LABQUALITY

External Quality Assessment Scheme

Antibody Screening and Compatibility Testing
Round 1, 2023

2023-02-27

INSTRUCTIONS

Product no. 4460
LQ714323011-012/BE
LQ714223013-016/BE

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 20, 2023.**

Specimens
Please find enclosed 2 whole blood samples S001 and S002, each 4 mL and four 15% red cell suspension in preservation medium S003, S004, S005 and S006, each 3 mL.

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

Examinations
Antibody screening
Compatibility testing

Storage and use
Analyse the samples on the arrival day, if possible. Otherwise store in a refrigerator (+2 … 8 °C) until the tests can be performed. The samples will be stable for 4 weeks from the date of this letter.

Samples S001 and S002 will be screened for unexpected antibodies. Samples S003, S004, S005 and S006 are for compatibility testing. The cells should be centrifuged to the bottom of the tube and the laboratory should prepare a suspension appropriate to the method. Compatibility tests simulate situation where four units of donor red blood cells (samples S003, S004, S005 and S006) are each crossmatched for two patients (samples S001 and S002).

Result reporting
Please enter the results and methods via LabScala (www.labscala.com). The compatibility tests should always be answered according to the serological tests. At the request of customers, the possibility of responding to a possibly identified antibody has been added to this round. This section is completely optional and will not be scored. Both reaction strength and interpretation are scored for the antibody screening. Reaction strengths are not scored in compatibility testing, only crossmatches are scored.

S001
LQ714323011

S004
LQ714223014

S002
LQ714323012

S005
LQ714223015

S003
LQ714223013

S006
LQ714223016

Inquiries
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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
Antibody screening and compatibility testing, February, 1-2023	142	140	98.6 %

Summary

Summary	Own score	Max score	Own success rate
Sample S001	44	44	100 %
Sample S002	44	44	100 %
Average:			100 %

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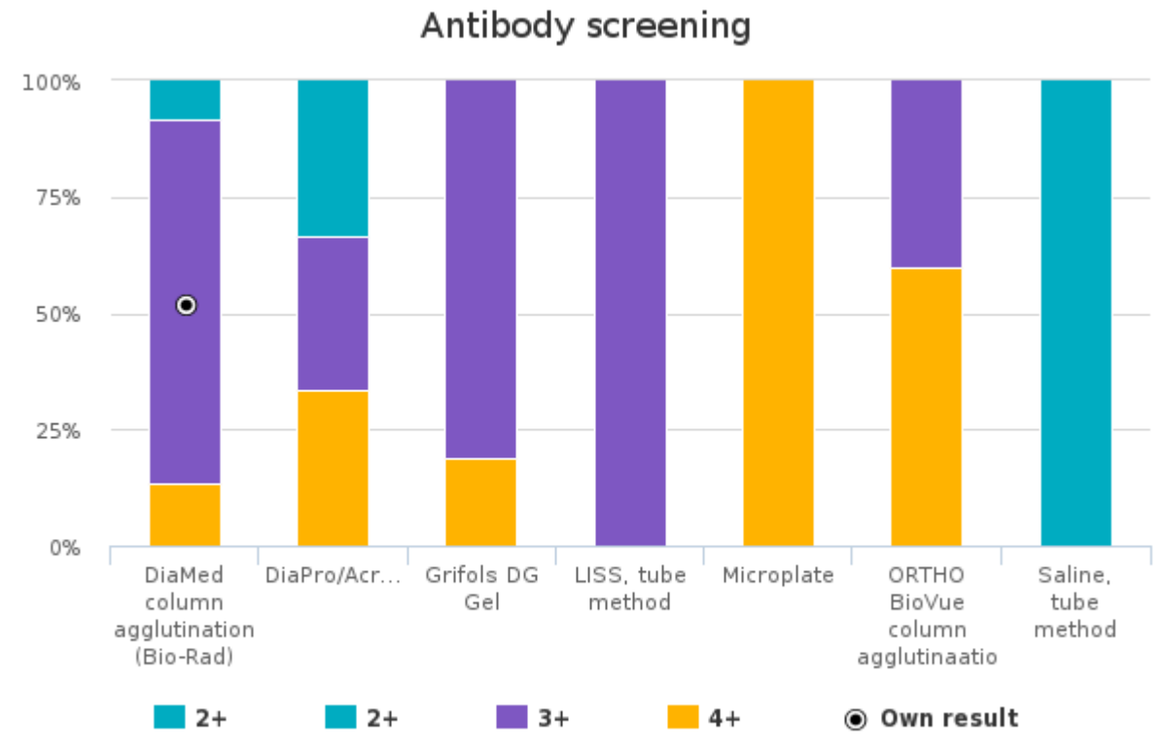
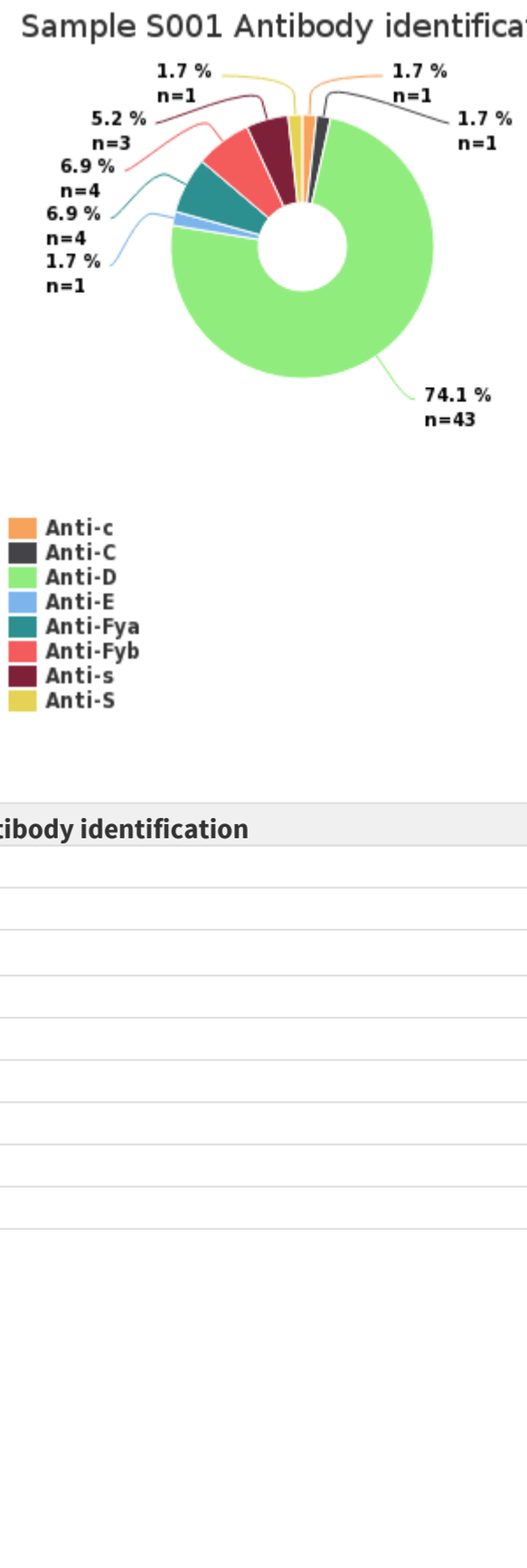
Sample S001



ANTIBODY SCREENING

Antibody screening	Method	Reaction strength	n	Reaction strength Score	Interpretation: Positive	Interpretation: Positive Score
	DiaMed column agglutination (Bio-Rad)	2+	7	1	7	2
		◉ 3+	65	2	◉ 65	2
		4+	11	2	11	2
	Total:		83			



Antibody identification	Result	Result count
	Anti-c	1
	Anti-C	1
	◉ Anti-D	43
	Anti-E	1
	Anti-Fya	4
	Anti-Fyb	4
	Anti-s	3
	Anti-S	1
	Total:	58

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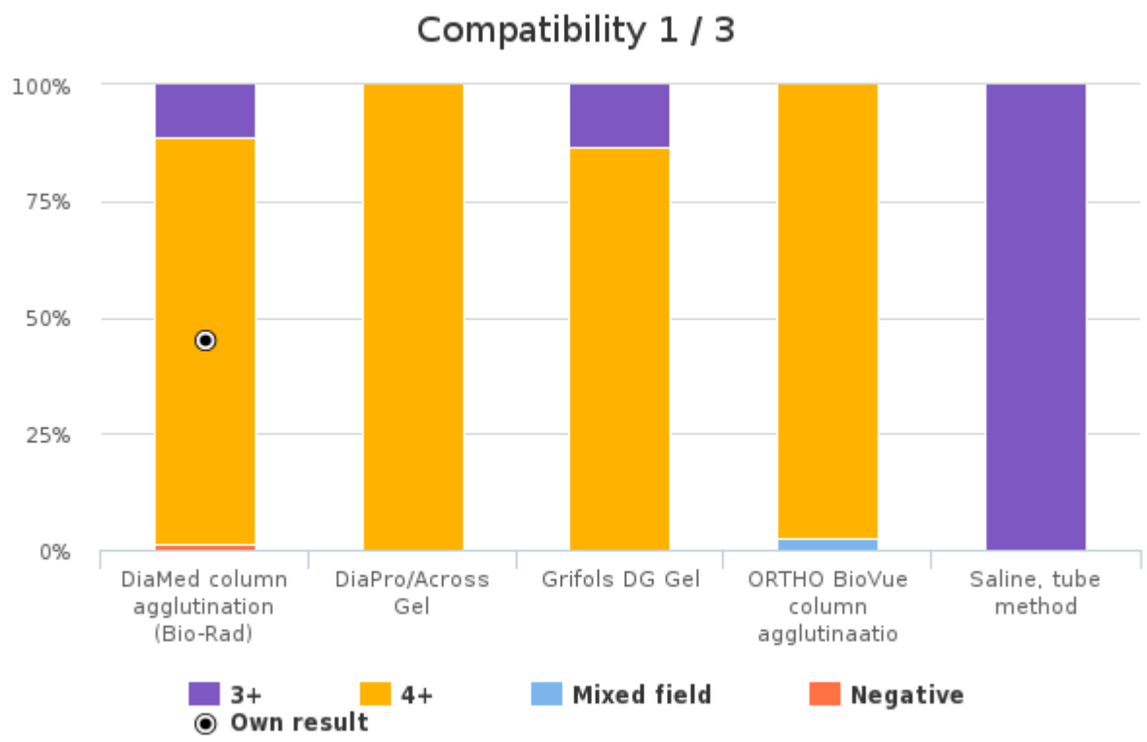

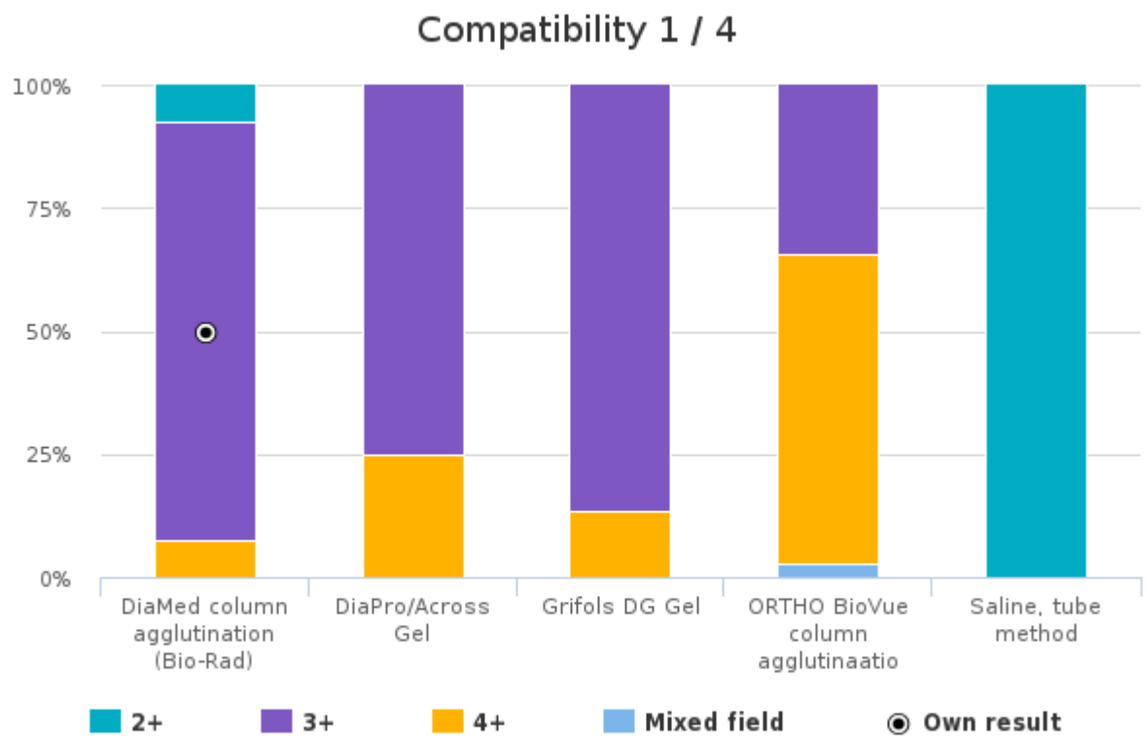

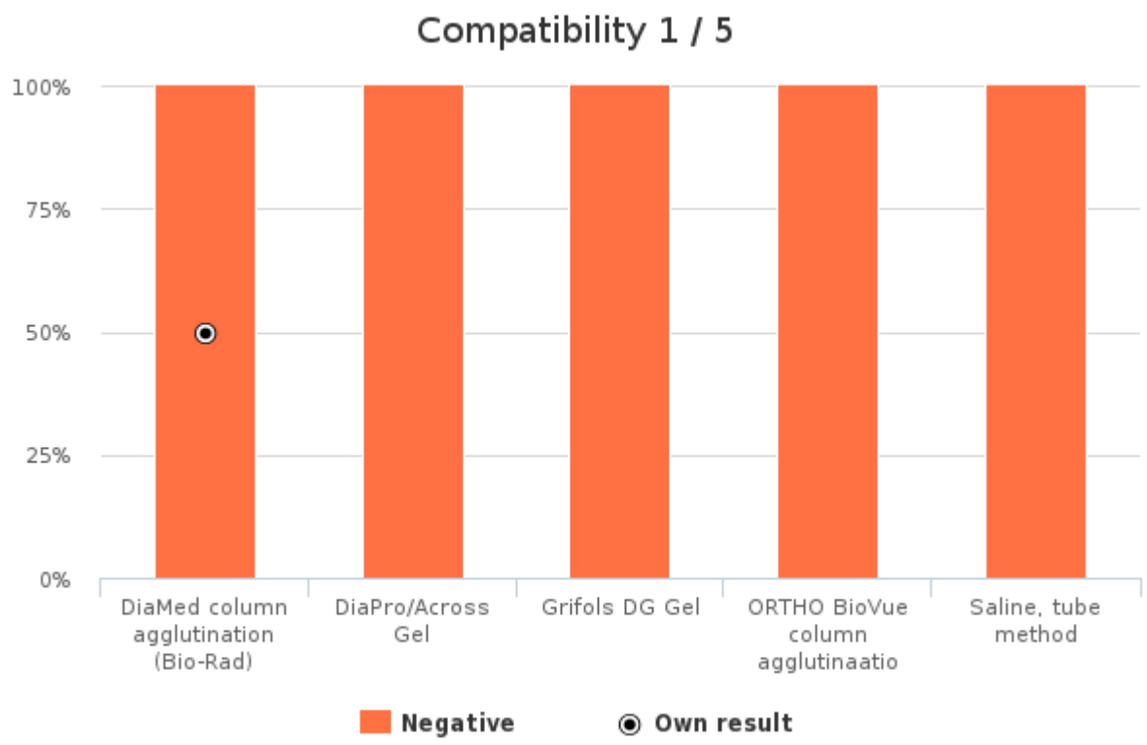

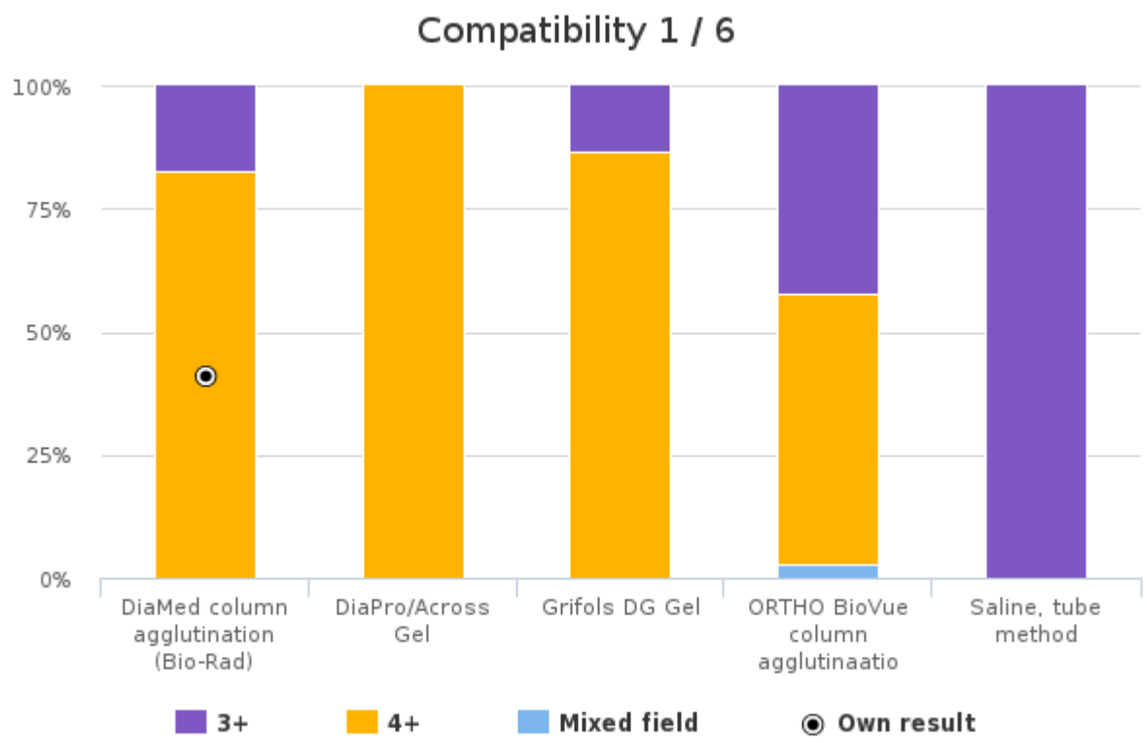

Compatibility 1 / 3	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	3+		9		10	9
		◉ 4+		◉ 70		10	70
		Negative	1		0		1
	Total:						80

Compatibility 1 / 4	Method	Reaction strength	Interpretation: Incompatible	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	2+	6	10	6
		◉ 3+	◉ 68	10	68
		4+	6	10	6
	Total:				80

Compatibility 1 / 5	Method	Reaction strength	Interpretation: Compatible	Interpretation: Compatible Score	n
	DiaMed column agglutination (Bio-Rad)	◉ Negative	◉ 80	10	80
	Total:				80

Compatibility 1 / 6	Method	Reaction strength	Interpretation: Incompatible	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	3+	14	10	14
		◉ 4+	◉ 66	10	66
	Total:				80

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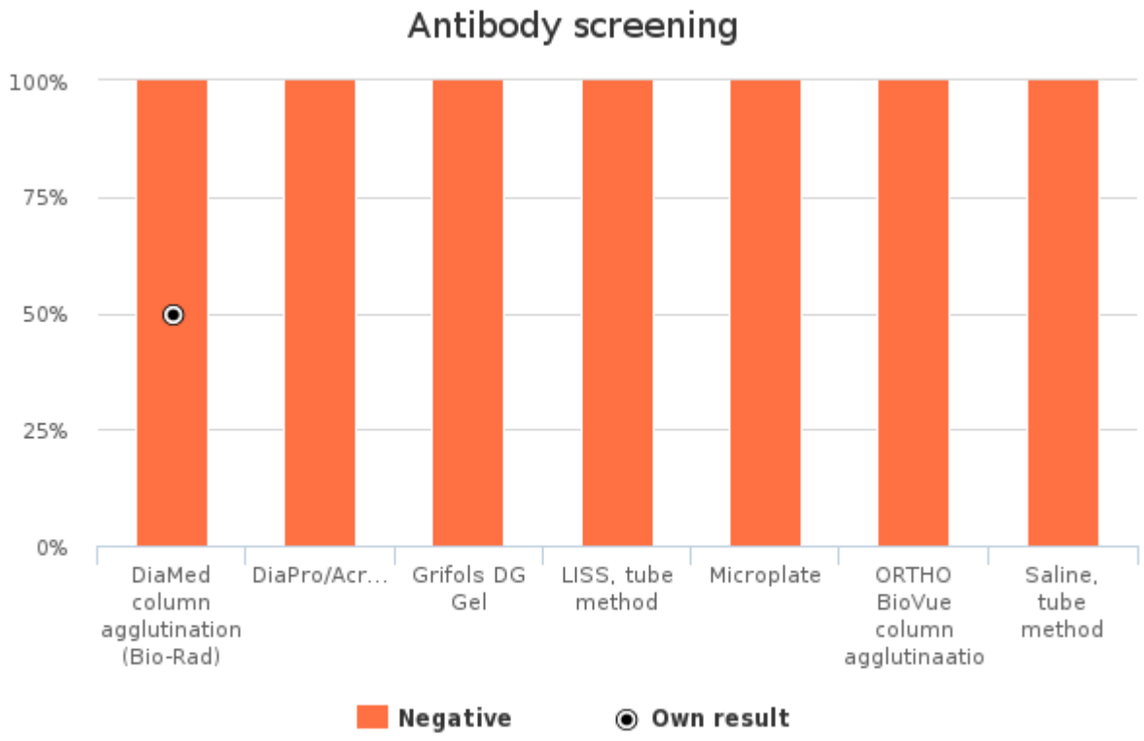
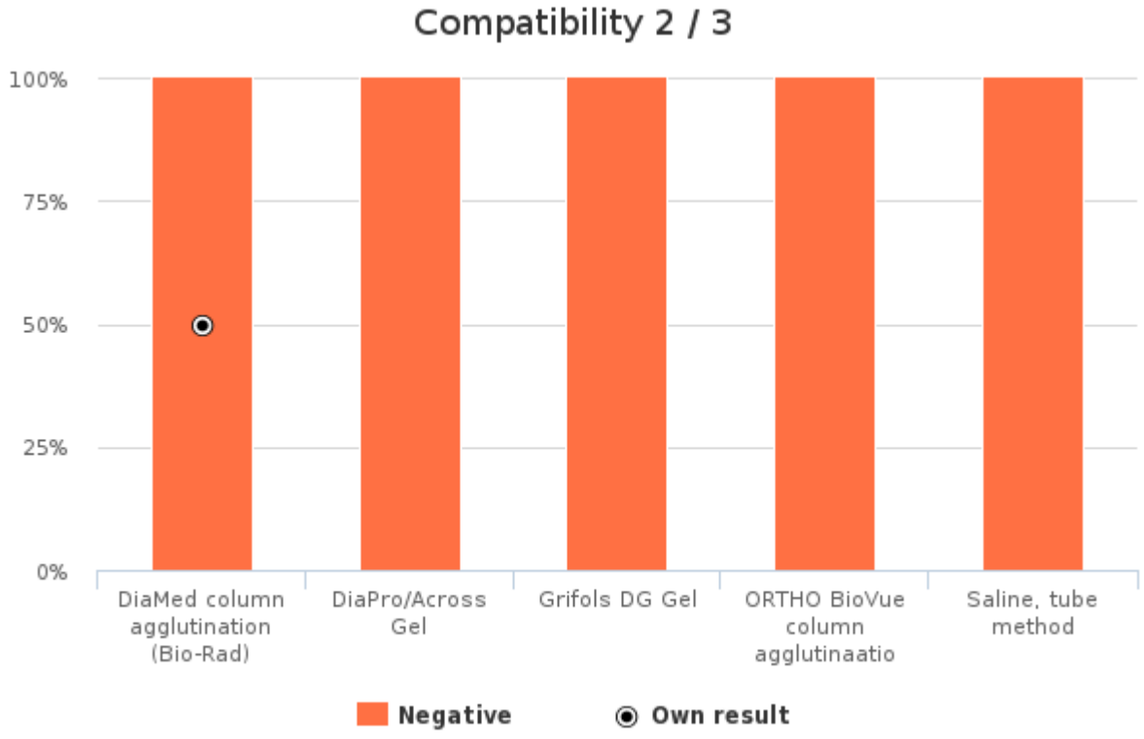
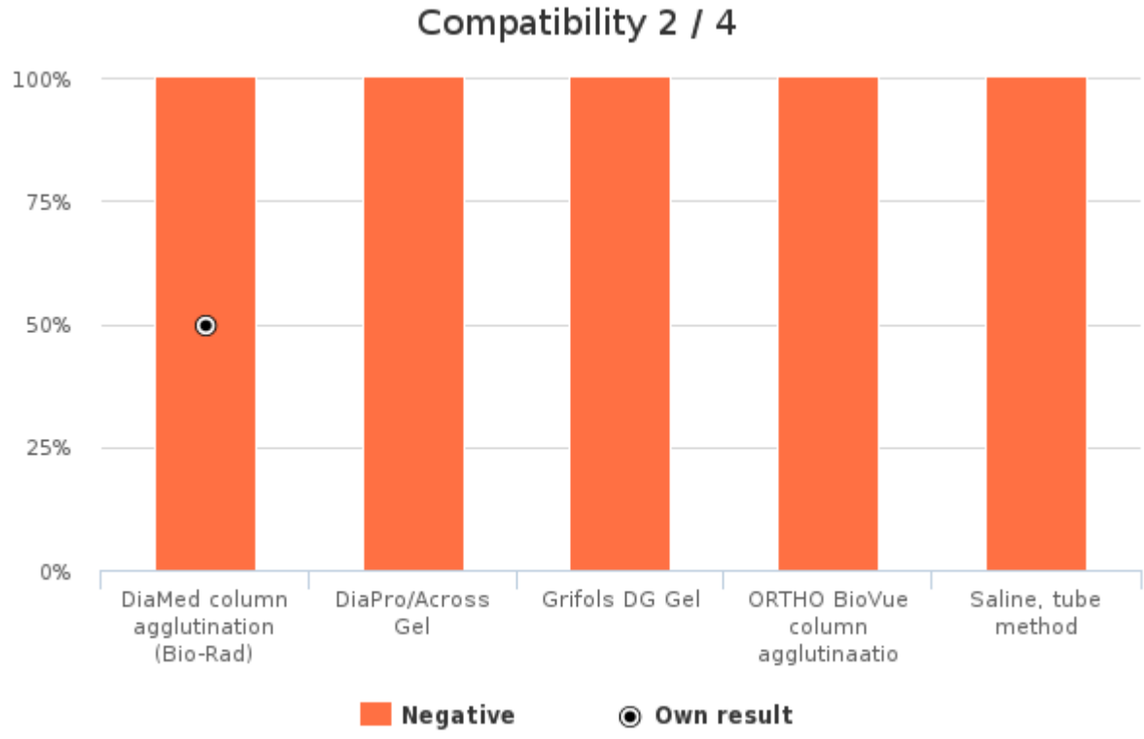
Sample S002

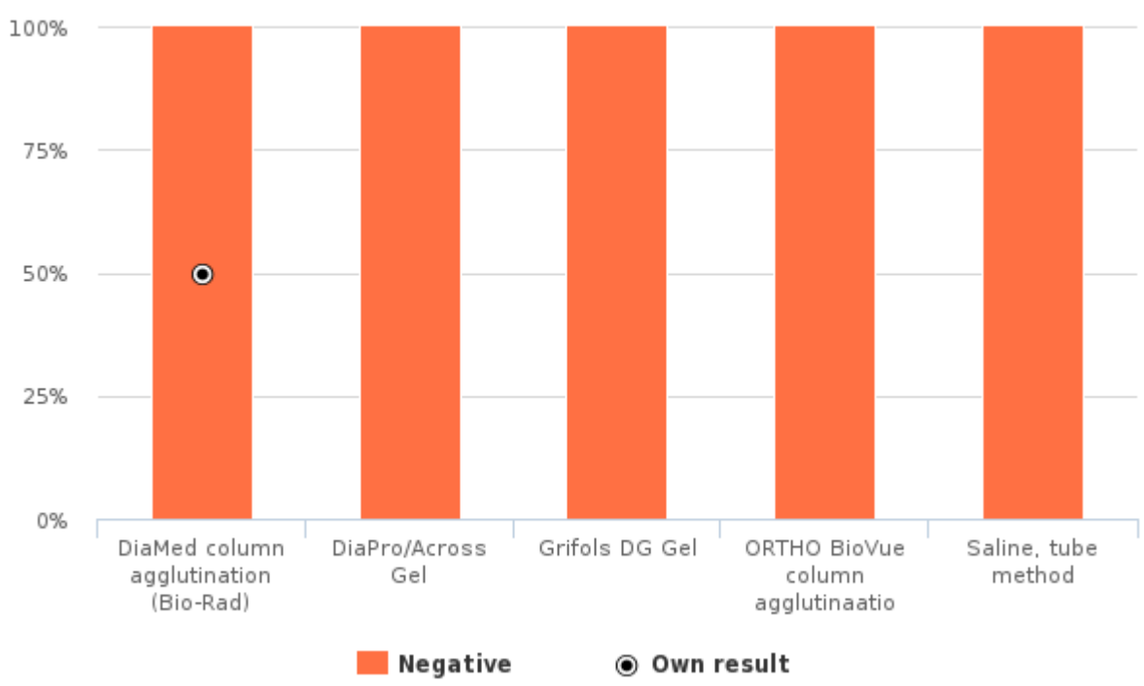


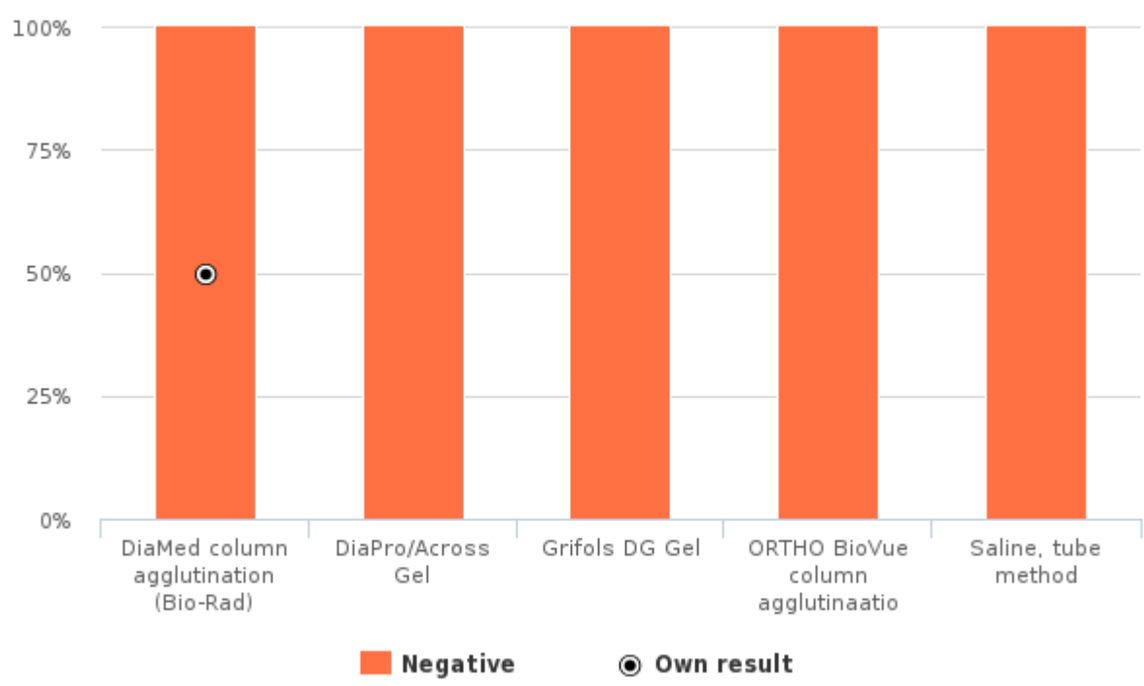
ANTIBODY SCREENING

Antibody screening	Method	Reaction strength	n	Reaction strength Score	Interpretation: Negative	Interpretation: Negative Score
	DiaMed column agglutination (Bio-Rad)	◉ Negative	83	2	◉ 82	2
	Total:		83			









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Compatibility 2 / 3	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	◉ Negative	◉ 80	1	10	5	81
	Total:						81

Compatibility 2 / 4	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	◉ Negative	◉ 80	1	10	5	81
	Total:						81

Compatibility 2 / 5	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	◉ Negative	◉ 80	1	10	5	81
	Total:						81

Compatibility 2 / 6	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	◉ Negative	◉ 80	1	10	5	81
	Total:						81

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Report Info

PARTICIPANTS

Altogether 142 laboratories from 12 countries participated in this EQA round.

REPORT INFO

The principles of the scoring will be as follows:
Antibody screening
1. Reaction strengths

Correct agglutination reaction and grade: 2 points/reaction
Correct reaction, but large difference in reaction grade from the expected: 1 point (eg. + for an expected +++)
Wrong reaction: 0 points / reaction

2. Interpretation

Correct interpretation 2 points / specimen
Wrong interpretation 0 points / specimen, maximum points / specimen = 4

Compatibility testing

Correct compatibility 10 points / specimen
Correct incompatibility 10 points / specimen
False compatibility 0 points / specimen
False incompatibility 5 points / specimen

There are 8 compatibility tests in the survey-> maximum points / survey = 80

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LABQUALITY Antibody screening and compatibility testing, February, 1-2023

GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Antibody screening and compatibility testing, February, 1-2023	142	140	98.6 %

Summary

Summary	AVR success rate
Sample S001	99.7 %
Sample S002	99.7 %
Average:	99.7 %

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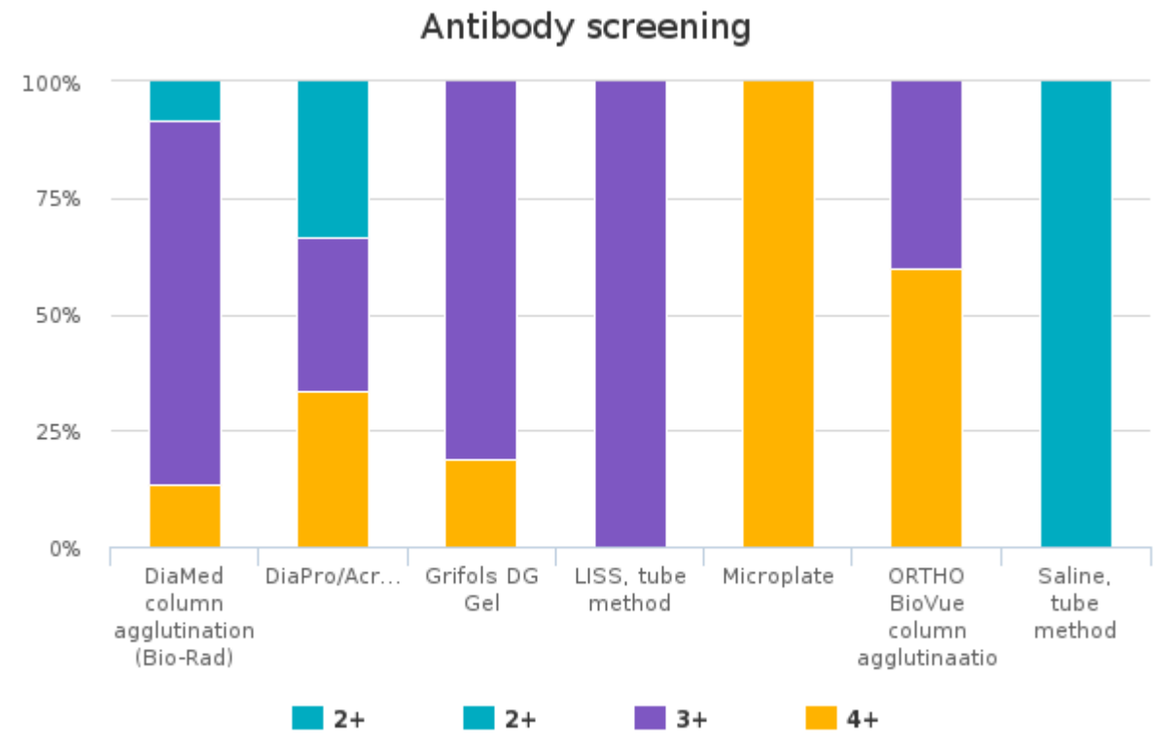
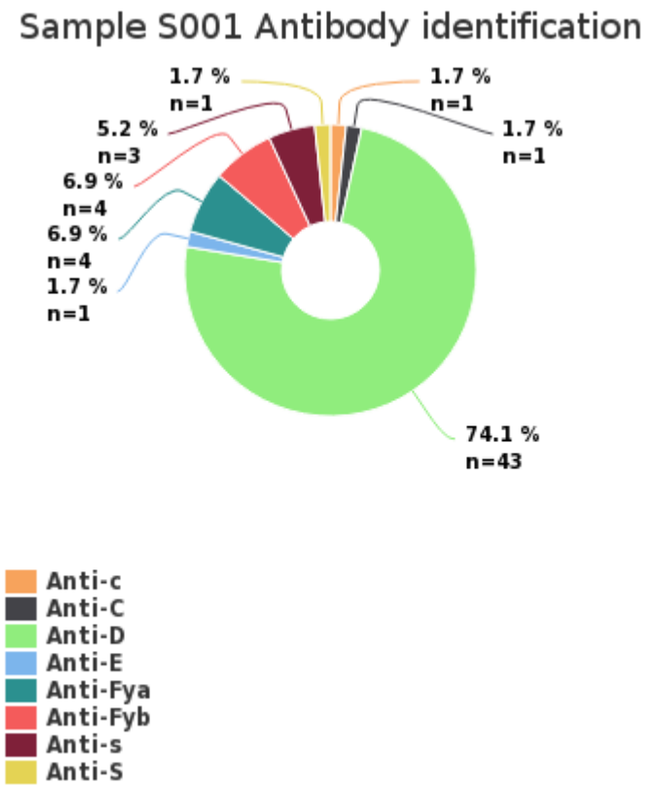
Sample S001



ANTIBODY SCREENING

Antibody screening	Method	Reaction strength	n	Reaction strength Score	Interpretation: Positive	Interpretation: Positive Score
	DiaMed column agglutination (Bio-Rad)	2+	7	1	7	2
		3+	65	2	65	2
		4+	11	2	11	2
	DiaPro/Across Gel	2+	1	2	1	2
		3+	1	2	1	2
		4+	1	2	1	2
	Grifols DG Gel	3+	13	2	13	2
		4+	3	2	3	2
	LISS, tube method	3+	1	2	1	2
	Microplate	4+	3	2	3	2
	ORTHO BioVue column agglutinaatio	3+	14	2	14	2
		4+	21	2	21	2
	Saline, tube method	2+	1	2	1	2
	Total:		142			



Antibody identification	Result	Result count
	Anti-c	1
	Anti-C	1
	Anti-D	43
	Anti-E	1
	Anti-Fya	4

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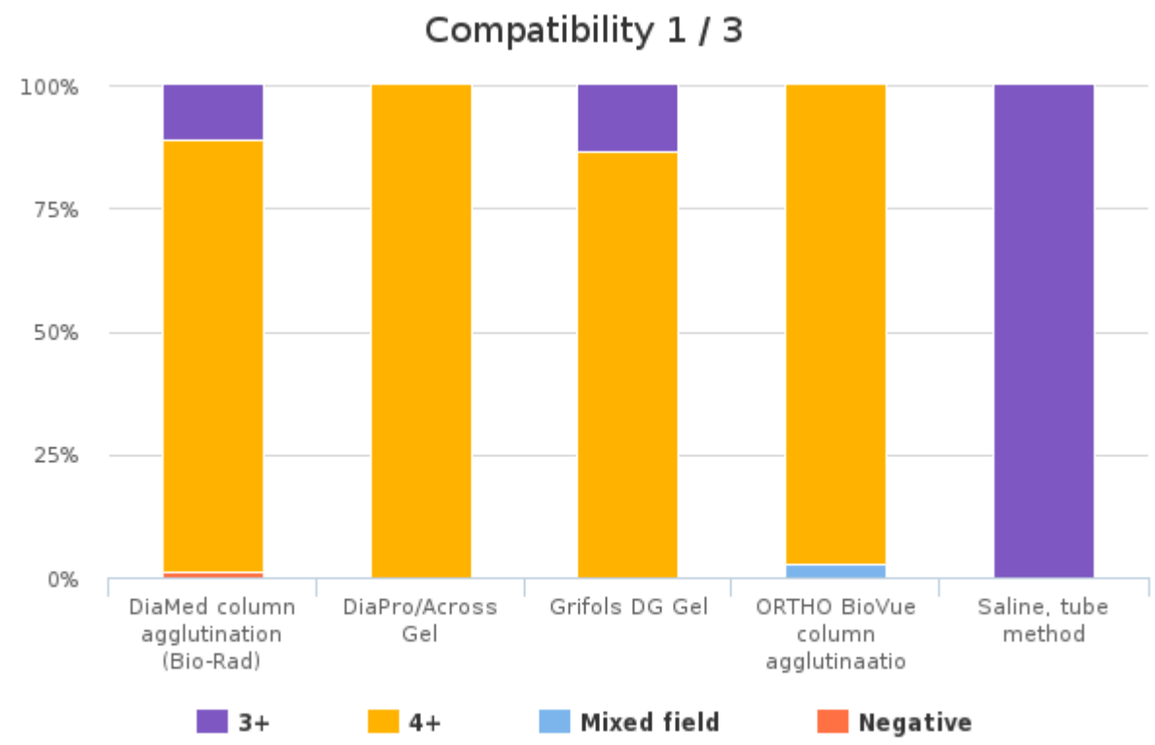
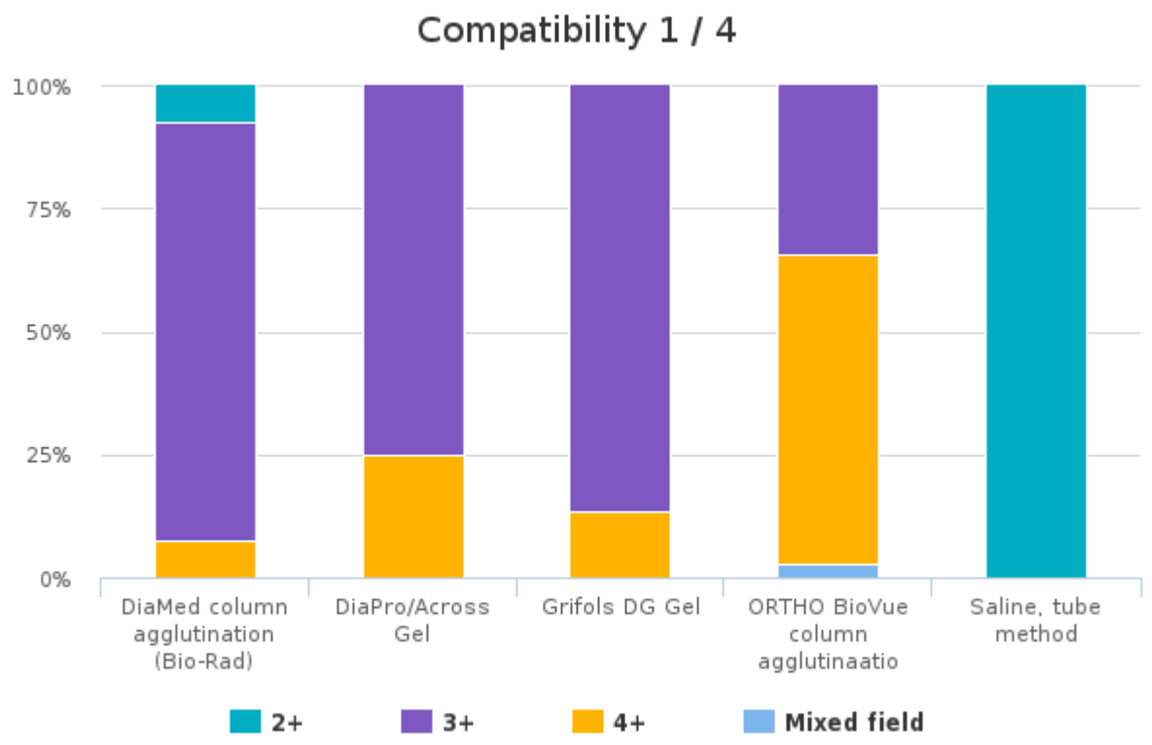
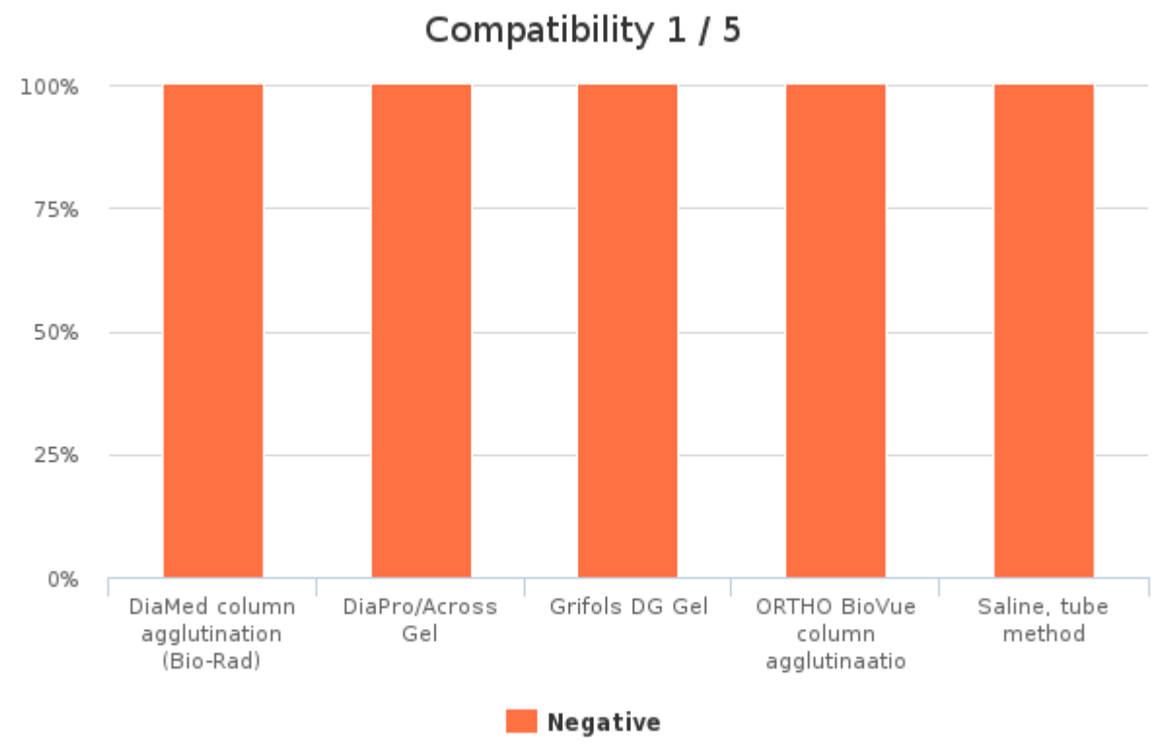
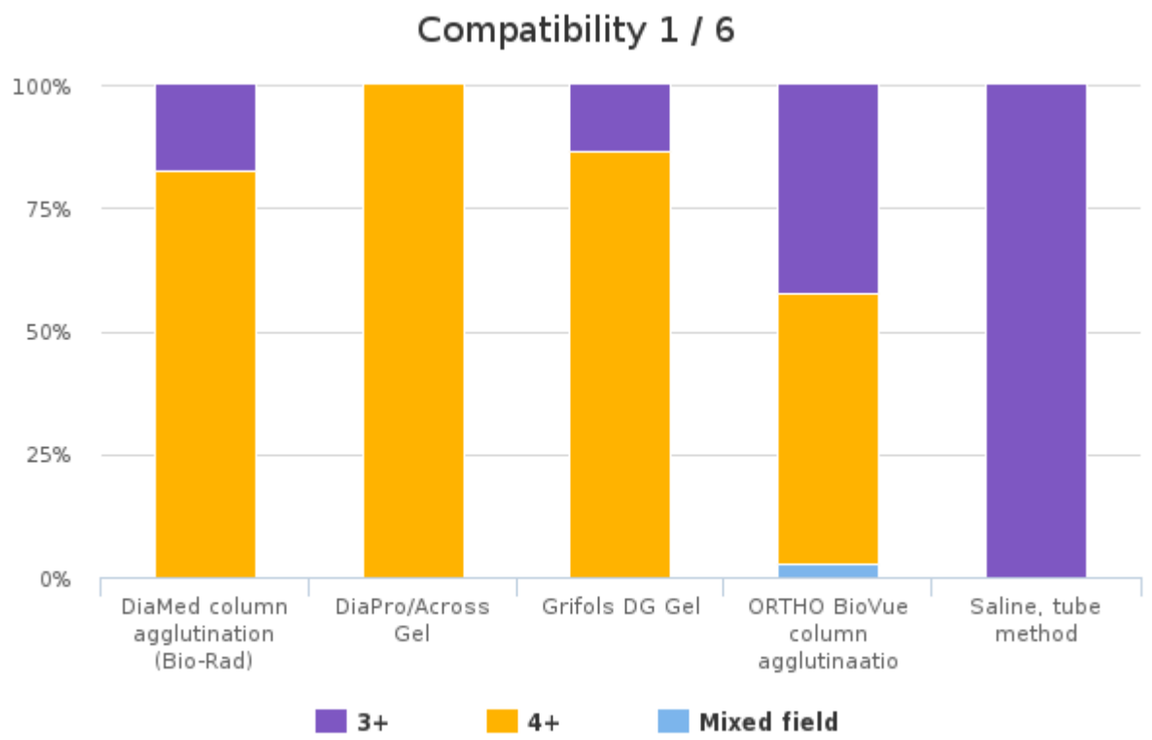
	Anti-Fyb	4
	Anti-s	3
	Anti-S	1
	Total:	58









Compatibility 1 / 3	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	3+		9		10	9
		4+		70		10	70
		Negative	1		0		1
	DiaPro/Across Gel	4+		4		10	4
	Grifols DG Gel	3+		2		10	2
		4+		13		10	13
	ORTHO BioVue column agglutinaatio	4+		37		10	37
		Mixed field		1		10	1
	Saline, tube method	3+		1		10	1
	Total:						138

Compatibility 1 / 4	Method	Reaction strength	Interpretation: Incompatible	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	2+	6	10	6
		3+	68	10	68
		4+	6	10	6
	DiaPro/Across Gel	3+	3	10	3
		4+	1	10	1
	Grifols DG Gel	3+	13	10	13
		4+	2	10	2
	ORTHO BioVue column agglutinaatio	3+	13	10	13

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		4+	24	10	24
		Mixed field	1	10	1
	Saline, tube method	2+	1	10	1
	Total:				138

Compatibility 1 / 5	Method	Reaction strength	Interpretation: Compatible	Interpretation: Compatible Score	n
	DiaMed column agglutination (Bio-Rad)	Negative	80	10	80
	DiaPro/Across Gel	Negative	4	10	4
	Grifols DG Gel	Negative	15	10	15
	ORTHO BioVue column agglutinaatio	Negative	38	10	38
	Saline, tube method	Negative	1	10	1
	Total:				138

Compatibility 1 / 6	Method	Reaction strength	Interpretation: Incompatible	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	3+	14	10	14
		4+	66	10	66
	DiaPro/Across Gel	4+	4	10	4
	Grifols DG Gel	3+	2	10	2
		4+	13	10	13
	ORTHO BioVue column agglutinaatio	3+	16	10	16
		4+	21	10	21
		Mixed field	1	10	1
	Saline, tube method	3+	1	10	1
	Total:				138

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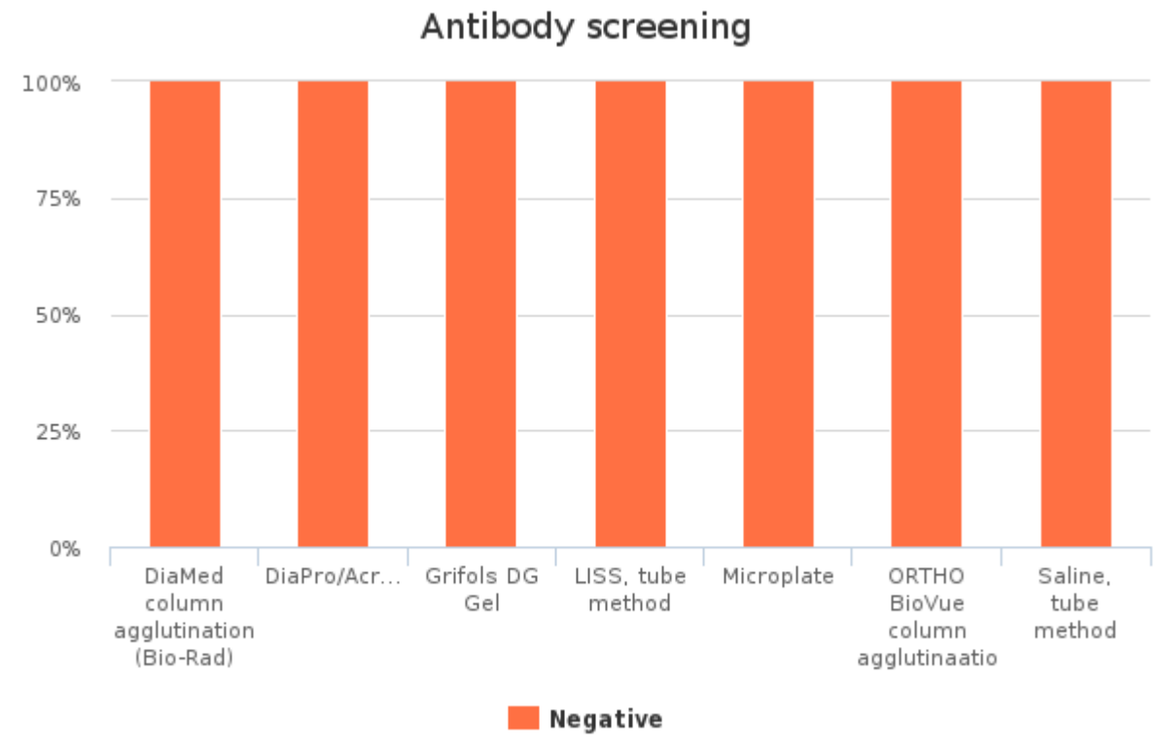
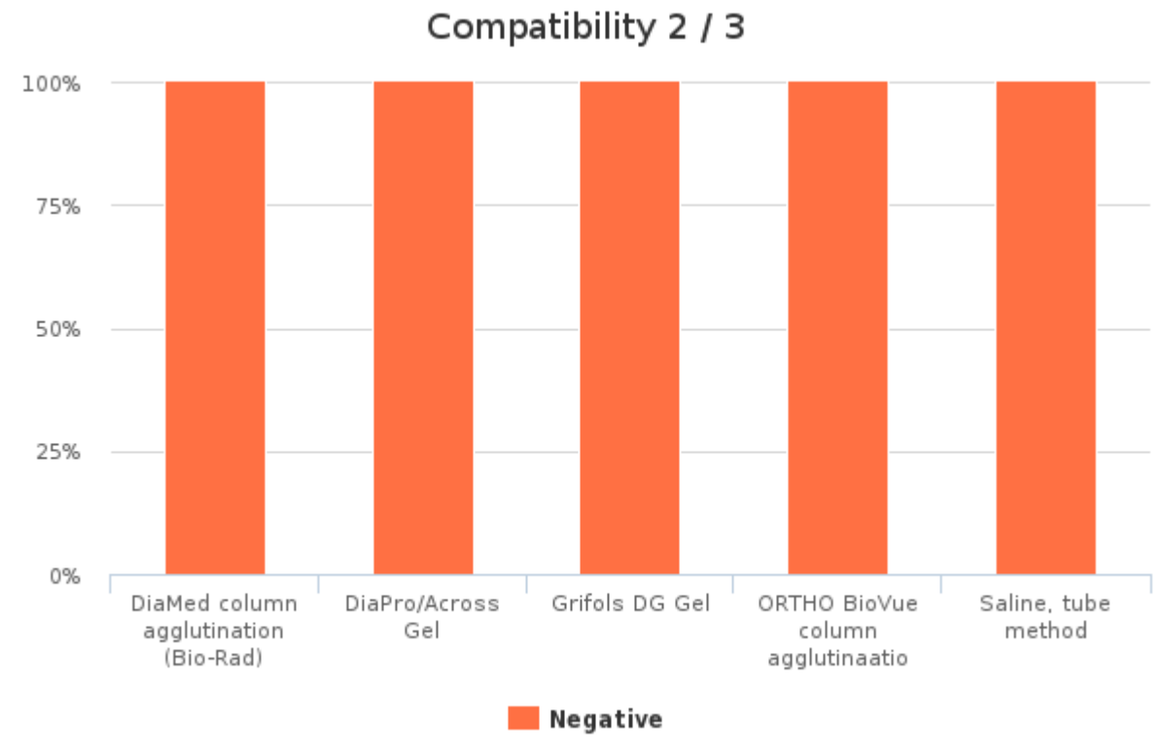
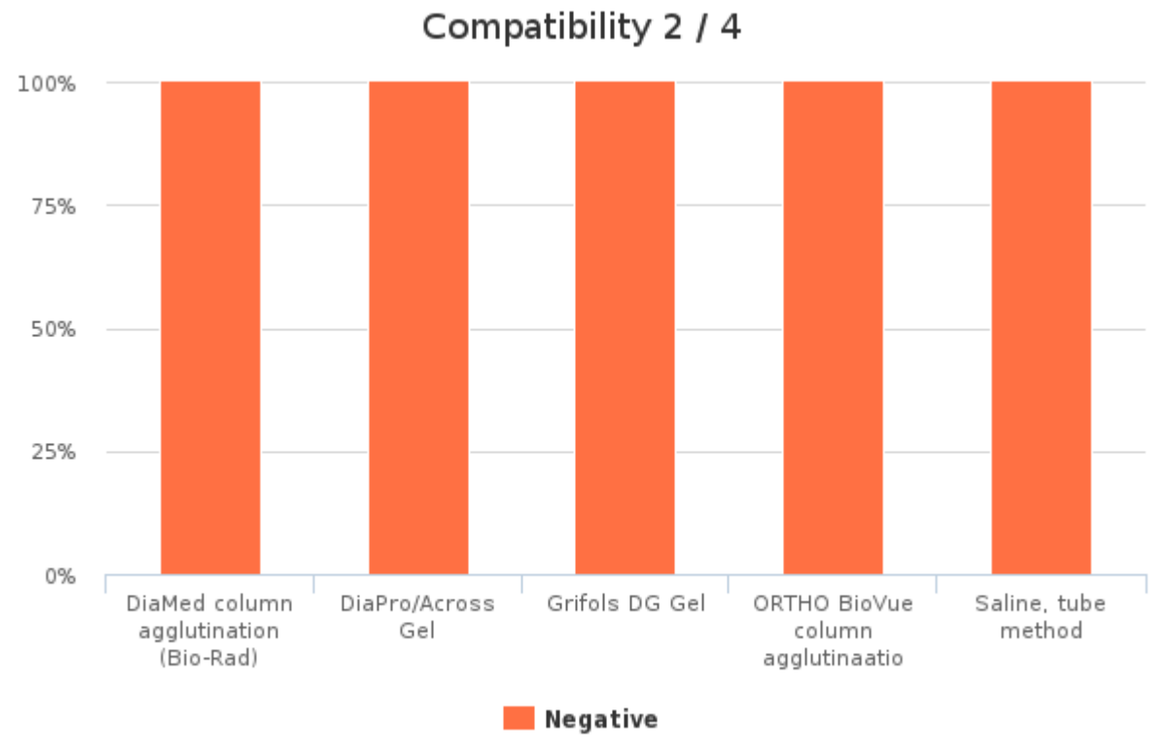
Sample S002

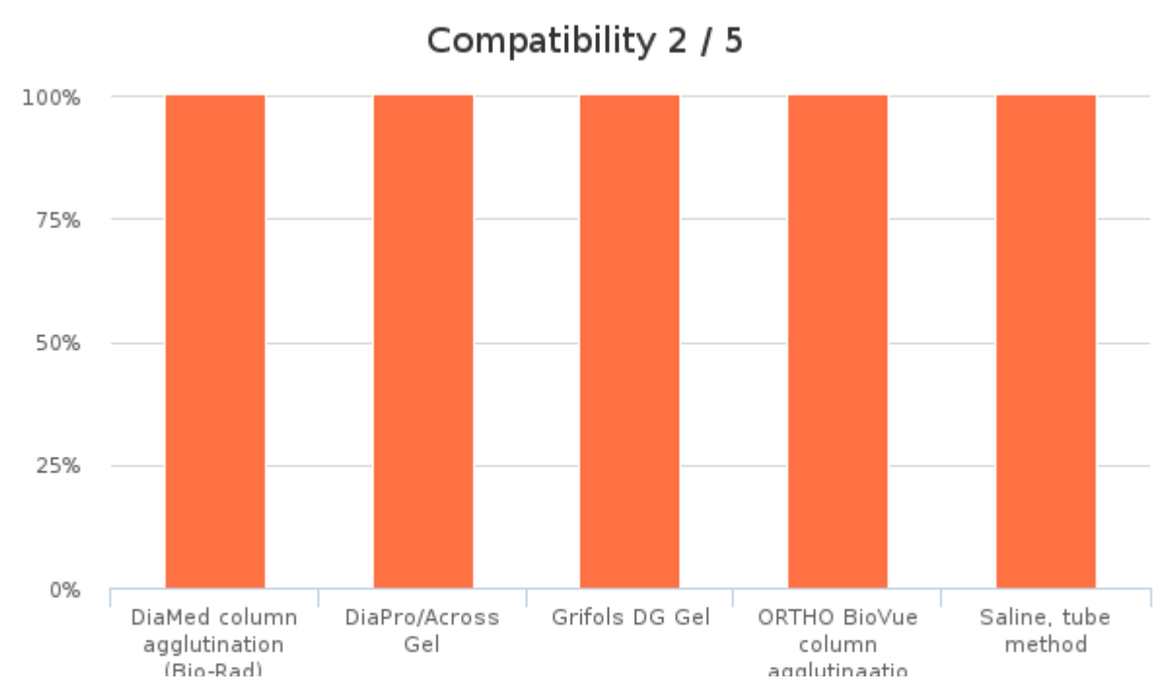


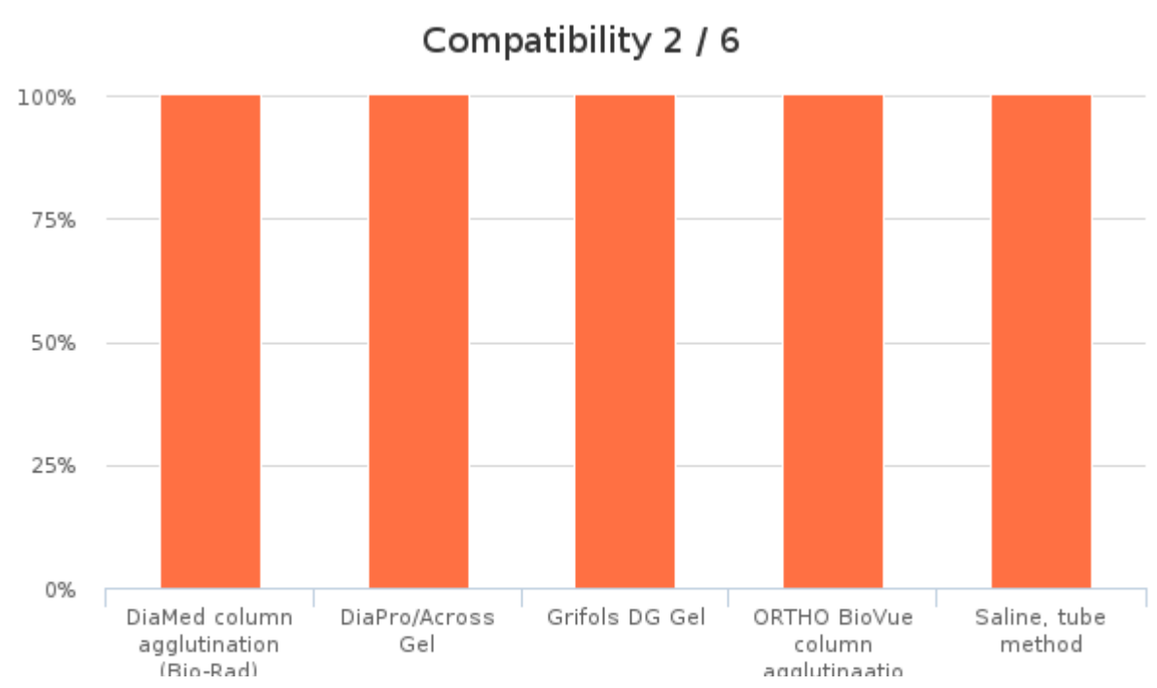
ANTIBODY SCREENING

Antibody screening	Method	Reaction strength	n	Reaction strength Score	Interpretation: Negative	Interpretation: Negative Score
	DiaMed column agglutination (Bio-Rad)	Negative	83	2	82	2
	DiaPro/Across Gel	Negative	2	2	2	2
	Grifols DG Gel	Negative	16	2	16	2
	LISS, tube method	Negative	1	2	1	2
	Microplate	Negative	3	2	3	2
	ORTHO BioVue column agglutinaatio	Negative	35	2	35	2
	Saline, tube method	Negative	1	2	1	2
	Total:		141			









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Compatibility 2 / 3	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	Negative	80	1	10	5	81
	DiaPro/Across Gel	Negative	3		10		3
	Grifols DG Gel	Negative	15		10		15
	ORTHO BioVue column agglutinaatio	Negative	37		10		37
	Saline, tube method	Negative	1		10		1
	Total:						137

Compatibility 2 / 4	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	Negative	80	1	10	5	81
	DiaPro/Across Gel	Negative	3		10		3
	Grifols DG Gel	Negative	15		10		15
	ORTHO BioVue column agglutinaatio	Negative	37		10		37
	Saline, tube method	Negative	1		10		1
	Total:						137

Compatibility 2 / 5	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	Negative	80	1	10	5	81
	DiaPro/Across Gel	Negative	3		10		3
	Grifols DG Gel	Negative	15		10		15
	ORTHO BioVue column agglutinaatio	Negative	37		10		37
	Saline, tube method	Negative	1		10		1
	Total:						137

Compatibility 2 / 6	Method	Reaction strength	Interpretation: Compatible	Interpretation: Incompatible	Interpretation: Compatible Score	Interpretation: Incompatible Score	n
	DiaMed column agglutination (Bio-Rad)	Negative	80	1	10	5	81
	DiaPro/Across Gel	Negative	3		10		3
	Grifols DG Gel	Negative	15		10		15
	ORTHO BioVue column agglutinaatio	Negative	37		10		37
	Saline, tube method	Negative	1		10		1
	Total:						137

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Report Info

PARTICIPANTS

Altogether 142 laboratories from 12 countries participated in this EQA round.

REPORT INFO

The principles of the scoring will be as follows:
Antibody screening
1. Reaction strengths

Correct agglutination reaction and grade: 2 points/reaction
Correct reaction, but large difference in reaction grade from the expected: 1 point (eg. + for an expected +++)
Wrong reaction: 0 points / reaction

2. Interpretation

Correct interpretation 2 points / specimen
Wrong interpretation 0 points / specimen, maximum points / specimen = 4

Compatibility testing

Correct compatibility 10 points / specimen
Correct incompatibility 10 points / specimen
False compatibility 0 points / specimen
False incompatibility 5 points / specimen

There are 8 compatibility tests in the survey-> maximum points / survey = 80

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LABQUALITY

External Quality Assessment Scheme

Compatibility test and antibody screening Round 1, 2023

Specimens
Sample S001 and sample S002 were human-based whole blood samples. Samples S003-S006 were red-cell suspensions.

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 any temperature control packaging.

Sample S001 (LQ714323011): Blood from A RhD negative patient, anti-D and anti-B in plasma.

Sample S002 (LQ714323012): Blood from AB RhD positive patient.

Sample S003 (LQ714223013): Cells from a donor with blood group B RhD positive.

Sample S004 (LQ714223014): Cells from a donor with blood group O RhD positive.

Sample S005 (LQ714223015): Cells from a donor with blood group A RhD negative.

Sample S006 (LQ714223016): Cells from a donor with blood group AB RhD negative.

Report info
Please see the description of the scoring 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
Antibody screening
Sample S001: The expected result was a positive screening due to anti-D.

Sample S002: The expected result was a negative screening.

Compatibility test
Sample S001: The expected results were a negative compatibility test 1/5 and positive compatibility tests 1/3 (anti-B and anti-D and a B RhD pos donor), 1/4 (anti-D and a RhD pos donor) and 1/6 (anti-B and AB donor). Only one false compatibility 1/3 was found (Diamed)

Sample S002: The expected results were negative compatibility tests 2/3, 2/4, 2/5 and 2/6.

Comment
The results were excellent.

This scheme is designed for antibody screening and compatibility testing. However, the participants may also do the antibody identification. For patient 1 an almost 25 % of the participant reported other antibodies than the correct (anti-D), this is alarming if the participants perform antibody identification routinely.

2023-04-17

FINAL REPORT

Product no. 4460

Samples sent	2023-02-27
Round closed	2023-03-20
Final report	2023-04-17

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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MD, Head of Department
Tomi Koski
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Finland

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

Quality Management
LQ
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Exceptions in scoring
No exceptions.

End of report

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