interpretation		7		-				-
	Total:		35		4	4	100 %	0 %	100 %

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TBEAbM POCT	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		14		-				100 %
		Reagena ReaScan TBE IgM		14					
	Total:		14		-	-	-	-	100 %

## **OWN DEVICE: VIROTECH REAGENTS**

TBEAbG	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<ul><li>Negative</li></ul>		34		2	2	100 %	0 %	100 %
		Diesse Chorus Tick-borne Encephalitis Virus IgG		1					
		Euroimmun Anti-TBE virus ELISA		13					
		Euroimmun TBE IFA		2					
		Euroimmun TBEV Vienna IgG		1					
		TestLine SmartEIA TBE Virus IgG		1					
		Vidia VIDITEST anti-TBEV IgG ELISA		1					
		Vircell TBE VirClia IgG		7					
		Virion/Serion SERION ELISA classic TBE Virus IgG		4					
		ViroTech FSME/TBE ELISA		4					
	Total:		34		2	2	100 %	0 %	100 %

# **OWN DEVICE: VIROTECH REAGENTS**

TBEAbM	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<ul><li>Negative</li></ul>		32		2	2	100 %	0 %	100 %
		Diesse Chorus Tick-borne Encephalitis Virus IgM		1					
		Euroimmun Anti-TBE virus ELISA		12					
		Euroimmun TBE IFA		3					
		TestLine SmartEIA TBE Virus IgM		1					
		Vidia VIDITEST anti-TBEV IgM ELISA		1					
		Vircell TBE VirClia IgM		7					
		Virion/Serion Virion/Serion SERION ELISA classic TBE Virus IgM		3					
		ViroTech FSME/TBE ELISA		4					
	Positive		1		-				0 %
		Euroimmun Anti-TBE virus ELISA		1					
	Total:		33		2	2	100 %	3 %	97 %

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# LABQUALITY Tick-borne encephalitis virus, antibodies, March, 1-2023



# **Report Info**

## **PARTICIPANTS**

Altogether 43 laboratories from 14 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.

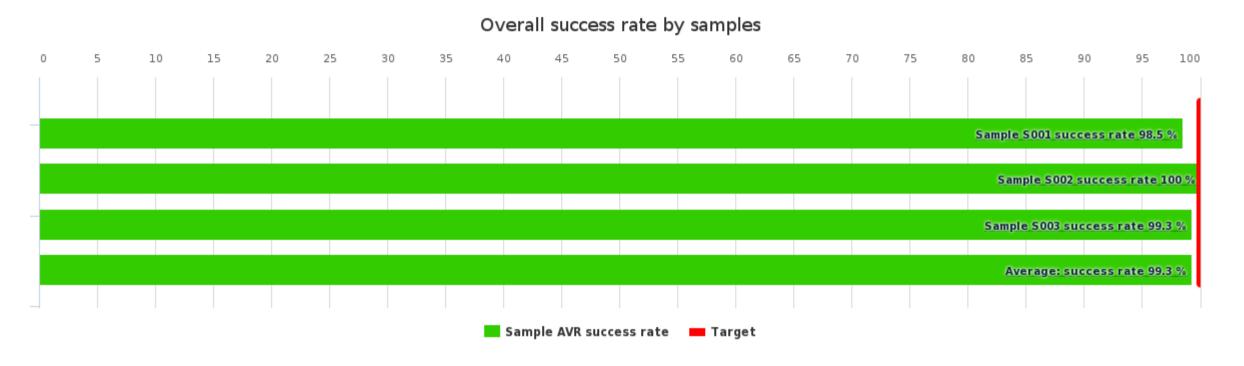
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# **GLOBAL REPORT**

	No of participants	No of responded participants	Response percentage
Tick-borne encephalitis virus, antibodies, March, 1-2023	43	41	95.3 %

# Summary



Summary	AVR success rate
Sample S001	98.5 %
Sample S002	100 %
Sample S003	99.3 %
Average:	99.3 %

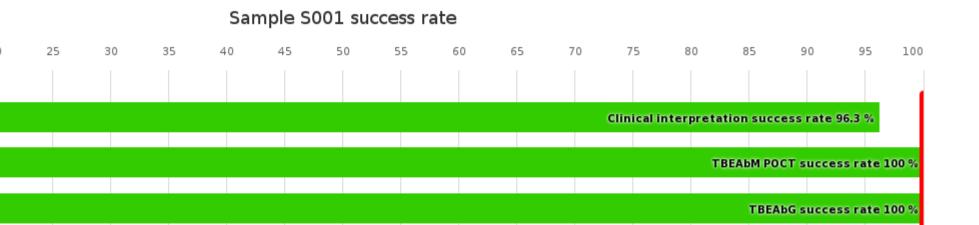
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10

15

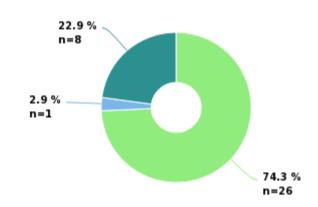
# Sample S001

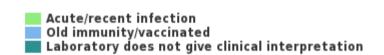


TBEAbM success rate 100 %

Sample S001 results	Responded	AVR success rate	Count
	Clinical interpretation	96.3 %	35
	TBEAbM POCT	100 %	15
	TBEAbG	100 %	34
	TBEAbM	100 %	33
Tota	:	98.5 %	117

# Sample S001 Clinical interpretation



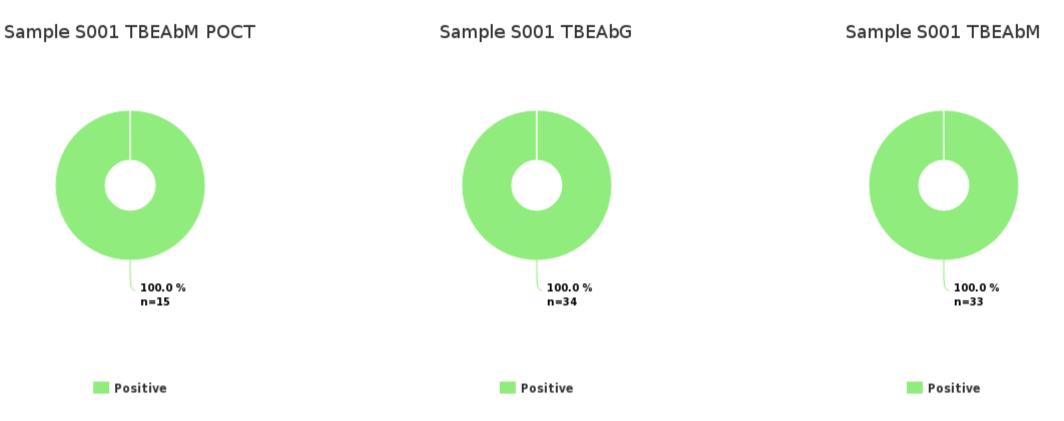


Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	AVR success rate	Interpretation Score	Further action Score
	Acute/recent infection		26		100 %	4	
		A second sample is requested		4	-		-
		Referred to confirmation		1	-		-
	Old immunity/vaccinated		1		0 %	0	
	Laboratory does not give clinical interpretation		8		-	-	
	Total:		35		96.3 %		

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# **LΔBQUΔLITY** Tick-borne encephalitis virus, antibodies, March, 1-2023



TBEAbM POCT	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Positive		15		100 %	2
		Reagena ReaScan TBE IgM		15		
	Total:		15		100 %	

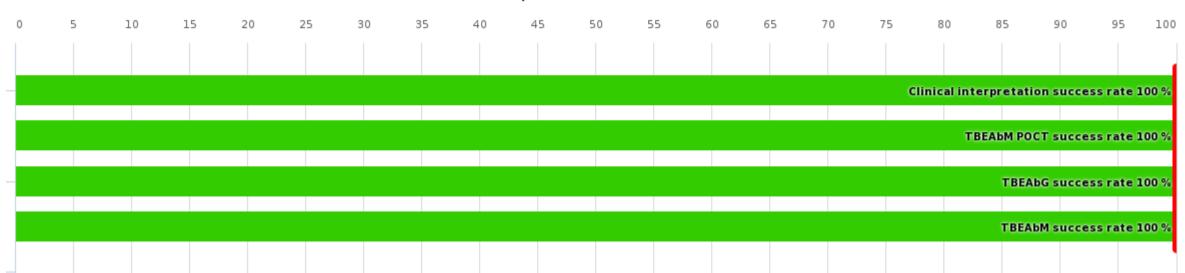
TBEAbG	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Positive		34		100 %	2
		Diesse Chorus Tick-borne Encephalitis Virus IgG		1		
		Euroimmun Anti-TBE virus ELISA		13		
		Euroimmun TBE IFA		2		
		Euroimmun TBEV Vienna IgG		1		
		TestLine SmartEIA TBE Virus IgG		1		
		Vidia VIDITEST anti-TBEV IgG ELISA		1		
		Vircell TBE VirClia IgG		7		
		Virion/Serion SERION ELISA classic TBE Virus IgG		4		
		ViroTech FSME/TBE ELISA		4		
	Total:		34		100 %	

TBEAbM	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Positive		33		100 %	2
		Diesse Chorus Tick-borne Encephalitis Virus IgM		1		
		Euroimmun Anti-TBE virus ELISA		13		
		Euroimmun TBE IFA		3		
		TestLine SmartEIA TBE Virus IgM		1		
		Vidia VIDITEST anti-TBEV IgM ELISA		1		
		Vircell TBE VirClia IgM		7		
		Virion/Serion Virion/Serion SERION ELISA classic TBE Virus IgM		3		
		ViroTech FSME/TBE ELISA		4		
	Total:		33		100 %	

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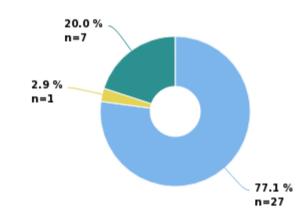


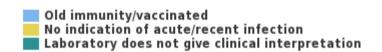




Sample S002 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	35
	TBEAbM POCT	100 %	14
	TBEAbG	100 %	34
	TBEAbM	100 %	33
Total:		100 %	116

# Sample S002 Clinical interpretation



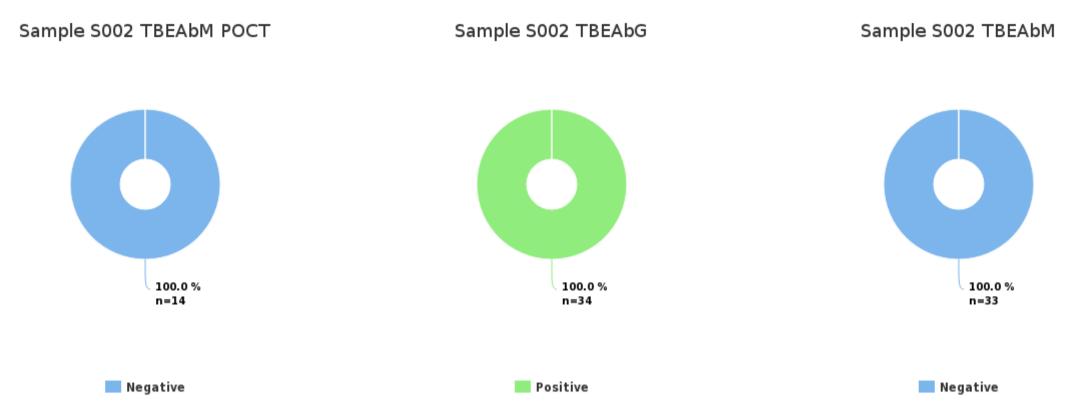


Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	AVR success rate	Interpretation Score	Further action Score
	Old immunity/vaccinated		27		100 %	4	
		A second sample is requested		2	-		-
	No indication of acute/recent infection		1		100 %	4	
	Laboratory does not give clinical interpretation		7		-	-	
	Total:		35		100 %		

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# **LΔBQUΔLITY** Tick-borne encephalitis virus, antibodies, March, 1-2023



TBEAbM POCT	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Negative		14		100 %	2
		Reagena ReaScan TBE IgM		14		
	Total:		14		100 %	

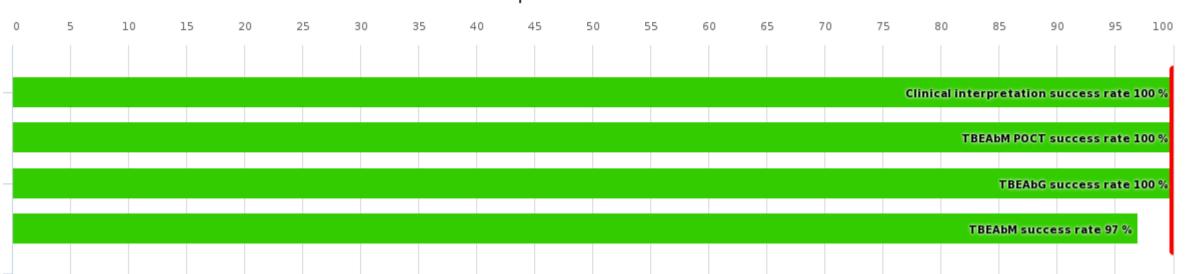
TBEAbG	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Positive		34		100 %	2
		Diesse Chorus Tick-borne Encephalitis Virus IgG		1		
		Euroimmun Anti-TBE virus ELISA		13		
		Euroimmun TBE IFA		2		
		Euroimmun TBEV Vienna IgG		1		
		TestLine SmartEIA TBE Virus IgG		1		
		Vidia VIDITEST anti-TBEV IgG ELISA		1		
		Vircell TBE VirClia IgG		7		
		Virion/Serion SERION ELISA classic TBE Virus IgG		4		
		ViroTech FSME/TBE ELISA		4		
	Total:		34		100 %	

TBEAbM	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Negative		33		100 %	2
		Diesse Chorus Tick-borne Encephalitis Virus IgM		1		
		Euroimmun Anti-TBE virus ELISA		13		
		Euroimmun TBE IFA		3		
		TestLine SmartEIA TBE Virus IgM		1		
		Vidia VIDITEST anti-TBEV IgM ELISA		1		
		Vircell TBE VirClia IgM		7		
		Virion/Serion Virion/Serion SERION ELISA classic TBE Virus IgM		3		
		ViroTech FSME/TBE ELISA		4		
	Total:		33		100 %	

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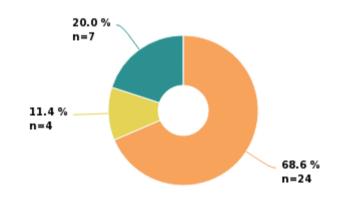


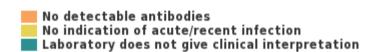




Sample S003 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	35
	TBEAbM POCT	100 %	14
	TBEAbG	100 %	34
	TBEAbM	97 %	33
Total:		99.3 %	116

# Sample S003 Clinical interpretation





Clinical interpretation	Interpretation	Further action	Interpretation count	Further action count	AVR success rate	Interpretation Score	Further action Score
	No detectable antibodies		24		100 %	4	
		A second sample is requested		4	-		-
	No indication of acute/recent infection		4		100 %	4	
	Laboratory does not give clinical interpretation		7		-	-	
	Total:		35		100 %		

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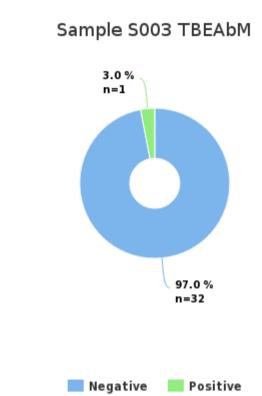


# **LΔBQUΔLITY** Tick-borne encephalitis virus, antibodies, March, 1-2023

# Sample S003 TBEAbM POCT

Negative





TBEAbM POCT	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Negative		14		100 %	2
		Reagena ReaScan TBE IgM		14		
	Total:		14		100 %	

Negative

Sample S003 TBEAbG

TBEAbG	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Negative		34		100 %	2
		Diesse Chorus Tick-borne Encephalitis Virus IgG		1		
		Euroimmun Anti-TBE virus ELISA		13		
		Euroimmun TBE IFA		2		
		Euroimmun TBEV Vienna IgG		1		
		TestLine SmartEIA TBE Virus IgG		1		
		Vidia VIDITEST anti-TBEV IgG ELISA		1		
		Vircell TBE VirClia IgG		7		
		Virion/Serion SERION ELISA classic TBE Virus IgG		4		
		ViroTech FSME/TBE ELISA		4		
	Total:		34		100 %	

TBEAbM	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Negative		32		100 %	2
		Diesse Chorus Tick-borne Encephalitis Virus IgM		1		
		Euroimmun Anti-TBE virus ELISA		12		
		Euroimmun TBE IFA		3		
		TestLine SmartEIA TBE Virus IgM		1		
		Vidia VIDITEST anti-TBEV IgM ELISA		1		
		Vircell TBE VirClia IgM		7		
		Virion/Serion Virion/Serion SERION ELISA classic TBE Virus IgM		3		
		ViroTech FSME/TBE ELISA		4		
	Positive		1		0 %	0
		Euroimmun Anti-TBE virus ELISA		1		
	Total:		33		97 %	

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# LABQUALITY Tick-borne encephalitis virus, antibodies, March, 1-2023

## **Report Info**

## **PARTICIPANTS**

Altogether 43 laboratories from 14 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.

31.03.2023 8/8

# LABQUALITY

**External Quality Assessment Scheme** 

# Tick-borne encephalitis virus, antibodies Round 1, 2023

#### **Specimens**

Samples of this EQA round were human plasma or serum, each of which originated from a single donor. Based on the pre-testing and the results obtained in the round, the samples were homogeneous, stable and suitable for the external quality assessment scheme. The materials were sent without temperature control packaging.

The expected results were as follows:

Sample S001 (LQ774123011)
TBEAbG Positive
TBEAbM Positive

Sample S002 (LQ774123012)
TBEAbG Positive
TBEAbM Negative

Clinical interpretation Old immunity/vaccinated

Sample S003 (LQ774123013)
TBEAbG Negative
TBEAbM Negative

Clinical interpretation No detectable antibodies

Pre-test methods: The samples have been tested in reference laboratory by a  $\mu$ -capture IgM-EIA (Jääskeläinen et al., J. Clin. Microbiol. 2003), with hemagglutination inhibition test and a commercial IgG test (IBL).

## Report info

Please see the description of the data analysis on the last page of the laboratory-specific reports and global reports. It is important to read the Final report first, because it contains important information of the samples and results in each round.

#### Comments - EQA Coordinator

This round included one acute/recent infection sample (S001), one old immunity sample (S002) and one antibody negative sample (S003).

Participants performed very well in this EQA round. One deviating clinical interpretation was reported for sample S001, and one false positive IgM test result was reported for sample S003. All other test results and clinical interpretations were reported correctly/as expected.

#### **Exceptions in scoring**

No exceptions.

## **End of report**

#### 2023-03-31

#### FINAL REPORT

Product no. 5099

Subcontracting: Sample pretesting

 Samples sent
 2023-03-07

 Round closed
 2023-03-30

 Expected results
 2023-03-31

 Final report
 2023-03-31

#### 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.

#### Authorized by

EQA Coordinator Marsa Järvenpää marsa.jarvenpaa@labquality.fi

#### **Experts**

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