

External Quality Assessment Scheme

Hepatitis E, 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 may contain infectious viruses. The specimens have not been inactivated.

Examinations

HEVAb
HEVAbG
HEVAbM
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. 5682
LQ775023011-013/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

EQA Coordinator
Marsa Järvenpää
marsa.jarvenpaa@labquality.fi

Labquality Oy

Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

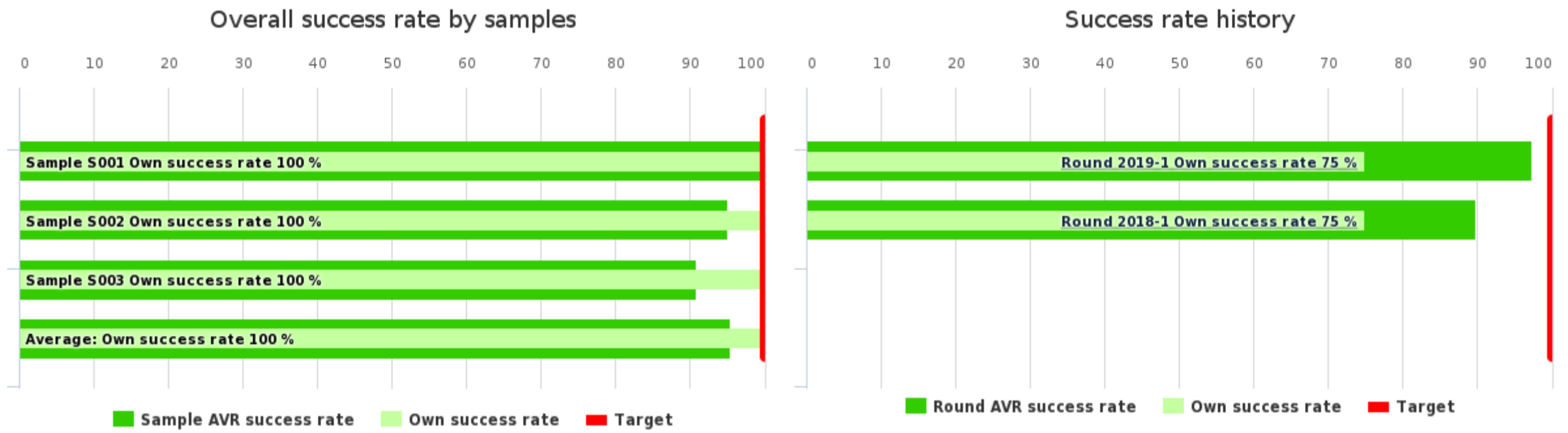
info@labquality.fi
www.labquality.com



Client report

	No of participants	No of responded participants	Response percentage
Hepatitis E, antibodies, May, 1-2023	32	28	87.5 %

Summary

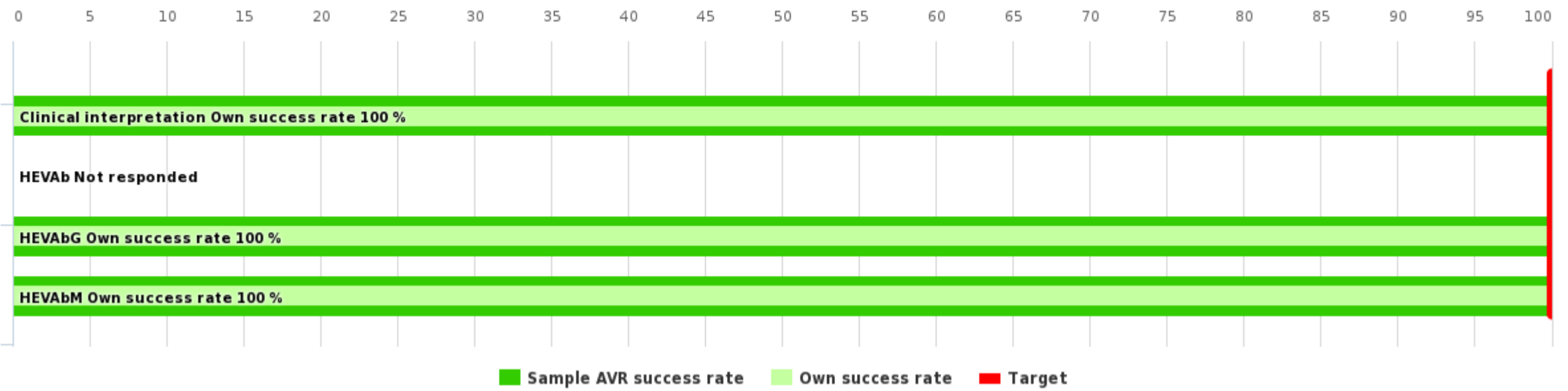


Summary	Own score	Max score	Own success rate	Difference	AVR success rate
Sample S001	8	8	100 %	0 %	100 %
Sample S002	8	8	100 %	4.9 %	95.1 %
Sample S003	8	8	100 %	9.1 %	90.9 %
Average:			100 %	4.6 %	95.4 %

History	Test nr.	Own success rate	Difference	AVR success rate
Round 2019-1	1-1	75 %	-22.4 %	97.4 %
Round 2018-1	1-1	75 %	-14.9 %	89.9 %

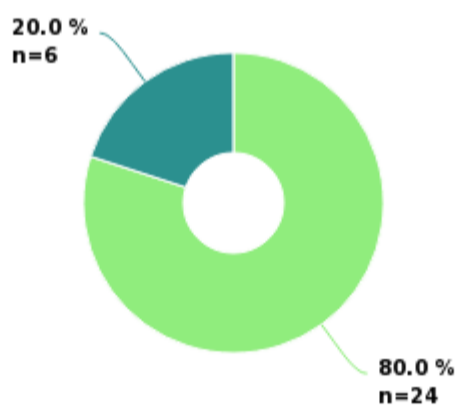
Sample S001

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 %	30
	HEVAb	-	-	-	-	-	2
	HEVAbG	2	2	100 %	0 %	100 %	26
	HEVAbM	2	2	100 %	0 %	100 %	28
	Total:	8	8	100 %	0 %	100 %	86

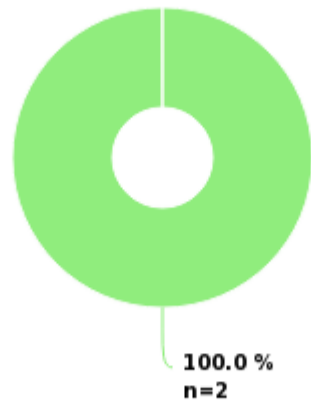
Sample S001 Clinical interpretation



■ Acute/recent infection
■ Laboratory does not give clinical interpretation

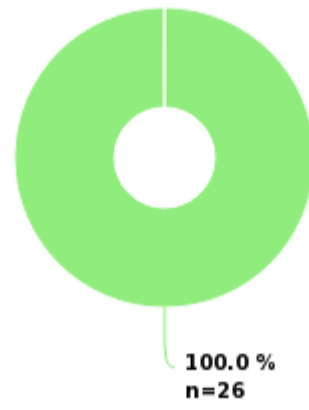
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Acute/recent infection		24		4	4	100 %	0 %	100 %
		<input checked="" type="radio"/> Would be referred to another laboratory for further examination		7	-	-			
		New sample requested		3	-	-			
	Laboratory does not give clinical interpretation		6		-	-			-
		Would be referred to another laboratory for further examination		1	-	-			
	Total:		30		4	4	100 %	0 %	100 %

Sample S001 HEVAb



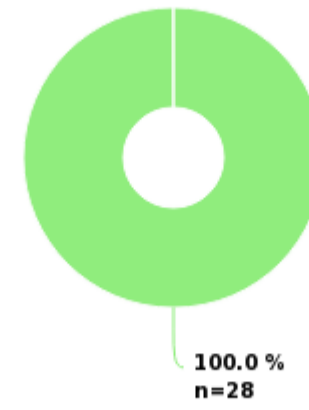
Positive

Sample S001 HEVAbG



Positive

Sample S001 HEVAbM



Positive

HEVAb	Test result	Methodics	Test result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Positive		2		-				-
		Fortress Diagnostics HEV ELISA		1					
		MP Diagnostics HEV ELISA 4.0		1					
	Total:		2		-	-	-	-	

OWN DEVICE: LIAISON

HEVAbG	Test result	Methodics	Test result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		26		2	2	100 %	0 %	100 %
		bioMerieux VIDAS Anti-HEV IgG (HEVG)		7					
		<input checked="" type="radio"/> DiaSorin LIAISON Murex Anti-HEV IgG		7					
		Euroimmun Anti-Hepatitis E-Virus IgG ELISA		1					
		Euroimmun EUROLINE Anti-Hepatitis E Virus (IgG)		1					
		Fortress Diagnostics HEV-IgG ELISA		2					
		Mikrogen Diagnostik recomLine HEV IgG (Strip)		1					
		Mikrogen Diagnostik recomWell HEV IgG (ELISA)		1					
		MP Diagnostics HEV IgG ELISA 4.0		2					
		Vircell Hepatitis E VIRCLIA IgG MONOTEST		3					
		Wantai HEV-IgG ELISA		1					
	Total:		26		2	2	100 %	0 %	100 %

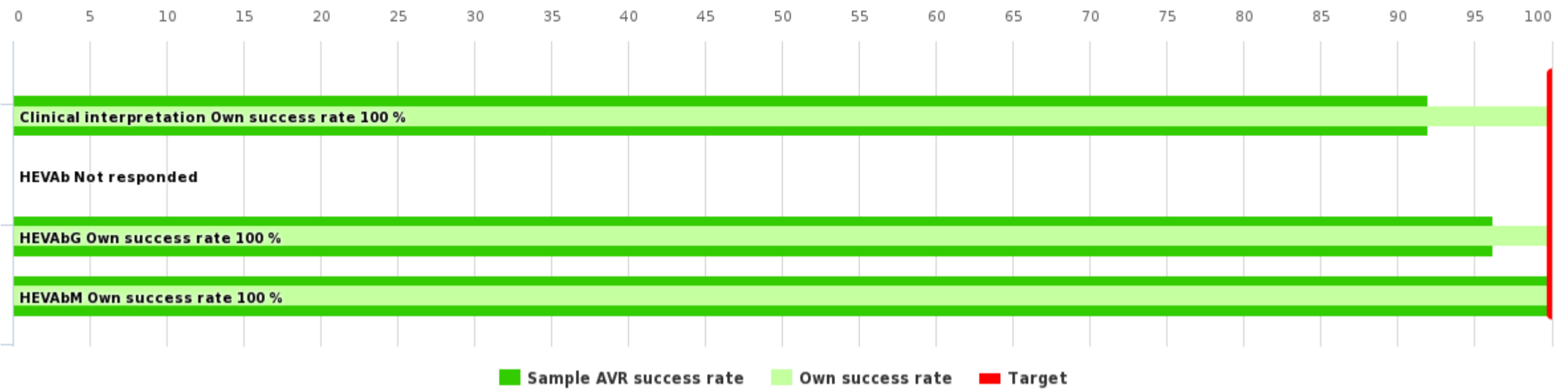
OWN DEVICE: LIAISON

HEVAbM	Test result	Methodics	Test result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Positive		28		2	2	100 %	0 %	100 %
		bioMerieux VIDAS Anti-HEV IgM (HEVM)		7					
		<input checked="" type="radio"/> DiaSorin LIAISON Murex Anti-HEV IgM		6					
		DRG Diagnostics HEV IgM		1					
		Fortress Diagnostics HEV-IgM ELISA		3					
		Mikrogen Diagnostik recomLine HEV IgM (Strip)		1					
		Mikrogen Diagnostik recomWell HEV IgM (ELISA)		1					
		MP Biomedicals ASSURE HEV IgM Test		1					
		MP Diagnostics HEV IgM ELISA 4.0		2					
		Orgentec Alegria Anti-Hepatitis E Virus IgM Abs.		1					
		Vircell Hepatitis E VIRCLIA IgM MONOTEST		3					

		Wantai HEV-IgM Antibody rapid test		1					
		Wantai HEV-IgM ELISA		1					
	Total:		28		2	2	100 %	0 %	100 %

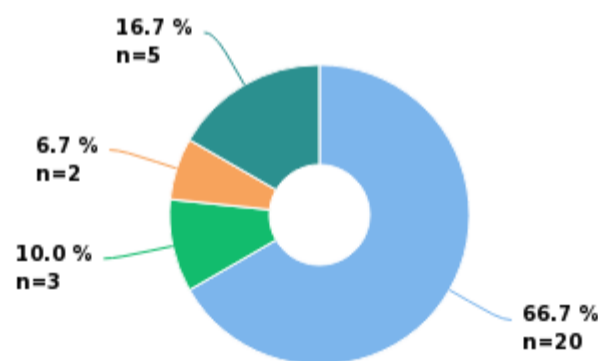
Sample S002

Sample S002 success rate



Sample S002 results	Responded	Own score	Max score	Own success rate	Difference	AVR success rate	Count
	Clinical interpretation	4	4	100 %	8 %	92 %	30
	HEVAb	-	-	-	-	-	2
	HEVAbG	2	2	100 %	3.8 %	96.2 %	26
	HEVAbM	2	2	100 %	0 %	100 %	27
	Total:	8	8	100 %	4.9 %	95.1 %	85

Sample S002 Clinical interpretation



- Old immunity
- No indication of acute/recent infection
- No detectable antibodies
- Laboratory does not give clinical interpretation

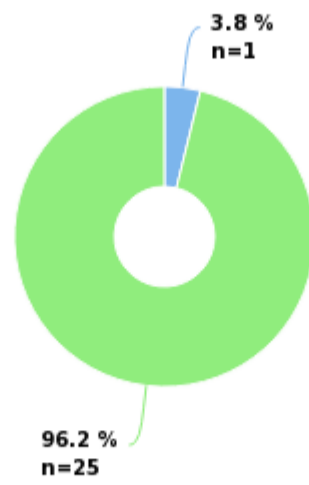
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Old immunity		20		4	4	100 %	0 %	100 %
	No indication of acute/recent infection		3		-				100 %
	No detectable antibodies		2		-				0 %
	Laboratory does not give clinical interpretation		5		-				-
	Total:		30		4	4	100 %	8 %	92 %

Sample S002 HEVAb



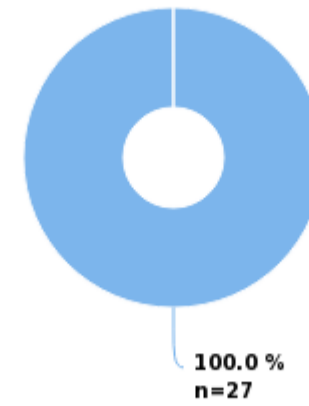
■ Negative ■ Positive

Sample S002 HEVAbG



■ Negative ■ Positive

Sample S002 HEVAbM



■ Negative

HEVAb	Test result	Methodics	Test result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				-
		MP Diagnostics HEV ELISA 4.0		1					
	Positive		1		-				-
		Fortress Diagnostics HEV ELISA		1					
	Total:		2		-	-	-	-	

OWN DEVICE: LIAISON

HEVAbG	Test result	Methodics	Test result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		1		-				0 %
		MP Diagnostics HEV IgG ELISA 4.0		1					
	<input checked="" type="radio"/> Positive		25		2	2	100 %	0 %	100 %
		bioMerieux VIDAS Anti-HEV IgG (HEVG)		7					
		<input checked="" type="radio"/> DiaSorin LIAISON Murex Anti-HEV IgG		7					
		Euroimmun Anti-Hepatitis E-Virus IgG ELISA		1					
		Euroimmun EUROLINE Anti-Hepatitis E Virus (IgG)		1					
		Fortress Diagnostics HEV-IgG ELISA		2					
		Mikrogen Diagnostik recomLine HEV IgG (Strip)		1					
		Mikrogen Diagnostik recomWell HEV IgG (ELISA)		1					
		MP Diagnostics HEV IgG ELISA 4.0		1					
		Vircell Hepatitis E VIRCLIA IgG MONOTEST		3					
		Wantai HEV-IgG ELISA		1					
	Total:		26		2	2	100 %	3.8 %	96.2 %

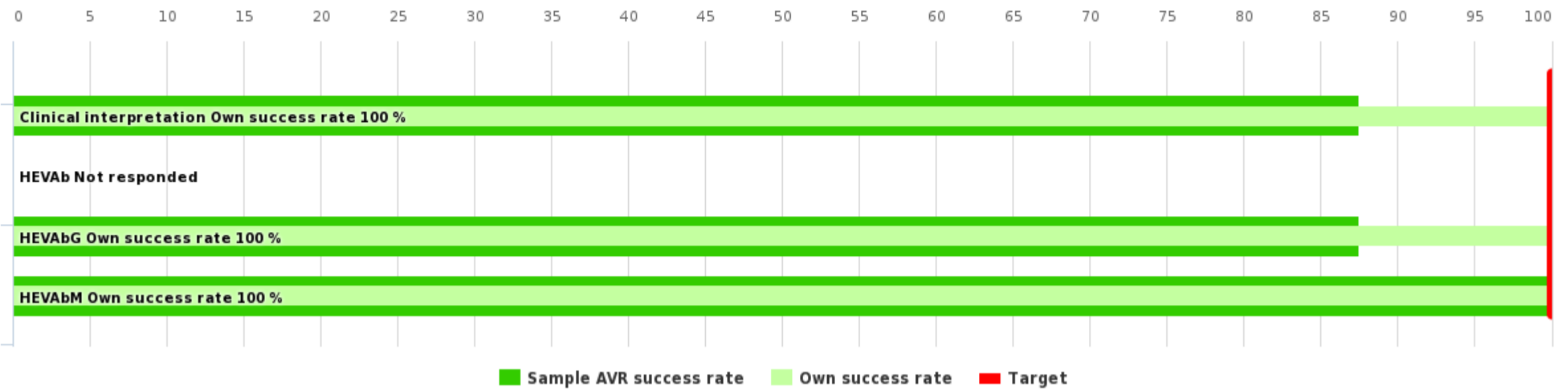
OWN DEVICE: LIAISON

HEVAbM	Test result	Methodics	Test result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		27		2	2	100 %	0 %	100 %
		bioMerieux VIDAS Anti-HEV IgM (HEVM)		7					
		<input checked="" type="radio"/> DiaSorin LIAISON Murex Anti-HEV IgM		6					
		DRG Diagnostics HEV IgM		1					
		Fortress Diagnostics HEV-IgM ELISA		3					
		Mikrogen Diagnostik recomWell HEV IgM (ELISA)		1					
		MP Biomedicals ASSURE HEV IgM Test		1					
		MP Diagnostics HEV IgM ELISA 4.0		2					
		Orgentec Alegria Anti-Hepatitis E Virus IgM Abs.		1					

		Vircell Hepatitis E VIRCLIA IgM MONOTEST		3					
		Wantai HEV-IgM Antibody rapid test		1					
		Wantai HEV-IgM ELISA		1					
	Total:		27		2	2	100 %	0 %	100 %

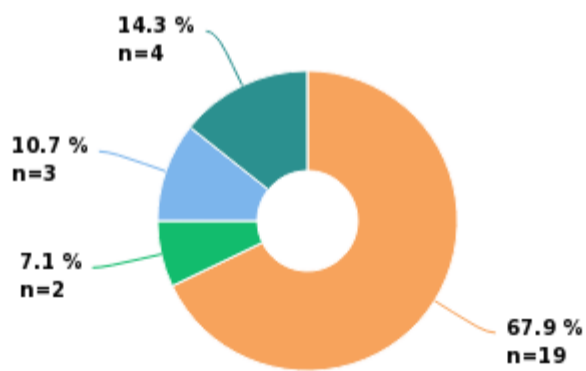
Sample S003

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 %	12.5 %	87.5 %	28
	HEVAb	-	-	-	-	-	2
	HEVAbG	2	2	100 %	12.5 %	87.5 %	24
	HEVAbM	2	2	100 %	0 %	100 %	27
	Total:	8	8	100 %	9.1 %	90.9 %	81

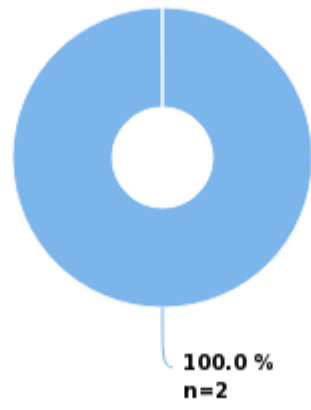
Sample S003 Clinical interpretation



- No detectable antibodies
- No indication of acute/recent infection
- Old immunity
- Laboratory does not give clinical interpretation

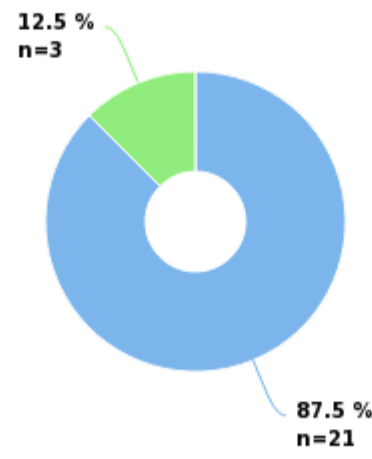
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> No detectable antibodies		19		4	4	100 %	0 %	100 %
		New sample requested		1	-	-			
	No indication of acute/recent infection		2		-				100 %
	Old immunity		3		-				0 %
	Laboratory does not give clinical interpretation		4		-				-
	Total:		28		4	4	100 %	12.5 %	87.5 %

Sample S003 HEVAb



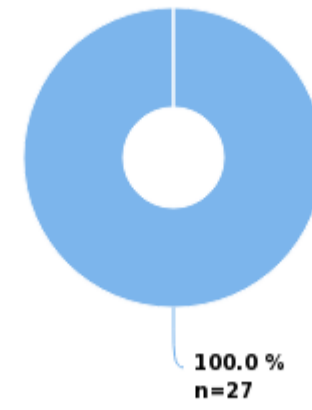
■ Negative

Sample S003 HEVAbG



■ Negative ■ Positive

Sample S003 HEVAbM



■ Negative

HEVAb	Test result	Methodics	Test result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	Negative		2		-				-
		Fortress Diagnostics HEV ELISA		1					
		MP Diagnostics HEV ELISA 4.0		1					
	Total:		2		-	-	-	-	

OWN DEVICE: LIAISON

HEVAbG	Test result	Methodics	Test result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		21		2	2	100 %	0 %	100 %
		bioMerieux VIDAS Anti-HEV IgG (HEVG)		7					
		<input checked="" type="radio"/> DiaSorin LIAISON Murex Anti-HEV IgG		7					
		Euroimmun Anti-Hepatitis E-Virus IgG ELISA		1					
		Fortress Diagnostics HEV-IgG ELISA		2					
		Mikrogen Diagnostik recomWell HEV IgG (ELISA)		1					
		MP Diagnostics HEV IgG ELISA 4.0		2					
		Wantai HEV-IgG ELISA		1					
	Positive		3		-				0 %
		Vircell Hepatitis E VIRCLIA IgG MONOTEST		3					
	Total:		24		2	2	100 %	12.5 %	87.5 %

OWN DEVICE: LIAISON

HEVAbM	Test result	Methodics	Test result count	Methodics count	Own score	Max score	Own success rate	Difference	AVR success rate
	<input checked="" type="radio"/> Negative		27		2	2	100 %	0 %	100 %
		bioMerieux VIDAS Anti-HEV IgM (HEVM)		7					
		<input checked="" type="radio"/> DiaSorin LIAISON Murex Anti-HEV IgM		6					
		DRG Diagnostics HEV IgM		1					
		Fortress Diagnostics HEV-IgM ELISA		3					
		Mikrogen Diagnostik recomWell HEV IgM (ELISA)		1					
		MP Biomedicals ASSURE HEV IgM Test		1					
		MP Diagnostics HEV IgM ELISA 4.0		2					
		Orgentec Alegria Anti-Hepatitis E Virus IgM Abs.		1					
		Vircell Hepatitis E VIRCLIA IgM MONOTEST		3					
		Wantai HEV-IgM Antibody rapid test		1					
		Wantai HEV-IgM ELISA		1					
	Total:		27		2	2	100 %	0 %	100 %

Report Info**PARTICIPANTS**

Altogether 32 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 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
Hepatitis E, antibodies, May, 1-2023	32	28	87.5 %

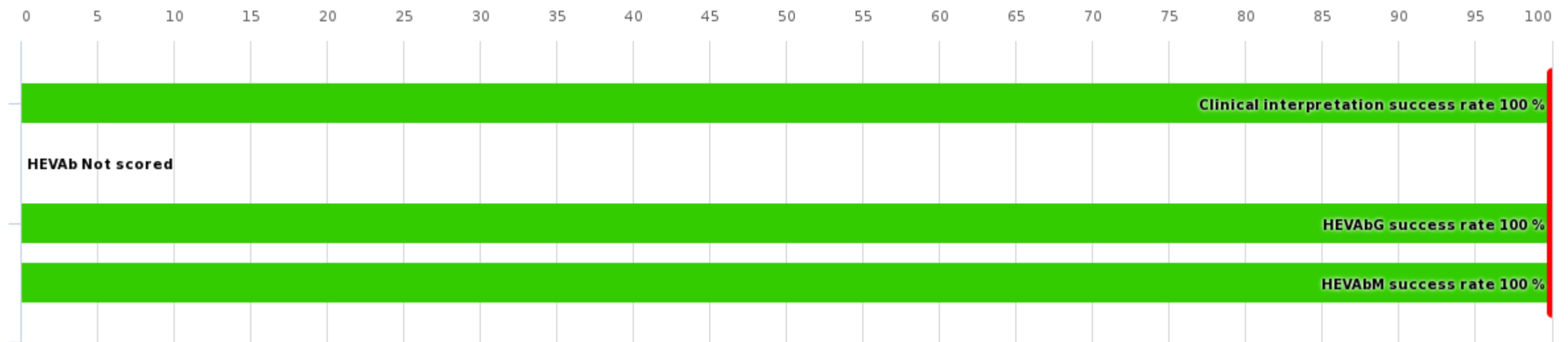
Summary



Summary	AVR success rate
Sample S001	100 %
Sample S002	95.1 %
Sample S003	90.9 %
Average:	95.4 %

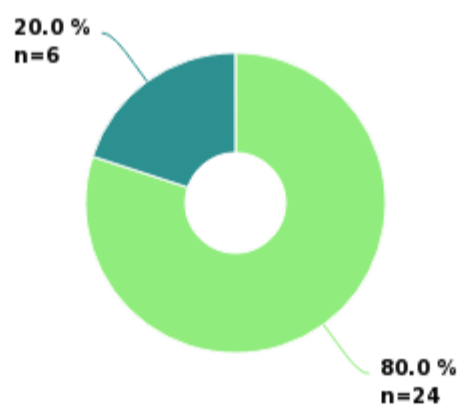
Sample S001

Sample S001 success rate



Sample S001 results	Responded	AVR success rate	Count
	Clinical interpretation	100 %	30
	HEVAb	-	2
	HEVAbG	100 %	26
	HEVAbM	100 %	28
	Total:	100 %	86

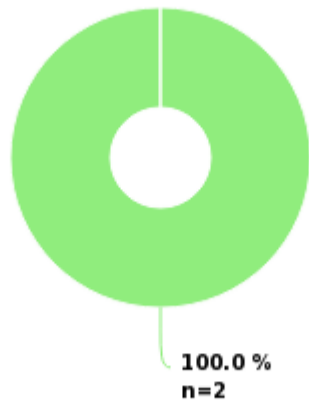
Sample S001 Clinical interpretation



■ Acute/recent infection
■ Laboratory does not give clinical interpretation

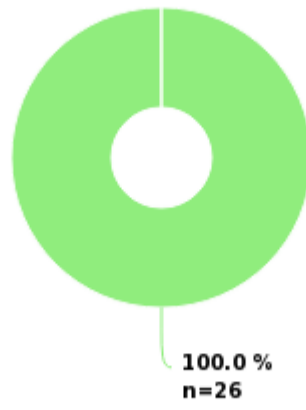
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	AVR success rate	Clinical interpretation Score
	Acute/recent infection		24		100 %	4
		Would be referred to another laboratory for further examination		7		
		New sample requested		3		
	Laboratory does not give clinical interpretation		6		-	-
		Would be referred to another laboratory for further examination		1		
	Total:		30		100 %	

Sample S001 HEVAb



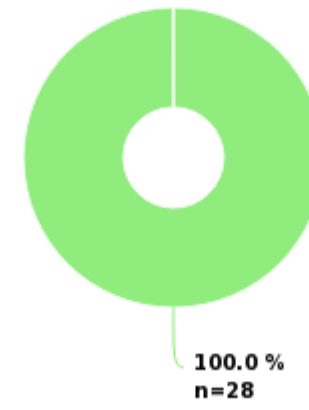
Positive

Sample S001 HEVAbG



Positive

Sample S001 HEVAbM



Positive

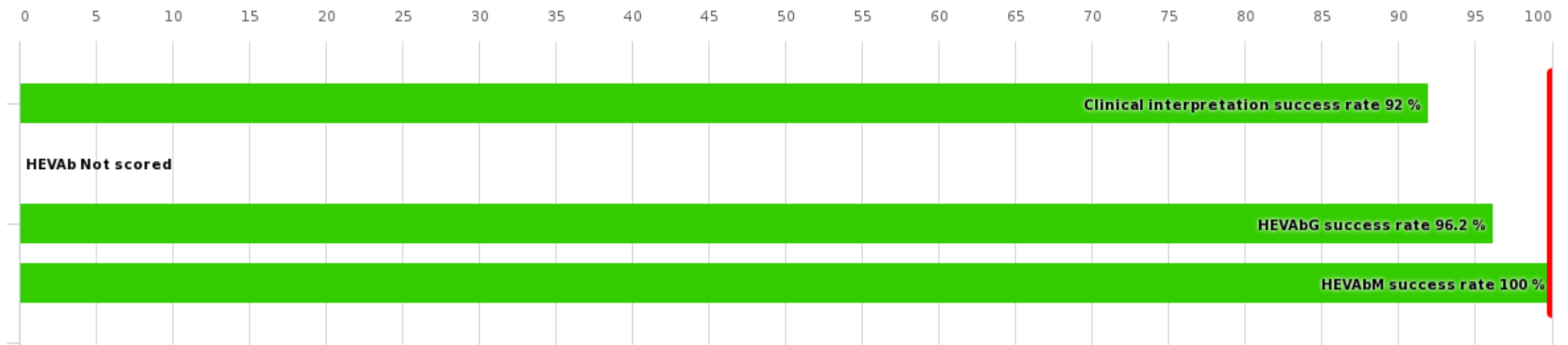
HEVAb	Test result	Methodics	Test result count	Methodics count	AVR success rate	Test result Score
	Positive		2		-	-
		Fortress Diagnostics HEV ELISA		1		
		MP Diagnostics HEV ELISA 4.0		1		
	Total:		2			

HEVAbG	Test result	Methodics	Test result count	Methodics count	AVR success rate	Test result Score
	Positive		26		100 %	2
		bioMerieux VIDAS Anti-HEV IgG (HEVG)		7		
		DiaSorin LIAISON Murex Anti-HEV IgG		7		
		Euroimmun Anti-Hepatitis E-Virus IgG ELISA		1		
		Euroimmun EUROLINE Anti-Hepatitis E Virus (IgG)		1		
		Fortress Diagnostics HEV-IgG ELISA		2		
		Mikrogen Diagnostik recomLine HEV IgG (Strip)		1		
		Mikrogen Diagnostik recomWell HEV IgG (ELISA)		1		
		MP Diagnostics HEV IgG ELISA 4.0		2		
		Vircell Hepatitis E VIRCLIA IgG MONOTEST		3		
		Wantai HEV-IgG ELISA		1		
	Total:		26		100 %	

HEVAbM	Test result	Methodics	Test result count	Methodics count	AVR success rate	Test result Score
	Positive		28		100 %	2
		bioMerieux VIDAS Anti-HEV IgM (HEVM)		7		
		DiaSorin LIAISON Murex Anti-HEV IgM		6		
		DRG Diagnostics HEV IgM		1		
		Fortress Diagnostics HEV-IgM ELISA		3		
		Mikrogen Diagnostik recomLine HEV IgM (Strip)		1		
		Mikrogen Diagnostik recomWell HEV IgM (ELISA)		1		
		MP Biomedicals ASSURE HEV IgM Test		1		
		MP Diagnostics HEV IgM ELISA 4.0		2		
		Orgentec Alegria Anti-Hepatitis E Virus IgM Abs.		1		
		Vircell Hepatitis E VIRCLIA IgM MONOTEST		3		
		Wantai HEV-IgM Antibody rapid test		1		
		Wantai HEV-IgM ELISA		1		
	Total:		28		100 %	

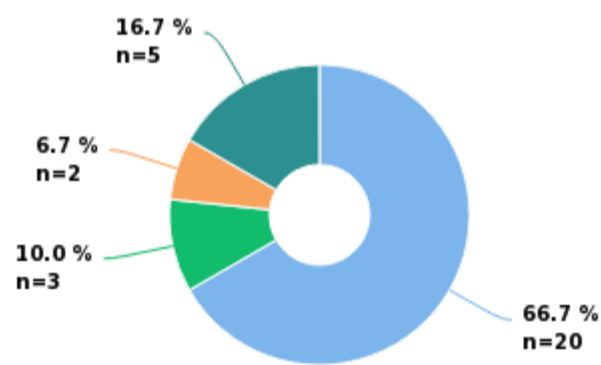
Sample S002

Sample S002 success rate



Sample S002 results	Responded	AVR success rate	Count
	Clinical interpretation	92 %	30
	HEVAb	-	2
	HEVAbG	96.2 %	26
	HEVAbM	100 %	27
	Total:	95.1 %	85

Sample S002 Clinical interpretation



- Old immunity
- No indication of acute/recent infection
- No detectable antibodies
- Laboratory does not give clinical interpretation

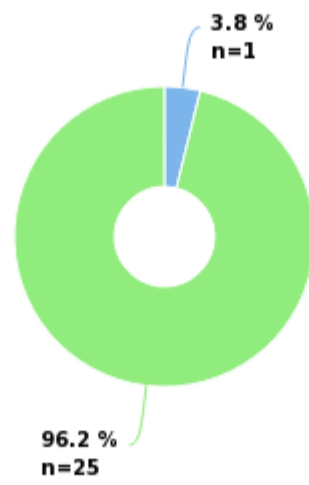
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	AVR success rate	Clinical interpretation Score
	Old immunity		20		100 %	4
	No indication of acute/recent infection		3		100 %	4
	No detectable antibodies		2		0 %	0
	Laboratory does not give clinical interpretation		5		-	-
	Total:		30		92 %	

Sample S002 HEVAb



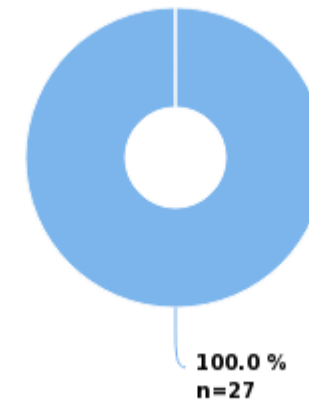
■ Negative ■ Positive

Sample S002 HEVAbG



■ Negative ■ Positive

Sample S002 HEVAbM



■ Negative

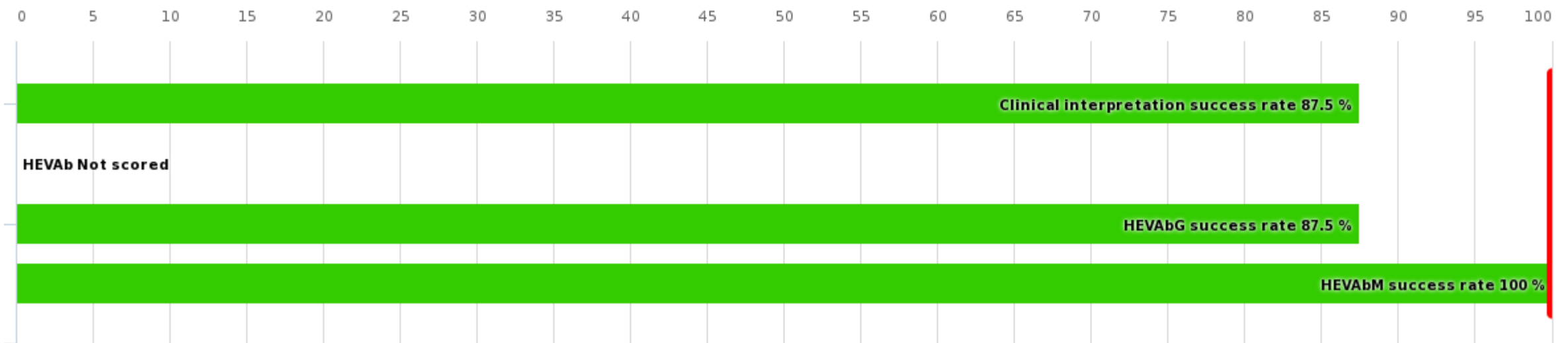
HEVAb	Test result	Methodics	Test result count	Methodics count	AVR success rate	Test result Score
	Negative		1		-	-
		MP Diagnostics HEV ELISA 4.0		1		
	Positive		1		-	-
		Fortress Diagnostics HEV ELISA		1		
	Total:		2			

HEVAbG	Test result	Methodics	Test result count	Methodics count	AVR success rate	Test result Score
	Negative		1		0 %	0
		MP Diagnostics HEV IgG ELISA 4.0		1		
	Positive		25		100 %	2
		bioMerieux VIDAS Anti-HEV IgG (HEVG)		7		
		DiaSorin LIAISON Murex Anti-HEV IgG		7		
		Euroimmun Anti-Hepatitis E-Virus IgG ELISA		1		
		Euroimmun EUROLINE Anti-Hepatitis E Virus (IgG)		1		
		Fortress Diagnostics HEV-IgG ELISA		2		
		Mikrogen Diagnostik recomLine HEV IgG (Strip)		1		
		Mikrogen Diagnostik recomWell HEV IgG (ELISA)		1		
		MP Diagnostics HEV IgG ELISA 4.0		1		
		Vircell Hepatitis E VIRCLIA IgG MONOTEST		3		
		Wantai HEV-IgG ELISA		1		
	Total:		26		96.2 %	

HEVAbM	Test result	Methodics	Test result count	Methodics count	AVR success rate	Test result Score
	Negative		27		100 %	2
		bioMerieux VIDAS Anti-HEV IgM (HEVM)		7		
		DiaSorin LIAISON Murex Anti-HEV IgM		6		
		DRG Diagnostics HEV IgM		1		
		Fortress Diagnostics HEV-IgM ELISA		3		
		Mikrogen Diagnostik recomWell HEV IgM (ELISA)		1		
		MP Biomedicals ASSURE HEV IgM Test		1		
		MP Diagnostics HEV IgM ELISA 4.0		2		
		Orgentec Alegria Anti-Hepatitis E Virus IgM Abs.		1		
		Vircell Hepatitis E VIRCLIA IgM MONOTEST		3		
		Wantai HEV-IgM Antibody rapid test		1		
		Wantai HEV-IgM ELISA		1		
	Total:		27		100 %	

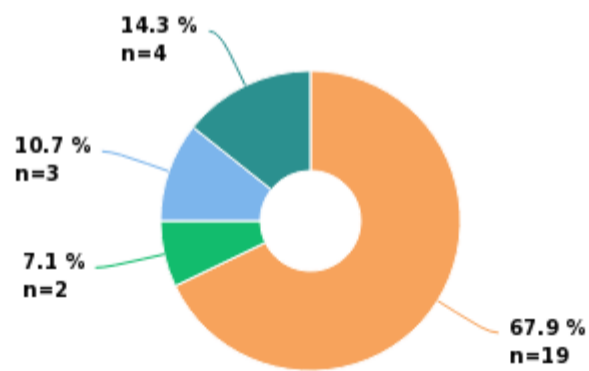
Sample S003

Sample S003 success rate



Sample S003 results	Responded	AVR success rate	Count
	Clinical interpretation	87.5 %	28
	HEVAb	-	2
	HEVAbG	87.5 %	24
	HEVAbM	100 %	27
	Total:	90.9 %	81

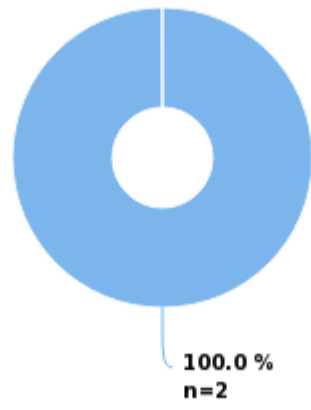
Sample S003 Clinical interpretation



- No detectable antibodies
- No indication of acute/recent infection
- Old immunity
- Laboratory does not give clinical interpretation

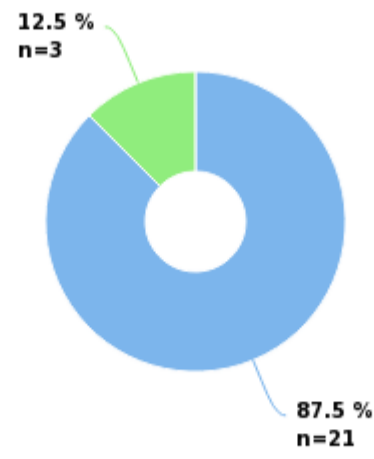
Clinical interpretation	Clinical interpretation	Further action	Clinical interpretation count	Further action count	AVR success rate	Clinical interpretation Score
	No detectable antibodies		19		100 %	4
		New sample requested		1		
	No indication of acute/recent infection		2		100 %	4
	Old immunity		3		0 %	0
	Laboratory does not give clinical interpretation		4		-	-
	Total:		28		87.5 %	

Sample S003 HEVAb



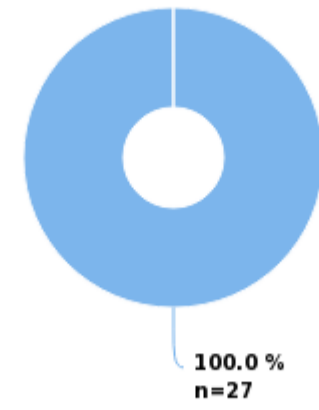
■ Negative

Sample S003 HEVAbG



■ Negative ■ Positive

Sample S003 HEVAbM



■ Negative

HEVAb	Test result	Methodics	Test result count	Methodics count	AVR success rate	Test result Score
	Negative		2		-	-
		Fortress Diagnostics HEV ELISA		1		
		MP Diagnostics HEV ELISA 4.0		1		
	Total:		2			

HEVAbG	Test result	Methodics	Test result count	Methodics count	AVR success rate	Test result Score
	Negative		21		100 %	2
		bioMerieux VIDAS Anti-HEV IgG (HEVG)		7		
		DiaSorin LIAISON Murex Anti-HEV IgG		7		
		Euroimmun Anti-Hepatitis E-Virus IgG ELISA		1		
		Fortress Diagnostics HEV-IgG ELISA		2		
		Mikrogen Diagnostik recomWell HEV IgG (ELISA)		1		
		MP Diagnostics HEV IgG ELISA 4.0		2		
		Wantai HEV-IgG ELISA		1		
	Positive		3		0 %	0
		Vircell Hepatitis E VIRCLIA IgG MONOTEST		3		
	Total:		24		87.5 %	

HEVAbM	Test result	Methodics	Test result count	Methodics count	AVR success rate	Test result Score
	Negative		27		100 %	2
		bioMerieux VIDAS Anti-HEV IgM (HEVM)		7		
		DiaSorin LIAISON Murex Anti-HEV IgM		6		
		DRG Diagnostics HEV IgM		1		
		Fortress Diagnostics HEV-IgM ELISA		3		
		Mikrogen Diagnostik recomWell HEV IgM (ELISA)		1		
		MP Biomedicals ASSURE HEV IgM Test		1		
		MP Diagnostics HEV IgM ELISA 4.0		2		
		Orgentec Alegria Anti-Hepatitis E Virus IgM Abs.		1		
		Vircell Hepatitis E VIRCLIA IgM MONOTEST		3		
		Wantai HEV-IgM Antibody rapid test		1		
		Wantai HEV-IgM ELISA		1		
	Total:		27		100 %	

Report Info**PARTICIPANTS**

Altogether 32 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 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.

External Quality Assessment Scheme

Hepatitis E, 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 (LQ775023011)

HEVAb	Positive
HEVAbG	Positive
HEVAbM	Positive
Clinical interpretation	Acute/recent infection

Sample S002 (LQ775023012)

HEVAb	Positive
HEVAbG	Positive
HEVAbM	Negative
Clinical interpretation	Old immunity

Sample S003 (LQ775023013)

HEVAb	Negative
HEVAbG	Negative
HEVAbM	Negative
Clinical interpretation	No detectable antibodies

Pre-test method: Mikrogen Diagnostik recomWell HEV IgG/IgM and/or DiaSorin LIAISON Murex Anti-HEV IgG/IgM.

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

Participants performed well in this EQA round. There were no problems with the acute/recent infection sample (S001). One negative total antibody result and one negative IgG antibody result were reported from the old immunity sample (S002). The deviating test results also led to a false clinical interpretation. There was also one “No detectable antibodies” interpretation reported based only on the IgM test result. Three deviating IgG test results were reported from the negative sample (S003). However, nothing in the results indicated that the samples would have been mixed up. Deviating test results also led to false clinical interpretations.

Exceptions in scoring

No exceptions.

End of report

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2023-05-29

FINAL REPORT

Product no. 5682

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

EQA Coordinator
Marsa Järvenpää
marsa.jarvenpaa@labquality.fi

Expert

MD, PhD, Adjunct professor,
Specialist in Clinical Microbiology,
Maija Lappalainen,
HUS Diagnostic Center,
Clinical Microbiology,
Helsinki, Finland

Labquality Oy

Kumpulantie 15
FI-00520 HELSINKI
Finland

Tel. + 358 9 8566 8200
Fax + 358 9 8566 8280

info@labquality.fi
www.labquality.com

