LABQUALITY

External Quality Assessment Scheme

Malaria, antigen and nucleic acid detection Round 1, 2023

Specimens
Please find enclosed 3 whole blood samples S001, S002 and S003, each ~0.2 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.

Examinations
Plasmodium Ag
Plasmodium NAT

Storage and use
After arrival, the samples should be stored at +2…8 °C and used as soon as possible, preferably within a week. Let the samples warm up to room temperature and mix well before proceeding with analysis. 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. Report only the results of examinations that are in use in your laboratory. All reported examinations will be scored.

S001

S002

S003

2023-02-07

INSTRUCTIONS

Product no. 5430
LQ769123011-013/FI
UN3373

Subcontracting: Sample preparation, 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 6, 2023**.

The expected results of the round are published in LabScala in the View Reports section by March 9, 2023.

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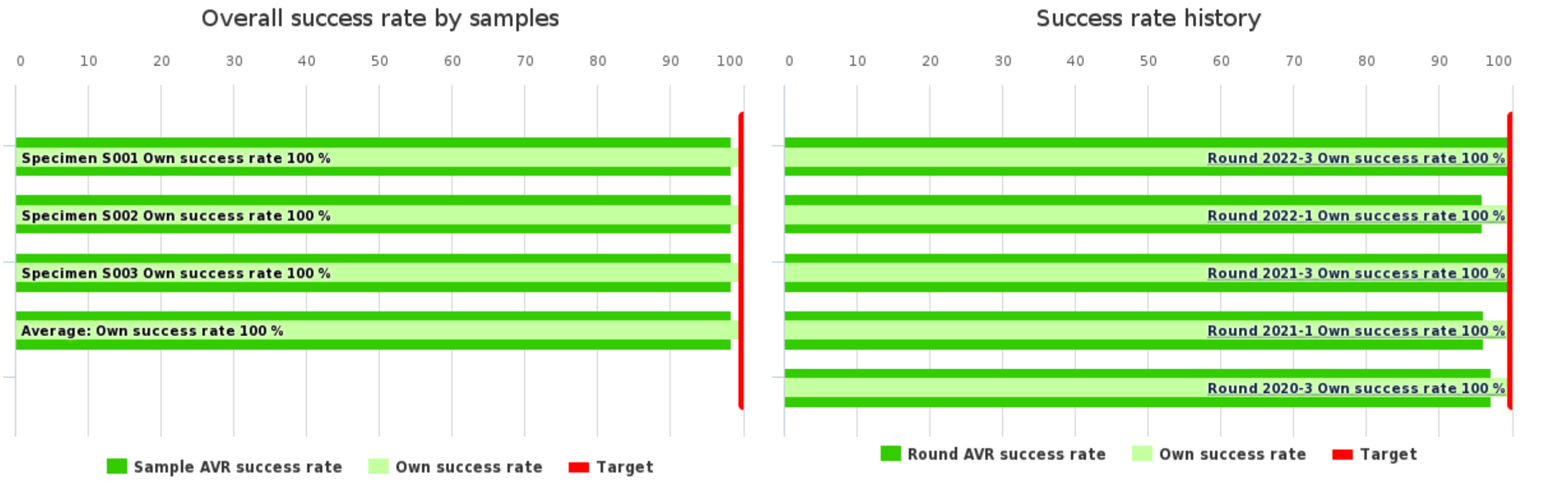
FINAS
Finnish Accreditation Service
PT02 (EN ISO/IEC 17043)

Quality Management
ISO 9001:2015

Client report

	No of participants	No of responded participants	Response percentage
Malaria, antigen and nucleic acid detection, February, 1-2023	53	53	100 %

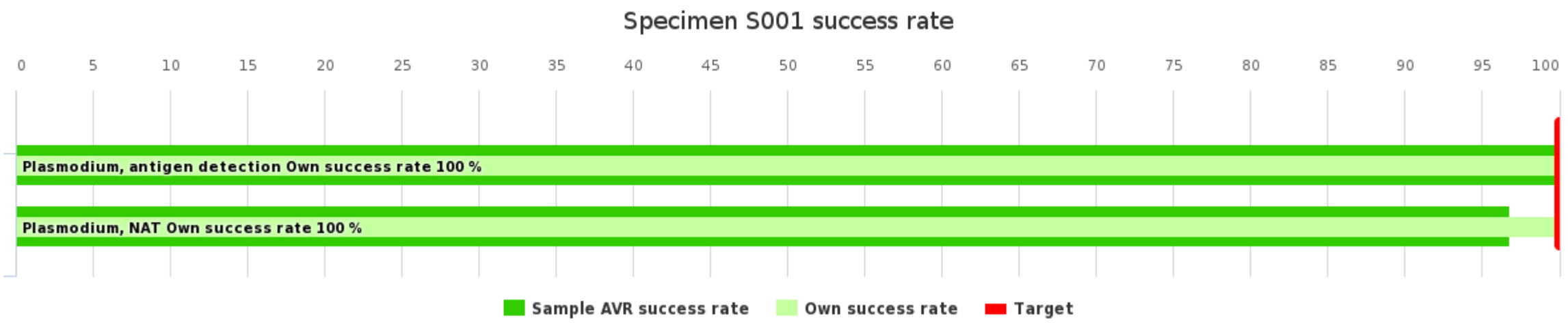
Summary



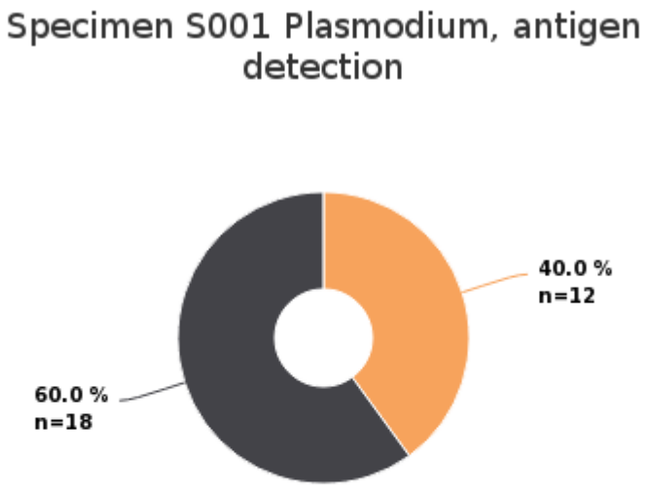
Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Specimen S001	4	4	100 %	1.6 %	98.4 %
Specimen S002	4	4	100 %	1.6 %	98.4 %
Specimen S003	4	4	100 %	1.6 %	98.4 %
Average:			100 %	1.6 %	98.4 %

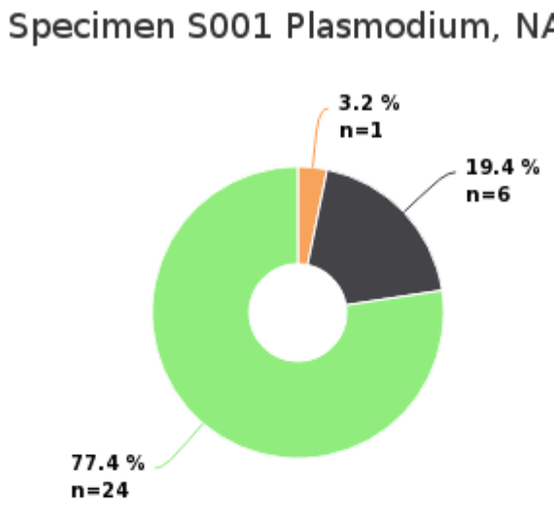
History	Test nr.	Own success rate	Difference	AVR success rate
Round 2022-3	1-1	100 %	0.6 %	99.4 %
Round 2022-1	1-1	100 %	4.1 %	95.9 %
Round 2021-3	1-1	100 %	0 %	100 %
Round 2021-1	1-1	100 %	3.8 %	96.2 %
Round 2020-3	1-1	100 %	2.8 %	97.2 %

Specimen S001



Specimen S001 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Plasmodium, antigen detection	2	2	100 %	0 %	100 %	30
	Plasmodium, NAT	2	2	100 %	3.2 %	96.8 %	31
Total:		4	4	100 %	1.6 %	98.4 %	61





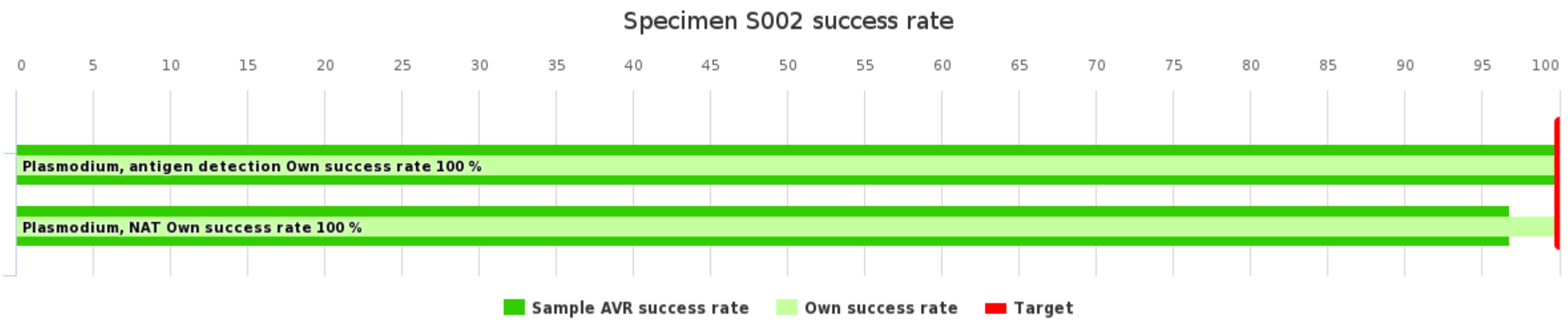
Plasmodium falciparum positive
Plasmodium falciparum positive or mixed infection (Pan-malaria)

Negative
Plasmodium falciparum positive
Plasmodium sp. positive

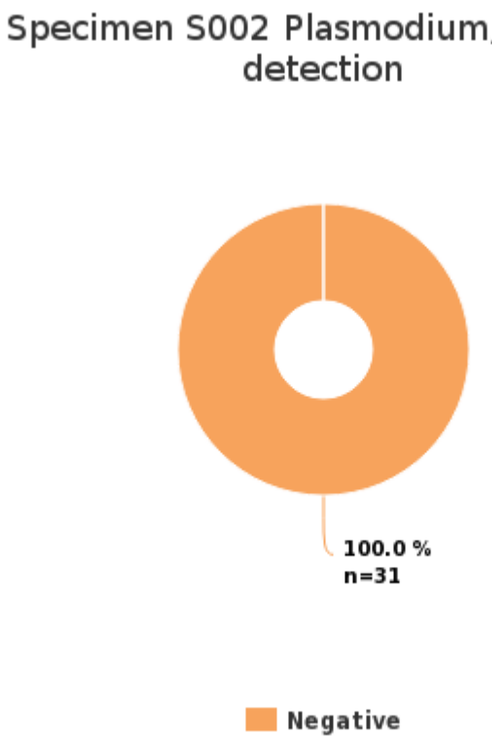
Plasmodium, antigen detection	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Plasmodium falciparum positive		12		-				100 %
		ACRO Biotech Malaria P.f./P.v. Rapid Test Cassette		1					
		Alere BinaxNOW Malaria		1					
		All Diag/Biosynex Palutop+ 4 Optima		4					
		Bio-Rad OptiMAL-IT		3					
		Nal von minden Dedicio Malaria Pf/Pan Ag 4 Species test cassette		1					
		Premier The First Response Malaria Ag Card test		1					
		Trinity Biotech NCS Malaria Rapid Test		1					
	◉ Plasmodium falciparum positive or mixed infection (Pan-malaria)		18		2	2	100 %	0 %	100 %
		ACRO Biotech Malaria P.f./Pan Rapid Test Cassette		1					
		Alere BinaxNOW Malaria		6					
		All Diag/Biosynex Palutop+ 4 Optima		6					
		◉ All Diag/Biosynex Palutop+ Pf		1					
		Boson Biotech Rapid Malaria pf/pan Antigen Test Card		1					
		SD Bioline Malaria Ag Pf/Pan		2					
		Trinity Biotech NCS Malaria Rapid Test		1					
	Total:		30		2	2	100 %	0 %	100 %

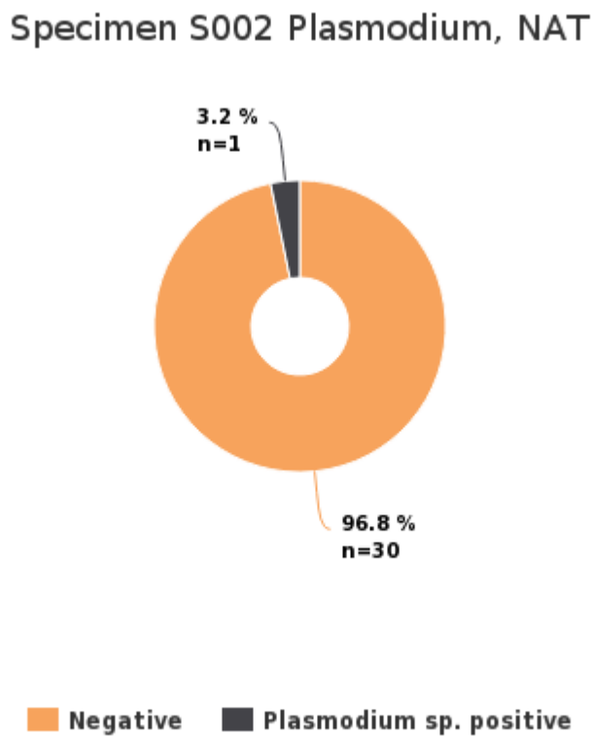
Plasmodium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		Meridian Bioscience Alethia Malaria		1					
	Plasmodium falciparum positive		6		-				100 %
		Altona Diagnostics RealStar Malaria PCR Kit		2					
		Altona Diagnostics RealStar Malaria Screen & Type PCR Kit		1					
		BioGX Malaria		1					
		In-house PCR		2					
	◉ Plasmodium sp. positive		24		2	2	100 %	0 %	100 %
		Meridian Bioscience Alethia Malaria		14					
		◉ Meridian Bioscience Illumigene Malaria		9					
		Meridian Bioscience Illumigene Malaria Plus		1					
	Total:		31		2	2	100 %	3.2 %	96.8 %

Specimen S002



Specimen S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Plasmodium, antigen detection	2	2	100 %	0 %	100 %	31
	Plasmodium, NAT	2	2	100 %	3.2 %	96.8 %	31
Total:		4	4	100 %	1.6 %	98.4 %	62



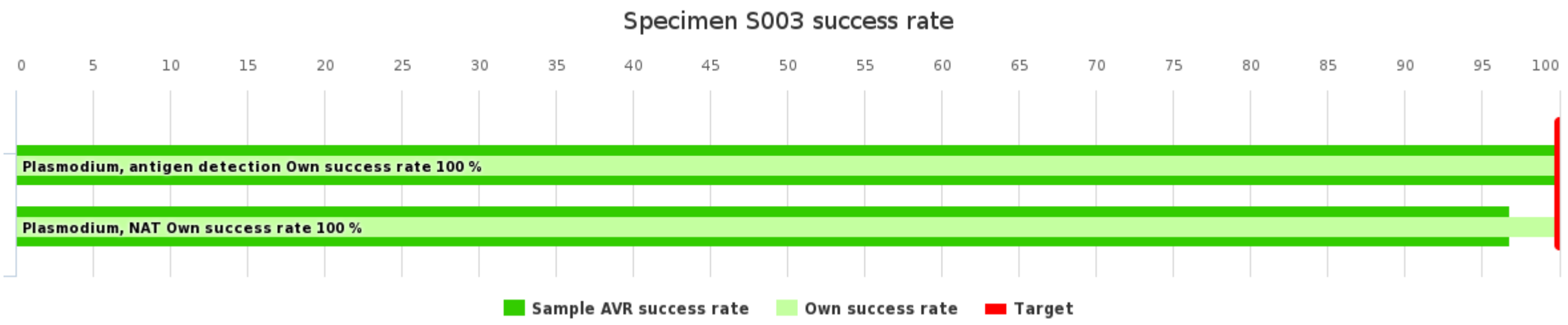


Plasmodium, antigen detection	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Negative		31		2	2	100 %	0 %	100 %
		ACRO Biotech Malaria P.f./P.v. Rapid Test Cassette		1					
		ACRO Biotech Malaria P.f./Pan Rapid Test Cassette		1					
		Alere BinaxNOW Malaria		7					
		All Diag/Biosynex Palutop+ 4 Optima		10					
		◉ All Diag/Biosynex Palutop+ Pf		1					
		Bio-Rad OptiMAL-IT		4					
		Boson Biotech Rapid Malaria pf/pan Antigen Test Card		1					
		Nal von minden Dedicio Malaria Pf/Pan Ag 4 Species test cassette		1					
		Premier The First Response Malaria Ag Card test		1					
		SD Bioline Malaria Ag Pf/Pan		2					
		Trinity Biotech NCS Malaria Rapid Test		2					
	Total:		31		2	2	100 %	0 %	100 %

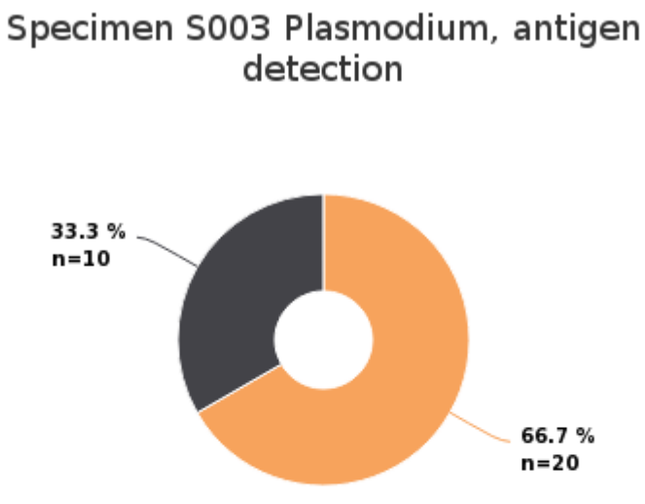
Plasmodium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Negative		30		2	2	100 %	0 %	100 %
		Altona Diagnostics RealStar Malaria PCR Kit		2					
		Altona Diagnostics RealStar Malaria Screen & Type PCR Kit		1					
		BioGX Malaria		1					

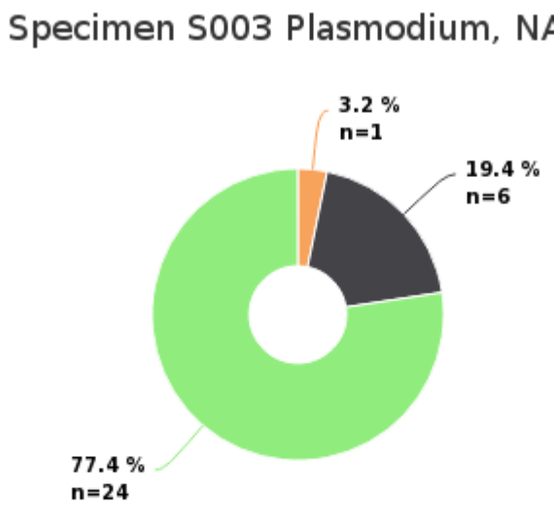
		In-house PCR		2					
		Meridian Bioscience Alethia Malaria		14					
		◉ Meridian Bioscience Illumigene Malaria		9					
		Meridian Bioscience Illumigene Malaria Plus		1					
	Plasmodium sp. positive		1		-				0 %
		Meridian Bioscience Alethia Malaria		1					
	Total:		31		2	2	100 %	3.2 %	96.8 %

Specimen S003



Specimen S003 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Plasmodium, antigen detection	2	2	100 %	0 %	100 %	30
	Plasmodium, NAT	2	2	100 %	3.2 %	96.8 %	31
Total:		4	4	100 %	1.6 %	98.4 %	61





Plasmodium falciparum positive
Plasmodium falciparum positive or mixed infection (Pan-malaria)

Negative
Plasmodium falciparum positive
Plasmodium sp. positive

Plasmodium, antigen detection	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	◉ Plasmodium falciparum positive		20		2	2	100 %	0 %	100 %
		ACRO Biotech Malaria P.f./P.v. Rapid Test Cassette		1					
		Alere BinaxNOW Malaria		4					
		All Diag/Biosynex Palutop+ 4 Optima		5					
		◉ All Diag/Biosynex Palutop+ Pf		1					
		Bio-Rad OptiMAL-IT		3					
		Boson Biotech Rapid Malaria pf/pan Antigen Test Card		1					
		Nal von minden Dedicio Malaria Pf/Pan Ag 4 Species test cassette		1					
		Premier The First Response Malaria Ag Card test		1					
		SD Bioline Malaria Ag Pf/Pan		2					
		Trinity Biotech NCS Malaria Rapid Test		1					
	Plasmodium falciparum positive or mixed infection (Pan-malaria)		10		-				100 %
		ACRO Biotech Malaria P.f./Pan Rapid Test Cassette		1					
		Alere BinaxNOW Malaria		3					
		All Diag/Biosynex Palutop+ 4 Optima		5					
		Trinity Biotech NCS Malaria Rapid Test		1					
	Total:		30		2	2	100 %	0 %	100 %

Plasmodium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		Meridian Bioscience Alethia Malaria		1					
	Plasmodium falciparum positive		6		-				100 %
		Altona Diagnostics RealStar Malaria PCR Kit		2					
		Altona Diagnostics RealStar Malaria Screen & Type PCR Kit		1					
		BioGX Malaria		1					
		In-house PCR		2					
	Plasmodium sp. positive		24		2	2	100 %	0 %	100 %
		Meridian Bioscience Alethia Malaria		14					
		Meridian Bioscience Illumigene Malaria		9					
		Meridian Bioscience Illumigene Malaria Plus		1					
	Total:		31		2	2	100 %	3.2 %	96.8 %

Report Info

PARTICIPANTS

Altogether 53 laboratories from 12 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 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

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.

Malaria, antigen and nucleic acid detection, February, 1-2023

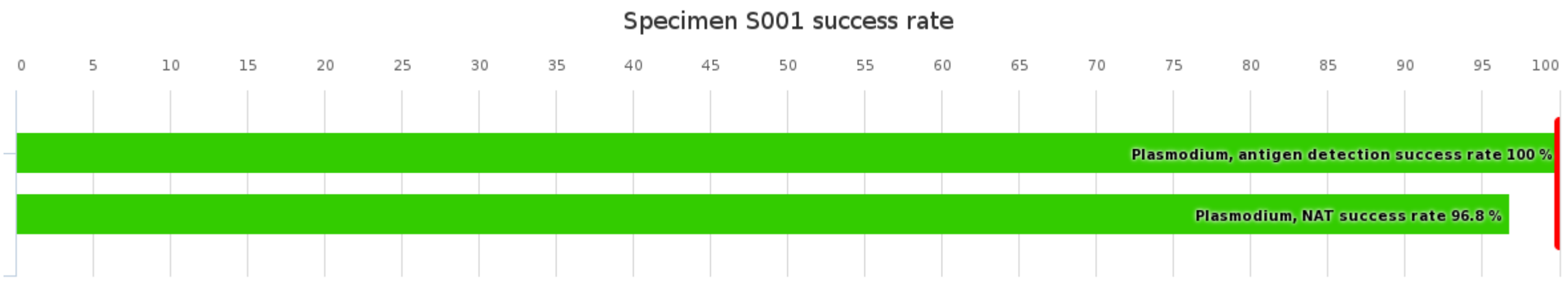
GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Malaria, antigen and nucleic acid detection, February, 1-2023	53	53	100 %

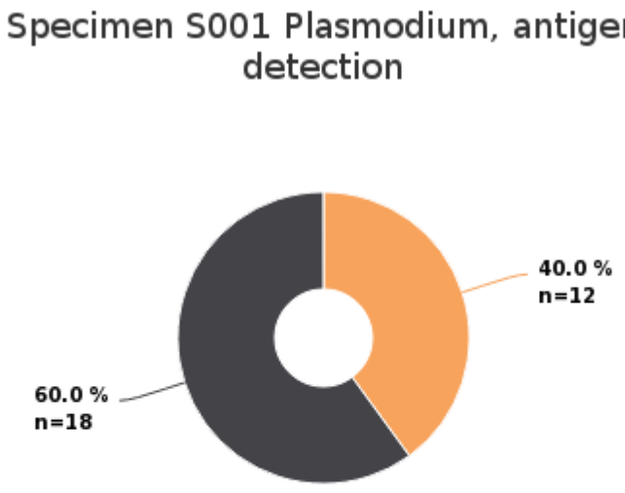
Summary

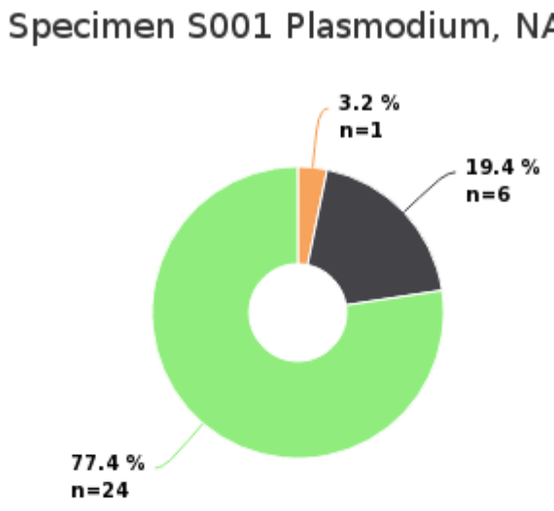
Summary	AVR success rate
Specimen S001	98.4 %
Specimen S002	98.4 %
Specimen S003	98.4 %
Average:	98.4 %

Specimen S001



Specimen S001 results	Responded	AVR success rate	Count
	Plasmodium, antigen detection	100 %	30
	Plasmodium, NAT	96.8 %	31
Total:		98.4 %	61





Plasmodium falciparum positive
Plasmodium falciparum positive or mixed infection (Pan-malaria)

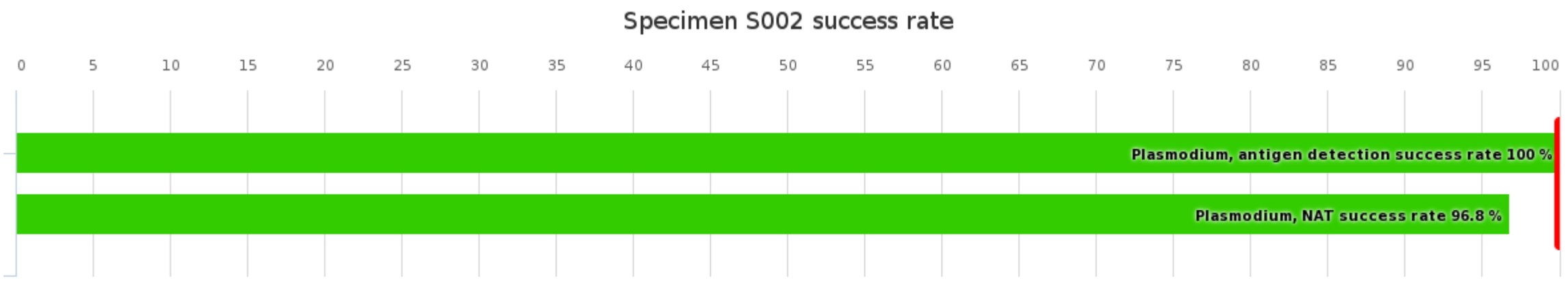
Negative
Plasmodium falciparum positive
Plasmodium sp. positive

Plasmodium, antigen detection	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Plasmodium falciparum positive		12		100 %	2
		ACRO Biotech Malaria P.f./P.v. Rapid Test Cassette		1		
		Alere BinaxNOW Malaria		1		
		All Diag/Biosynex Palutop+ 4 Optima		4		
		Bio-Rad OptiMAL-IT		3		
		Nal von minden Dedicio Malaria Pf/Pan Ag 4 Species test cassette		1		
		Premier The First Response Malaria Ag Card test		1		
		Trinity Biotech NCS Malaria Rapid Test		1		
	Plasmodium falciparum positive or mixed infection (Pan-malaria)		18		100 %	2
		ACRO Biotech Malaria P.f./Pan Rapid Test Cassette		1		
		Alere BinaxNOW Malaria		6		
		All Diag/Biosynex Palutop+ 4 Optima		6		
		All Diag/Biosynex Palutop+ Pf		1		
		Boson Biotech Rapid Malaria pf/pan Antigen Test Card		1		
		SD Bioline Malaria Ag Pf/Pan		2		
		Trinity Biotech NCS Malaria Rapid Test		1		
	Total:		30		100 %	

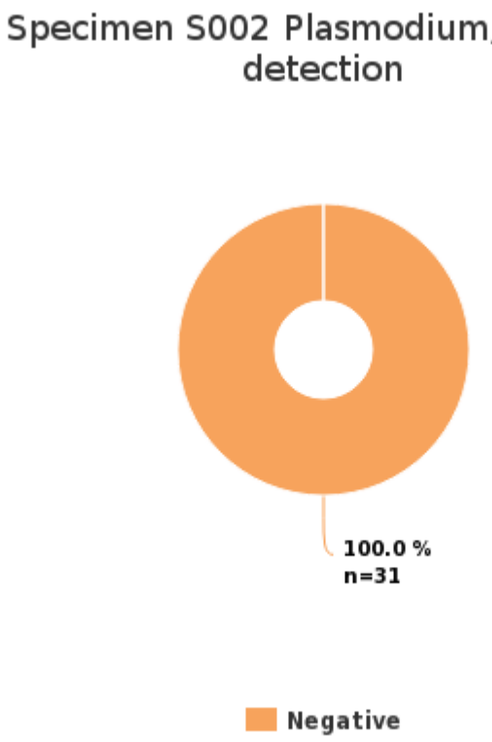
Plasmodium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		1		0 %	0

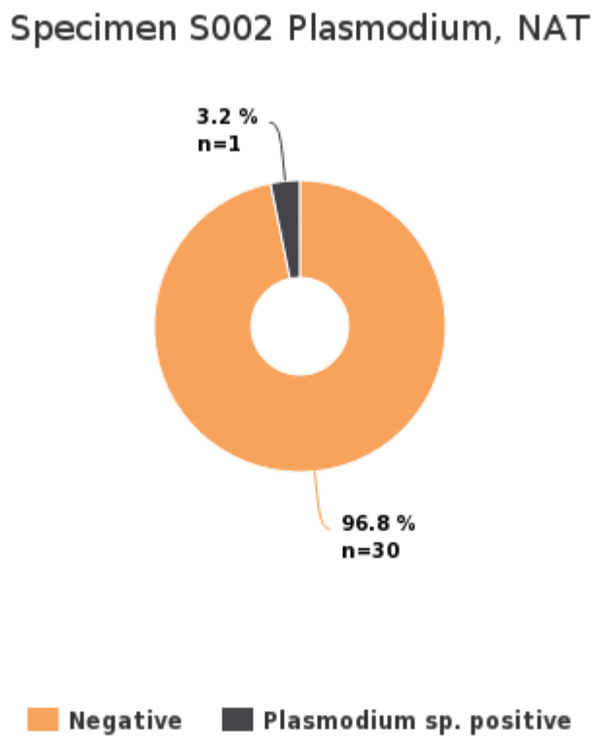
		Meridian Bioscience Alethia Malaria		1		
	Plasmodium falciparum positive		6		100 %	2
		Altona Diagnostics RealStar Malaria PCR Kit		2		
		Altona Diagnostics RealStar Malaria Screen & Type PCR Kit		1		
		BioGX Malaria		1		
		In-house PCR		2		
	Plasmodium sp. positive		24		100 %	2
		Meridian Bioscience Alethia Malaria		14		
		Meridian Bioscience Illumigene Malaria		9		
		Meridian Bioscience Illumigene Malaria Plus		1		
	Total:		31		96.8 %	

Specimen S002



Specimen S002 results	Responded	AVR success rate	Count
	Plasmodium, antigen detection	100 %	31
	Plasmodium, NAT	96.8 %	31
Total:		98.4 %	62



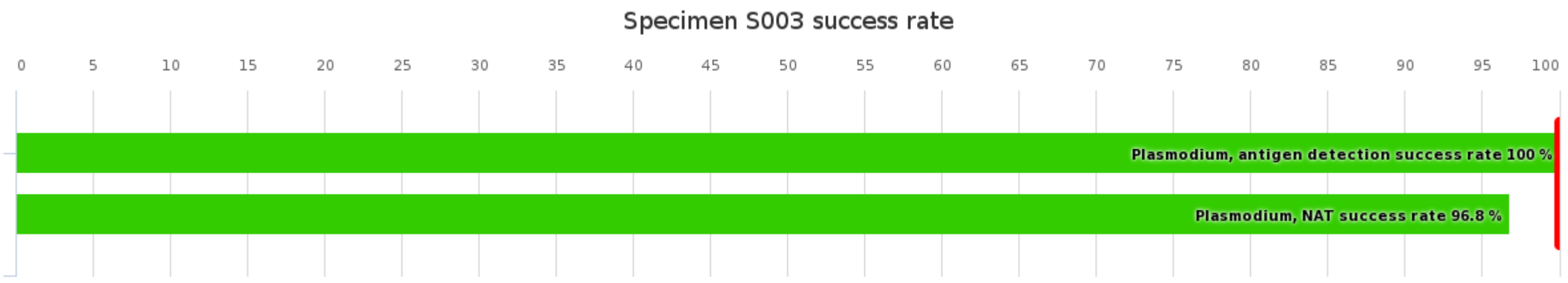


Plasmodium, antigen detection	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		31		100 %	2
		ACRO Biotech Malaria P.f./P.v. Rapid Test Cassette		1		
		ACRO Biotech Malaria P.f./Pan Rapid Test Cassette		1		
		Alere BinaxNOW Malaria		7		
		All Diag/Biosynex Palutop+ 4 Optima		10		
		All Diag/Biosynex Palutop+ Pf		1		
		Bio-Rad OptiMAL-IT		4		
		Boson Biotech Rapid Malaria pf/pan Antigen Test Card		1		
		Nal von minden Dedicio Malaria Pf/Pan Ag 4 Species test cassette		1		
		Premier The First Response Malaria Ag Card test		1		
		SD Bioline Malaria Ag Pf/Pan		2		
		Trinity Biotech NCS Malaria Rapid Test		2		
	Total:		31		100 %	

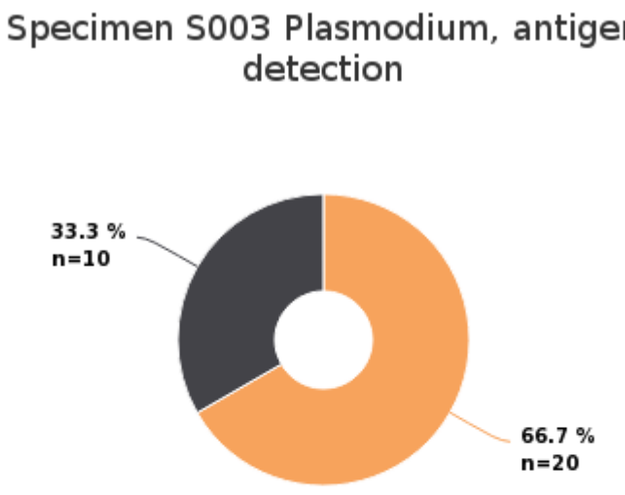
Plasmodium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		30		100 %	2
		Altona Diagnostics RealStar Malaria PCR Kit		2		
		Altona Diagnostics RealStar Malaria Screen & Type PCR Kit		1		
		BioGX Malaria		1		
		In-house PCR		2		
		Meridian Bioscience Alethia Malaria		14		

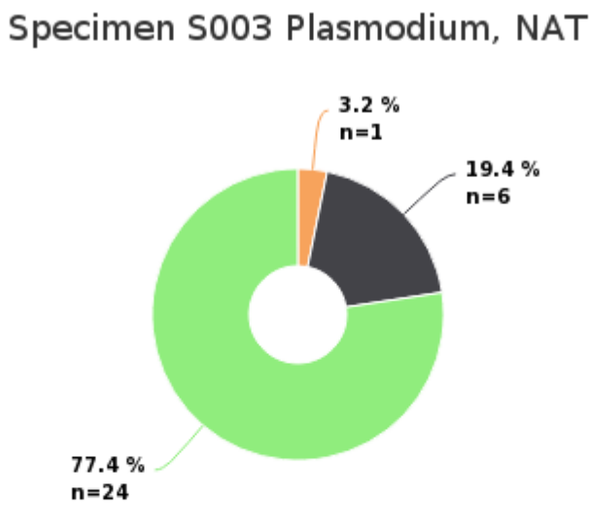
		Meridian Bioscience Illumigene Malaria		9		
		Meridian Bioscience Illumigene Malaria Plus		1		
	Plasmodium sp. positive		1		0 %	0
		Meridian Bioscience Alethia Malaria		1		
	Total:		31		96.8 %	

Specimen S003



Specimen S003 results	Responded	AVR success rate	Count
	Plasmodium, antigen detection	100 %	30
	Plasmodium, NAT	96.8 %	31
Total:		98.4 %	61





Plasmodium falciparum positive
Plasmodium falciparum positive or mixed infection (Pan-malaria)

Negative
Plasmodium falciparum positive
Plasmodium sp. positive

Plasmodium, antigen detection	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Plasmodium falciparum positive		20		100 %	2
		ACRO Biotech Malaria P.f./P.v. Rapid Test Cassette		1		
		Alere BinaxNOW Malaria		4		
		All Diag/Biosynex Palutop+ 4 Optima		5		
		All Diag/Biosynex Palutop+ Pf		1		
		Bio-Rad OptiMAL-IT		3		
		Boson Biotech Rapid Malaria pf/pan Antigen Test Card		1		
		Nal von minden Dedicio Malaria Pf/Pan Ag 4 Species test cassette		1		
		Premier The First Response Malaria Ag Card test		1		
		SD Bioline Malaria Ag Pf/Pan		2		
		Trinity Biotech NCS Malaria Rapid Test		1		
	Plasmodium falciparum positive or mixed infection (Pan-malaria)		10		100 %	2
		ACRO Biotech Malaria P.f./Pan Rapid Test Cassette		1		
		Alere BinaxNOW Malaria		3		
		All Diag/Biosynex Palutop+ 4 Optima		5		
		Trinity Biotech NCS Malaria Rapid Test		1		
	Total:		30		100 %	

Plasmodium, NAT	Interpretation	Test kit	Interpretation count	Test kit count	AVR success rate	Interpretation Score
	Negative		1		0 %	0

		Meridian Bioscience Alethia Malaria		1		
	Plasmodium falciparum positive		6		100 %	2
		Altona Diagnostics RealStar Malaria PCR Kit		2		
		Altona Diagnostics RealStar Malaria Screen & Type PCR Kit		1		
		BioGX Malaria		1		
		In-house PCR		2		
	Plasmodium sp. positive		24		100 %	2
		Meridian Bioscience Alethia Malaria		14		
		Meridian Bioscience Illumigene Malaria		9		
		Meridian Bioscience Illumigene Malaria Plus		1		
	Total:		31		96.8 %	

Report Info

PARTICIPANTS

Altogether 53 laboratories from 12 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 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

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.

LABQUALITY

External Quality Assessment Scheme

Malaria, antigen and nucleic acid detection Round 1, 2023

Specimens
Samples of this EQA round were human whole blood samples. 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.

The expected results were as follows:

Sample S001 (LQ769123011)
Plasmodium falciparum Ag/NAT positive, parasitemia level ~ 0.4%

Sample S002 (LQ769123012)
Plasmodium falciparum Ag/NAT negative

Sample S003 (LQ769123013)
Plasmodium falciparum Ag/NAT positive, parasitemia level ~ 0.1%

Pre-test methods: microscopy and primary antigen detection test BinaxNOW (Abbott).

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
Samples S001 and S003 were *Plasmodium falciparum* positive with a parasitemia of ~0.4% and ~0.1%, respectively. Sample S002 was *Plasmodium* sp. negative. The results of the malaria antigen POC and NAT tests were excellent - average success rate was 98.4%.

Sample S001 was *Plasmodium falciparum* positive with a parasitemia of ~ 0.4% that is above the malaria RDTs limit of detection, typically in the range of 200 parasites/µL (0.005% parasitemia).

100% (30/30) of the reported antigen test results were correct/expected; 12 laboratories reported "*Plasmodium falciparum* positive", and 18 reported "*Plasmodium falciparum* positive or mixed infection (Pan-malaria)".

Using nucleic acid tests (NAT) specific for the malaria parasites' nucleic acid, 24 laboratories reported the sample as "*Plasmodium* sp. positive" and 6 reported "*Plasmodium falciparum* positive" Success rate using NAT was 96.8% (30/31). This sample was incorrectly reported as *Plasmodium* sp. NAT negative by one laboratory.

Sample S002 was *Plasmodium* sp. negative. 100% (31/31) of the laboratories reported correct negative results for malaria antigen RDTs. 96.8% (30/31) of laboratories reported correct negative results for NAT. Overall success rate for sample S002 with both RDTs and NAT was 98.4%. This sample was incorrectly reported as *Plasmodium* sp. NAT positive by one laboratory.

Sample S003 was *Plasmodium falciparum* positive with a parasitemia of ~ 0.1% that is also above the malaria RDTs limit of detection.

2023-03-20

FINAL REPORT

Product no. 5430

Subcontracting: Sample preparation, sample pretesting

Samples sent	2023-02-07
Round closed	2023-03-06
Expected results	2023-03-07
Final report	2023-03-20

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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PT02 (EN ISO/IEC 17043)

Quality Management
LQ
ISO 9001:2015

100% (30/30) of the reported antigen test results were correct/expected; 20 laboratories reported "*Plasmodium falciparum* positive", and 10 reported "*Plasmodium falciparum* positive or mixed infection (Pan-malaria)".

Using nucleic acid tests (NAT) specific for the malaria parasites' nucleic acid, 24 laboratories reported the sample as "*Plasmodium* sp. positive" and 6 reported "*Plasmodium falciparum* positive". Success rate using NAT was 96.8% (30/31). This sample was incorrectly reported as *Plasmodium* sp. NAT negative by one laboratory.

Based on the result distrubution, it can be concluded that one laboratory has probably mixed up samples S001 and S002, which explains most of the reported erroneous results.

Background

Traditionally diagnosis of *Plasmodium* infection is based on microscopical analysis of thick and thin blood films. Antigen detection can be used in the diagnosis to provide support to the microscopical analysis, but it is not recommended or suitable to be used alone. Combined thick/thin film microscopy joined with the antigen detection is recommended.

Exceptions in scoring

No exceptions.

End of report