

External Quality Assessment Scheme

Zika 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. The specimens have not been inactivated.

Examinations

Zika virus IgG
Zika virus IgM
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



2023-05-02

INSTRUCTIONS

Product no. 5636
LQ775523011-013/FI
UN3373

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 **May 25, 2023.**

The expected results of the round are published in LabScala in the View Reports section by May 30, 2023.

Inquiries

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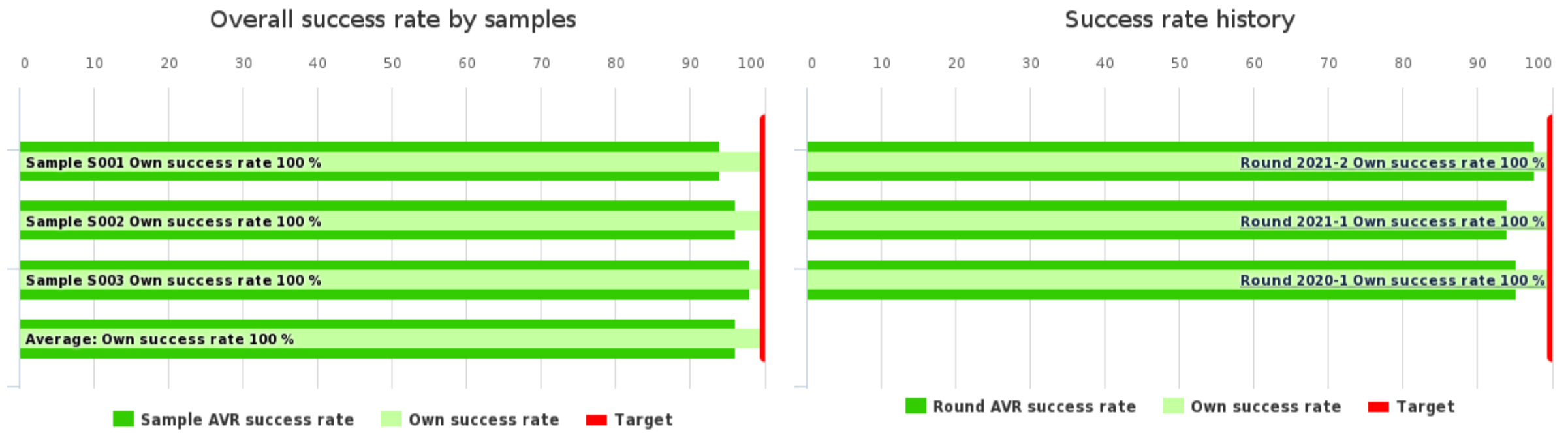
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Zika virus, antibodies, May, 1-2023	16	15	93.8 %

Summary

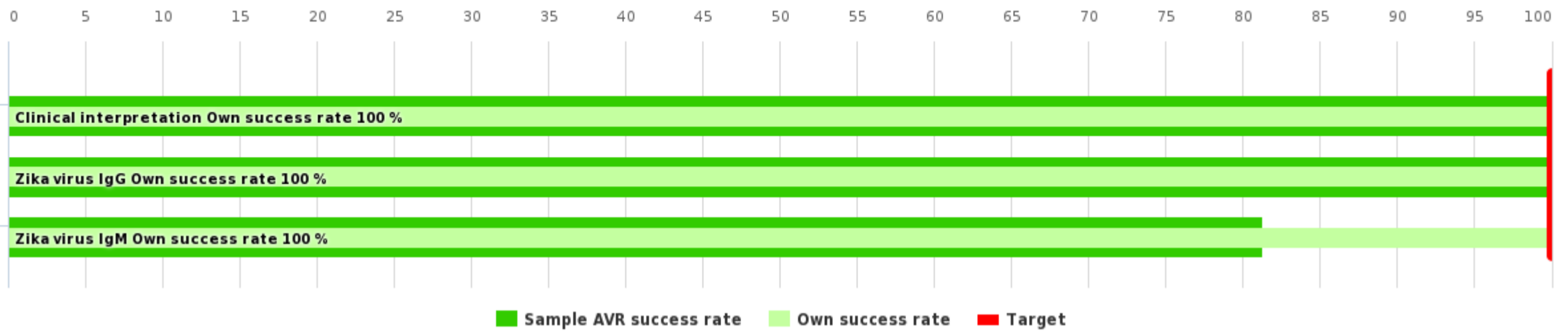


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	8	8	100 %	5.9 %	94.1 %
Sample S002	8	8	100 %	3.9 %	96.1 %
Sample S003	8	8	100 %	1.9 %	98.1 %
Average:			100 %	3.9 %	96.1 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2021-2	1-1	100 %	2.2 %	97.8 %
Round 2021-1	1-1	100 %	5.9 %	94.1 %
Round 2020-1	1-1	100 %	4.8 %	95.2 %

Sample S001

Sample S001 success rate



Sample S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	4	4	100 %	0 %	100 %	16
	Zika virus IgG	2	2	100 %	0 %	100 %	15
	Zika virus IgM	2	2	100 %	18.8 %	81.3 %	16
	Total:	8	8	100 %	5.9 %	94.1 %	47

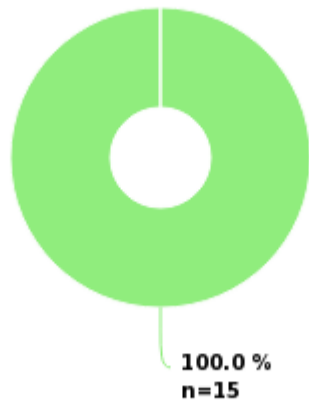
Sample S001 Clinical interpretation



■ Acute/recent infection
■ Laboratory does not give interpretation

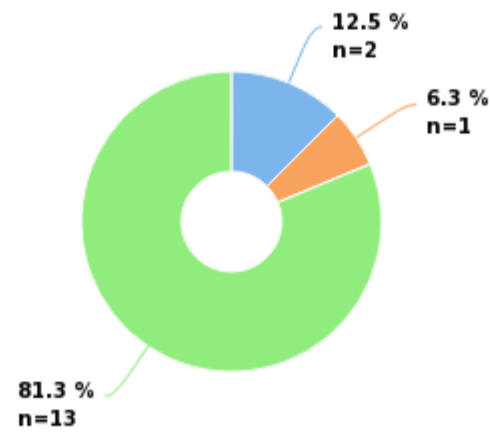
Clinical interpretation	Clinical interpretation	Further handling	Clinical interpretation count	Further handling count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Acute/recent infection		10		4	4	100 %	0 %	100 %
		New sample requested		1					
		Would be referred to another laboratory for further examination		1					
	Laboratory does not give interpretation		6		-				-
		New sample requested		1					
		Would be referred to another laboratory for further examination		1					
	Total:		16		4	4	100 %	0 %	100 %

Sample S001 Zika virus IgG



Positive

Sample S001 Zika virus IgM



Negative Borderline Positive

OWN DEVICE: ZIKA ELISA

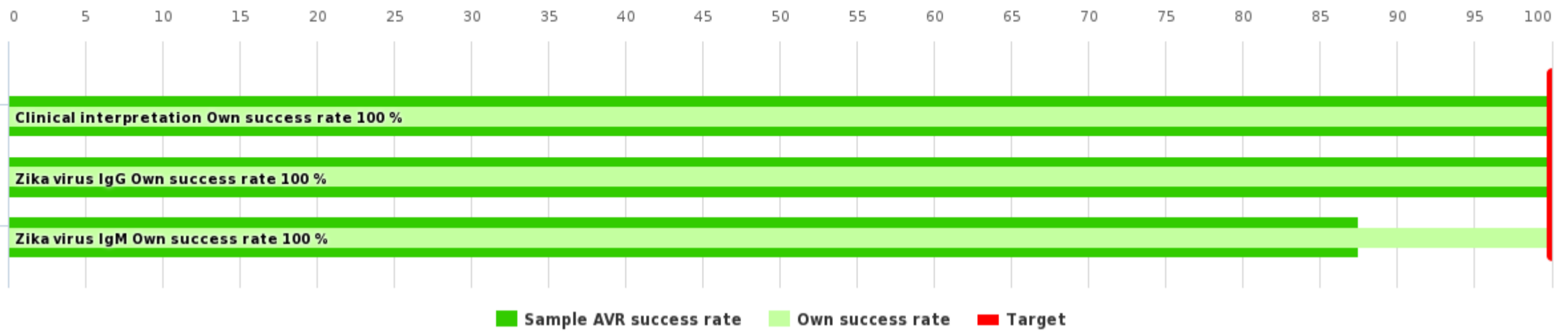
Zika virus IgG	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		15		2	2	100 %	0 %	100 %
		Dia.Pro ZIKA Virus IgG ELISA		1					
		<input checked="" type="radio"/> Euroimmun Anti-Zika Virus ELISA IgG		6					
		Euroimmun Arbovirus Fever Mosaic 2		1					
		Euroimmun Arbovirus Profile 3		1					
		In-house IFA		1					
		Mikrogen recomLine Tropical Fever IgG		1					
		NovaTec Immundiagnostica NovaLisa Zika Virus IgG capture ELISA		1					
		Vircell ZIKA VIRCLIA IgG MONOTEST		3					
	Total:		15		2	2	100 %	0 %	100 %

OWN DEVICE: ZIKA ELISA

Zika virus IgM	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				0 %
		Euroimmun Anti-Zika Virus IIFT IgM		1					
		Euroimmun Arbovirus Fever Mosaic 2		1					
	Borderline		1		-				0 %
		Vircell ZIKA VIRCLIA IgM MONOTEST		1					
	<input checked="" type="radio"/> Positive		13		2	2	100 %	0 %	100 %
		Dia.Pro ZIKA Virus IgM ELISA		1					
		DiaSorin LIAISON XL Zika Capture IgM II		1					
		<input checked="" type="radio"/> Euroimmun Anti-Zika Virus ELISA IgM		7					
		Mikrogen recomLine Tropical Fever IgM		1					
		NovaTec Immundiagnostica NovaLisa Zika Virus IgM μ-capture ELISA		1					
		Vircell ZIKA VIRCLIA IgM MONOTEST		2					
	Total:		16		2	2	100 %	18.8 %	81.3 %

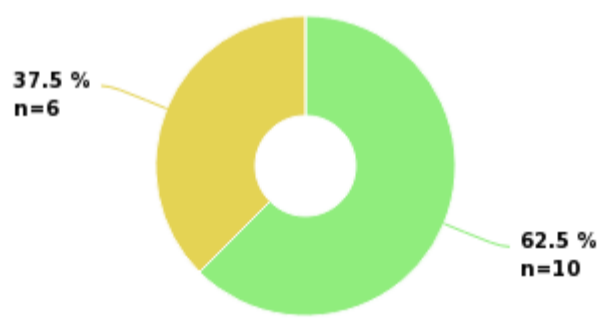
Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	4	4	100 %	0 %	100 %	16
	Zika virus IgG	2	2	100 %	0 %	100 %	15
	Zika virus IgM	2	2	100 %	12.5 %	87.5 %	16
	Total:	8	8	100 %	3.9 %	96.1 %	47

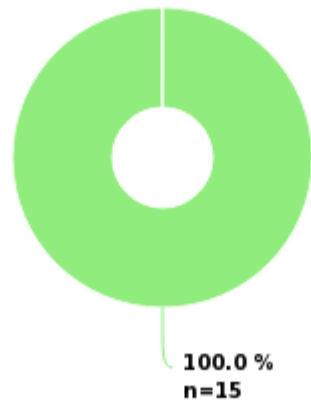
Sample S002 Clinical interpretation



■ Acute/recent infection
■ Laboratory does not give interpretation

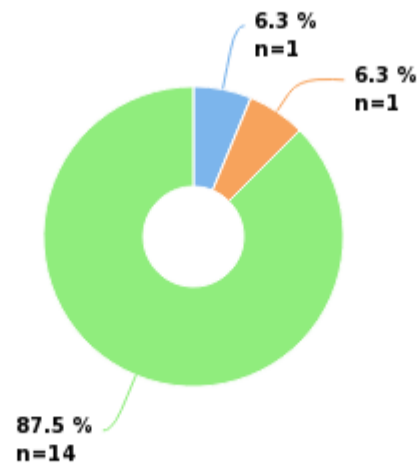
Clinical interpretation	Clinical interpretation	Further handling	Clinical interpretation count	Further handling count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Acute/recent infection		10		4	4	100 %	0 %	100 %
		New sample requested		1					
		Would be referred to another laboratory for further examination		1					
	Laboratory does not give interpretation		6		-				-
		New sample requested		1					
		Would be referred to another laboratory for further examination		1					
	Total:		16		4	4	100 %	0 %	100 %

Sample S002 Zika virus IgG



Positive

Sample S002 Zika virus IgM



Negative Borderline Positive

OWN DEVICE: ZIKA ELISA

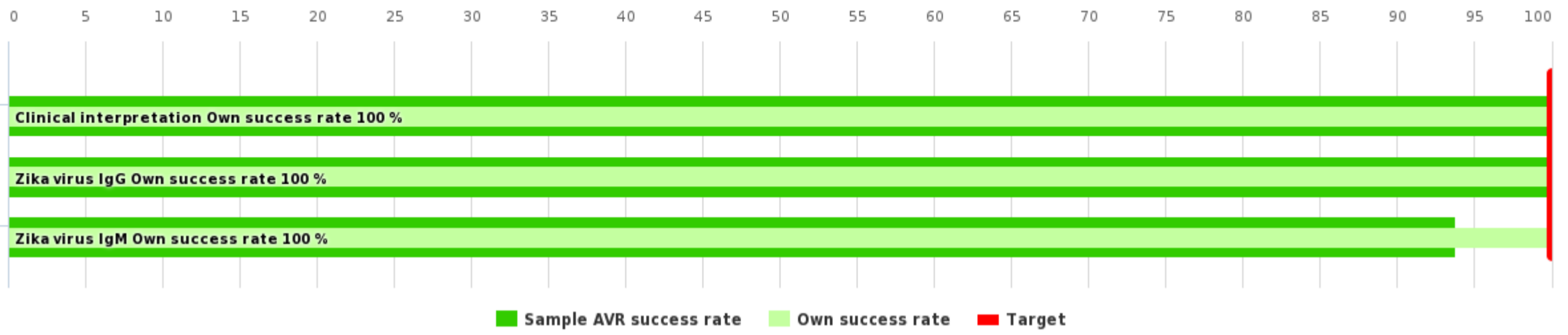
Zika virus IgG	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		15		2	2	100 %	0 %	100 %
		Dia.Pro ZIKA Virus IgG ELISA		1					
		<input checked="" type="radio"/> Euroimmun Anti-Zika Virus ELISA IgG		6					
		Euroimmun Arbovirus Fever Mosaic 2		1					
		Euroimmun Arbovirus Profile 3		1					
		In-house IFA		1					
		Mikrogen recomLine Tropical Fever IgG		1					
		NovaTec Immundiagnostica NovaLisa Zika Virus IgG capture ELISA		1					
		Vircell ZIKA VIRCLIA IgG MONOTEST		3					
	Total:		15		2	2	100 %	0 %	100 %

OWN DEVICE: ZIKA ELISA

Zika virus IgM	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		Euroimmun Anti-Zika Virus IIFT IgM		1					
	Borderline		1		-				0 %
		Vircell ZIKA VIRCLIA IgM MONOTEST		1					
	<input checked="" type="radio"/> Positive		14		2	2	100 %	0 %	100 %
		Dia.Pro ZIKA Virus IgM ELISA		1					
		DiaSorin LIAISON XL Zika Capture IgM II		1					
		<input checked="" type="radio"/> Euroimmun Anti-Zika Virus ELISA IgM		7					
		Euroimmun Arbovirus Fever Mosaic 2		1					
		Mikrogen recomLine Tropical Fever IgM		1					
		NovaTec Immundiagnostica NovaLisa Zika Virus IgM μ-capture ELISA		1					
		Vircell ZIKA VIRCLIA IgM MONOTEST		2					
	Total:		16		2	2	100 %	12.5 %	87.5 %

Sample S003

Sample S003 success rate



Sample S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	4	4	100 %	0 %	100 %	16
	Zika virus IgG	2	2	100 %	0 %	100 %	15
	Zika virus IgM	2	2	100 %	6.3 %	93.8 %	16
	Total:	8	8	100 %	1.9 %	98.1 %	47

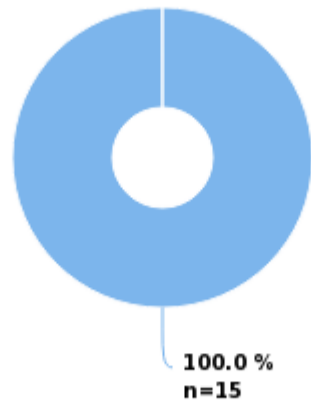
Sample S003 Clinical interpretation



■ No detectable antibodies
■ Laboratory does not give interpretation

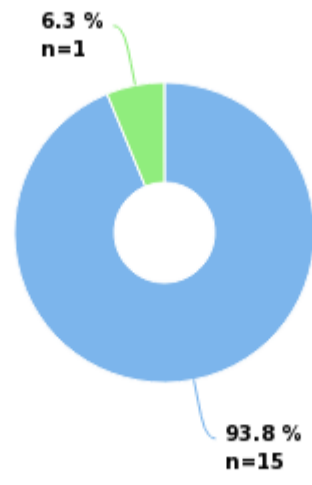
Clinical interpretation	Clinical interpretation	Further handling	Clinical interpretation count	Further handling count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> No detectable antibodies		11		4	4	100 %	0 %	100 %
		New sample requested		3					
	Laboratory does not give interpretation		5		-				-
	Total:		16		4	4	100 %	0 %	100 %

Sample S003 Zika virus IgG



■ Negative

Sample S003 Zika virus IgM



■ Negative ■ Positive

OWN DEVICE: ZIKA ELISA

Zika virus IgG	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		15		2	2	100 %	0 %	100 %
		Dia.Pro ZIKA Virus IgG ELISA		1					
		<input checked="" type="radio"/> Euroimmun Anti-Zika Virus ELISA IgG		6					
		Euroimmun Arbovirus Fever Mosaic 2		1					
		Euroimmun Arbovirus Profile 3		1					
		In-house IFA		1					
		Mikrogen recomLine Tropical Fever IgG		1					
		NovaTec Immundiagnostica NovaLisa Zika Virus IgG capture ELISA		1					
		Vircell ZIKA VIRCLIA IgG MONOTEST		3					
	Total:		15		2	2	100 %	0 %	100 %

OWN DEVICE: ZIKA ELISA

Zika virus IgM	Result	Methodics	Result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		15		2	2	100 %	0 %	100 %
		Dia.Pro ZIKA Virus IgM ELISA		1					
		DiaSorin LIAISON XL Zika Capture IgM II		1					
		<input checked="" type="radio"/> Euroimmun Anti-Zika Virus ELISA IgM		7					
		Euroimmun Anti-Zika Virus IIFT IgM		1					
		Mikrogen recomLine Tropical Fever IgM		1					
		NovaTec Immundiagnostica NovaLisa Zika Virus IgM μ-capture ELISA		1					
		Vircell ZIKA VIRCLIA IgM MONOTEST		3					
	Positive		1		-				0 %
		Euroimmun Arbovirus Fever Mosaic 2		1					
	Total:		16		2	2	100 %	6.3 %	93.8 %

Report Info

PARTICIPANTS

Altogether 16 laboratories from 10 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
Zika virus, antibodies, May, 1-2023	16	15	93.8 %

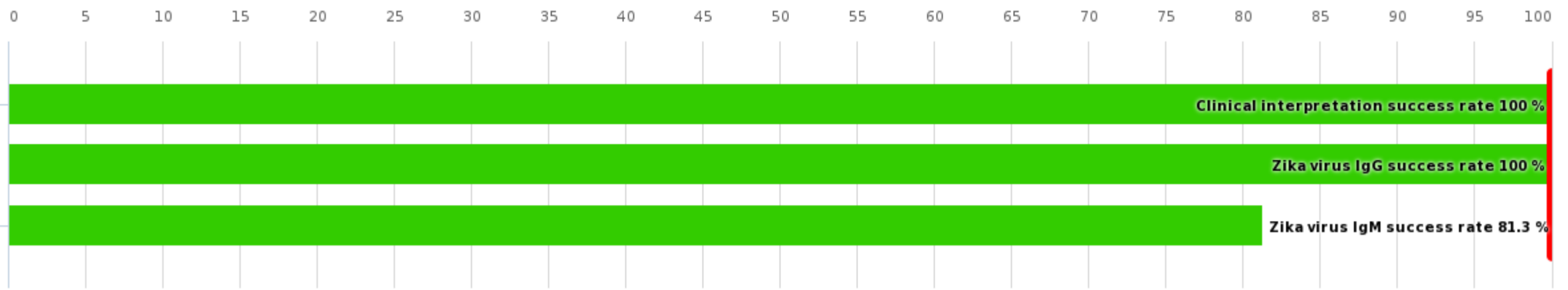
Summary



Summary	AVR success rate
Sample S001	94.1 %
Sample S002	96.1 %
Sample S003	98.1 %
Average:	96.1 %

Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	16
	Zika virus IgG	100 %	15
	Zika virus IgM	81.3 %	16
	Total:	94.1 %	47

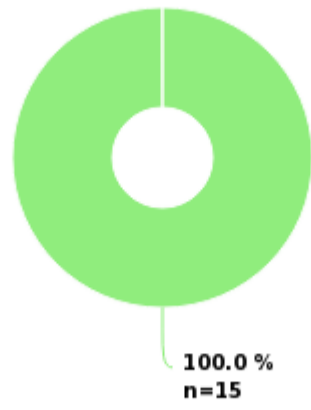
Sample S001 Clinical interpretation



■ Acute/recent infection
■ Laboratory does not give interpretation

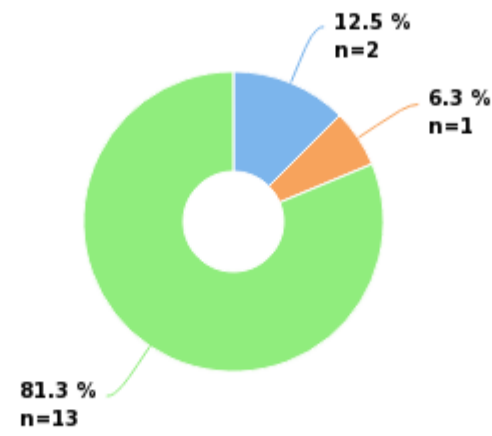
Clinical interpretation	Clinical interpretation	Further handling	Clinical interpretation count	Further handling count	AVR success rate	Clinical interpretation Score
	Acute/recent infection		10		100 %	4
		New sample requested		1		
		Would be referred to another laboratory for further examination		1		
	Laboratory does not give interpretation		6		-	-
		New sample requested		1		
		Would be referred to another laboratory for further examination		1		
	Total:		16		100 %	

Sample S001 Zika virus IgG



Positive

Sample S001 Zika virus IgM



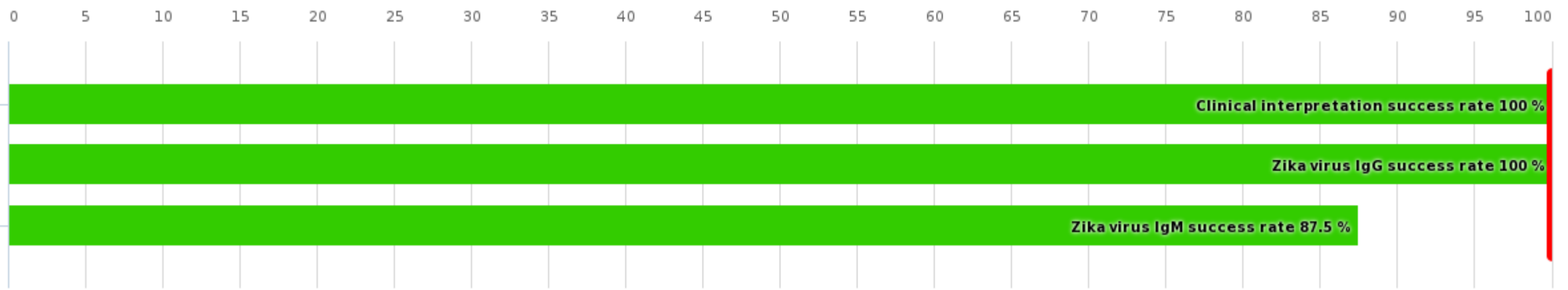
Negative Borderline Positive

Zika virus IgG	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Positive		15		100 %	2
		Dia.Pro ZIKA Virus IgG ELISA		1		
		Euroimmun Anti-Zika Virus ELISA IgG		6		
		Euroimmun Arbovirus Fever Mosaic 2		1		
		Euroimmun Arbovirus Profile 3		1		
		In-house IFA		1		
		Mikrogen recomLine Tropical Fever IgG		1		
		NovaTec Immundiagnostica NovaLisa Zika Virus IgG capture ELISA		1		
		Vircell ZIKA VIRCLIA IgG MONOTEST		3		
	Total:		15		100 %	

Zika virus IgM	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Negative		2		0 %	0
		Euroimmun Anti-Zika Virus IIFT IgM		1		
		Euroimmun Arbovirus Fever Mosaic 2		1		
	Borderline		1		0 %	0
		Vircell ZIKA VIRCLIA IgM MONOTEST		1		
	Positive		13		100 %	2
		Dia.Pro ZIKA Virus IgM ELISA		1		
		DiaSorin LIAISON XL Zika Capture IgM II		1		
		Euroimmun Anti-Zika Virus ELISA IgM		7		
		Mikrogen recomLine Tropical Fever IgM		1		
		NovaTec Immundiagnostica NovaLisa Zika Virus IgM μ-capture ELISA		1		
		Vircell ZIKA VIRCLIA IgM MONOTEST		2		
	Total:		16		81.3 %	

Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	16
	Zika virus IgG	100 %	15
	Zika virus IgM	87.5 %	16
	Total:	96.1 %	47

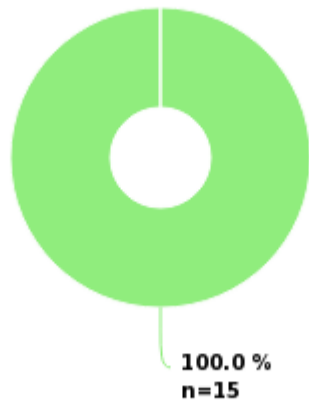
Sample S002 Clinical interpretation



■ Acute/recent infection
■ Laboratory does not give interpretation

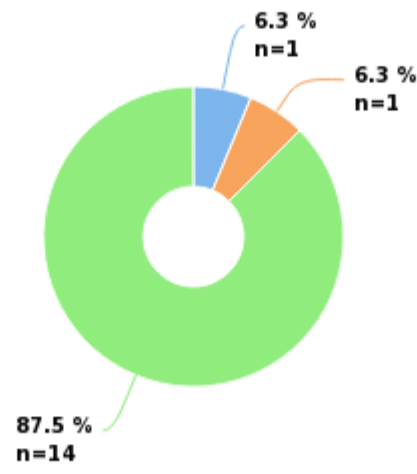
Clinical interpretation	Clinical interpretation	Further handling	Clinical interpretation count	Further handling count	AVR success rate	Clinical interpretation Score
	Acute/recent infection		10		100 %	4
		New sample requested		1		
		Would be referred to another laboratory for further examination		1		
	Laboratory does not give interpretation		6		-	-
		New sample requested		1		
		Would be referred to another laboratory for further examination		1		
	Total:		16		100 %	

Sample S002 Zika virus IgG



■ Positive

Sample S002 Zika virus IgM



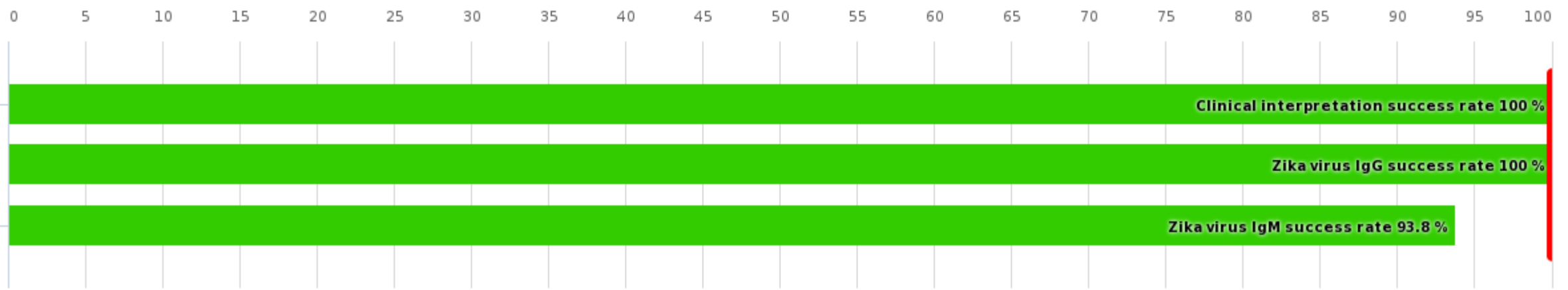
■ Negative ■ Borderline ■ Positive

Zika virus IgG	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Positive		15		100 %	2
		Dia.Pro ZIKA Virus IgG ELISA		1		
		Euroimmun Anti-Zika Virus ELISA IgG		6		
		Euroimmun Arbovirus Fever Mosaic 2		1		
		Euroimmun Arbovirus Profile 3		1		
		In-house IFA		1		
		Mikrogen recomLine Tropical Fever IgG		1		
		NovaTec Immundiagnostica NovaLisa Zika Virus IgG capture ELISA		1		
		Vircell ZIKA VIRCLIA IgG MONOTEST		3		
	Total:		15		100 %	

Zika virus IgM	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Negative		1		0 %	0
		Euroimmun Anti-Zika Virus IIFT IgM		1		
	Borderline		1		0 %	0
		Vircell ZIKA VIRCLIA IgM MONOTEST		1		
	Positive		14		100 %	2
		Dia.Pro ZIKA Virus IgM ELISA		1		
		DiaSorin LIAISON XL Zika Capture IgM II		1		
		Euroimmun Anti-Zika Virus ELISA IgM		7		
		Euroimmun Arbovirus Fever Mosaic 2		1		
		Mikrogen recomLine Tropical Fever IgM		1		
		NovaTec Immundiagnostica NovaLisa Zika Virus IgM μ-capture ELISA		1		
		Vircell ZIKA VIRCLIA IgM MONOTEST		2		
	Total:		16		87.5 %	

Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	16
	Zika virus IgG	100 %	15
	Zika virus IgM	93.8 %	16
	Total:	98.1 %	47

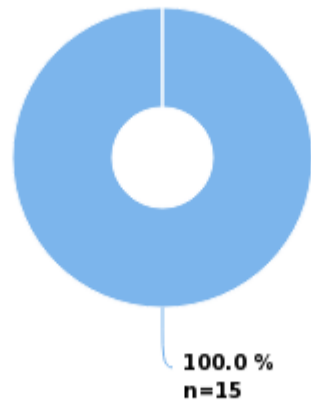
Sample S003 Clinical interpretation



■ No detectable antibodies
■ Laboratory does not give interpretation

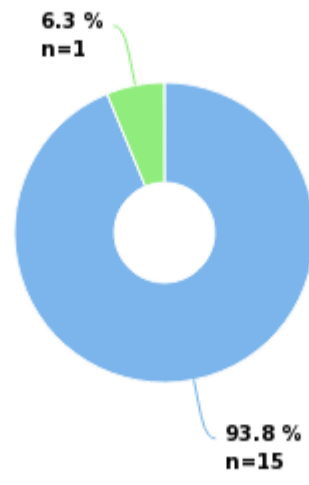
Clinical interpretation	Clinical interpretation	Further handling	Clinical interpretation count	Further handling count	AVR success rate	Clinical interpretation Score
	No detectable antibodies		11		100 %	4
		New sample requested		3		
	Laboratory does not give interpretation		5		-	-
	Total:		16		100 %	

Sample S003 Zika virus IgG



■ Negative

Sample S003 Zika virus IgM



■ Negative ■ Positive

Zika virus IgG	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Negative		15		100 %	2
		Dia.Pro ZIKA Virus IgG ELISA		1		
		Euroimmun Anti-Zika Virus ELISA IgG		6		
		Euroimmun Arbovirus Fever Mosaic 2		1		
		Euroimmun Arbovirus Profile 3		1		
		In-house IFA		1		
		Mikrogen recomLine Tropical Fever IgG		1		
		NovaTec Immundiagnostica Novalisa Zika Virus IgG capture ELISA		1		
		Vircell ZIKA VIRCLIA IgG MONOTEST		3		
	Total:		15		100 %	

Zika virus IgM	Result	Methodics	Result count	Methodics count	AVR success rate	Result Score
	Negative		15		100 %	2
		Dia.Pro ZIKA Virus IgM ELISA		1		
		DiaSorin LIAISON XL Zika Capture IgM II		1		
		Euroimmun Anti-Zika Virus ELISA IgM		7		
		Euroimmun Anti-Zika Virus IIFT IgM		1		
		Mikrogen recomLine Tropical Fever IgM		1		
		NovaTec Immundiagnostica Novalisa Zika Virus IgM μ-capture ELISA		1		
		Vircell ZIKA VIRCLIA IgM MONOTEST		3		
	Positive		1		0 %	0
		Euroimmun Arbovirus Fever Mosaic 2		1		
	Total:		16		93.8 %	

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External Quality Assessment Scheme

Zika 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 (LQ775523011)

Zika virus IgG	Positive
Zika virus IgM	Positive
Clinical interpretation	Acute/recent infection

Sample S002 (LQ775523012)

Zika virus IgG	Positive
Zika virus IgM	Positive
Clinical interpretation	Acute/recent infection

Sample S003 (LQ775523013)

Zika virus IgG	Negative
Zika virus IgM	Negative
Clinical interpretation	No detectable antibodies

Pre-test methods: Euroimmun Anti-Zika Virus ELISA IgG/IgM and In-house IFA IgG.

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 – Expert

Overall success rate (all samples) was good (96.1%). There were two samples representing acute/recent infection and one negative for Zika virus antibodies. All laboratories scored 100% in detection of IgG antibodies (S001-S003).

However, there were discrepant results reported using IgM assays. For S001 and S002, assays based on immunofluorescence method, gave false negative results. For S003, Zika virus IgM success rate was 93.8%. One false positive result was reported.

Exceptions in scoring

No exceptions.

End of report

2023-05-29

FINAL REPORT

Product no. 5636

Subcontracting: Sample pretesting

Samples sent	2023-05-02
Round closed	2023-05-25
Expected results	2023-05-26
Final report	2023-05-29

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

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