LABQUALITY

External Quality Assessment Scheme

Direct antiglobulin test
Round 1, 2023

Specimens
Please find enclosed two 5% red cell suspensions S001 and S002, 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
IgG + C3d
IgG
C3d
Interpretation

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 are stable for 4 weeks from the date of this letter if stored at +2…+8 °C. Cells should be centrifuged to the bottom of the tube and the laboratory should prepare a suspension appropriate to the used method. Analyse as patient samples.

Result reporting
Please enter the results and methods via LabScala (www.labscala.com). Method information is necessary for the result handling. Please remember to fill in the interpretation of the result. Some methods have given a positive reaction also in the control well for unknown reason. The options “negative, control positive” and “positive, also control positive” have been added to the interpretation section of the e-form. Please answer only the results of the examinations that are in use in your laboratory.

All reported examinations will be scored.

S001
LQ714123011

S002
LQ714123012

2023-02-27

INSTRUCTIONS

Product no. 4440
LQ714123011-012/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.**

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

Quality Management
ISO 9001:2015

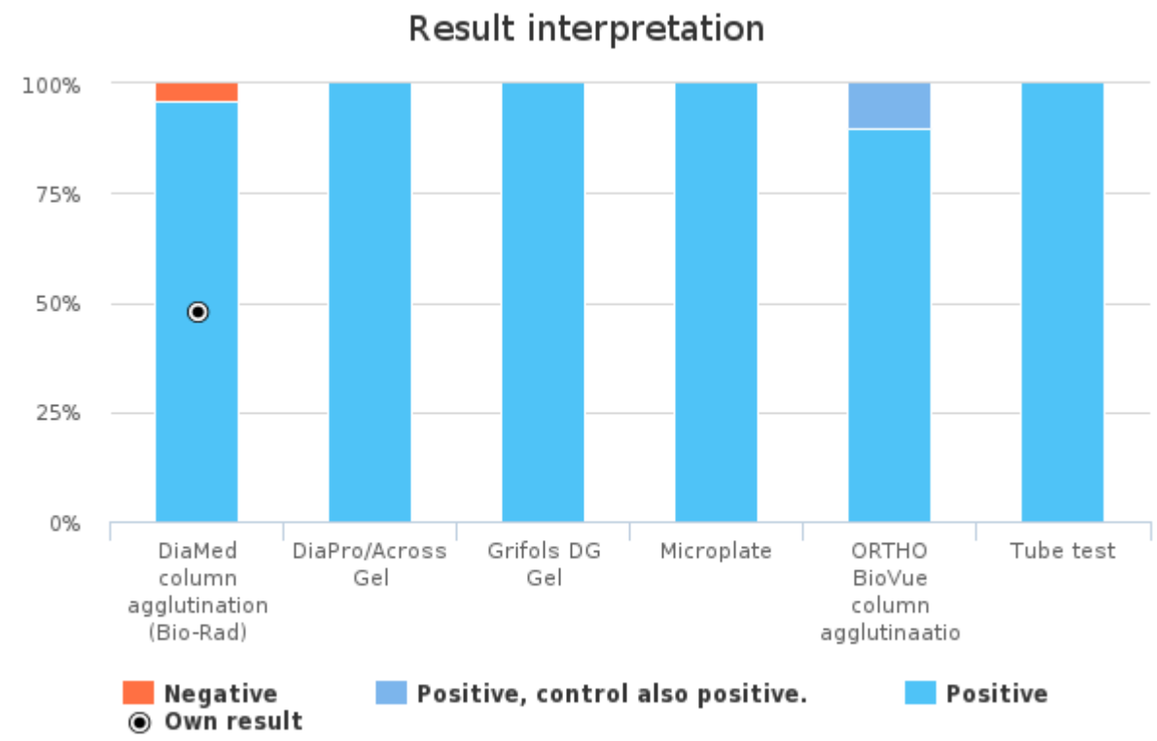
Client report

	No of participants	No of responded participants	Response percentage
Antiglobulin test, direct, February, 1-2023	154	154	100 %

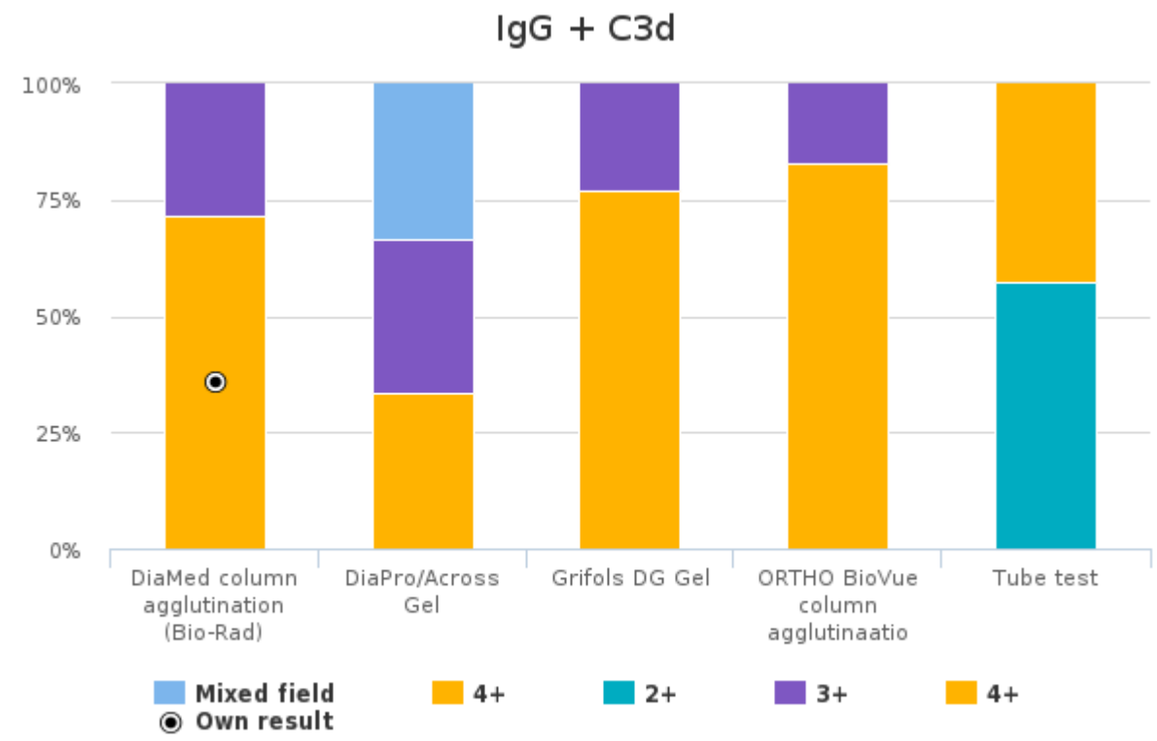
Summary

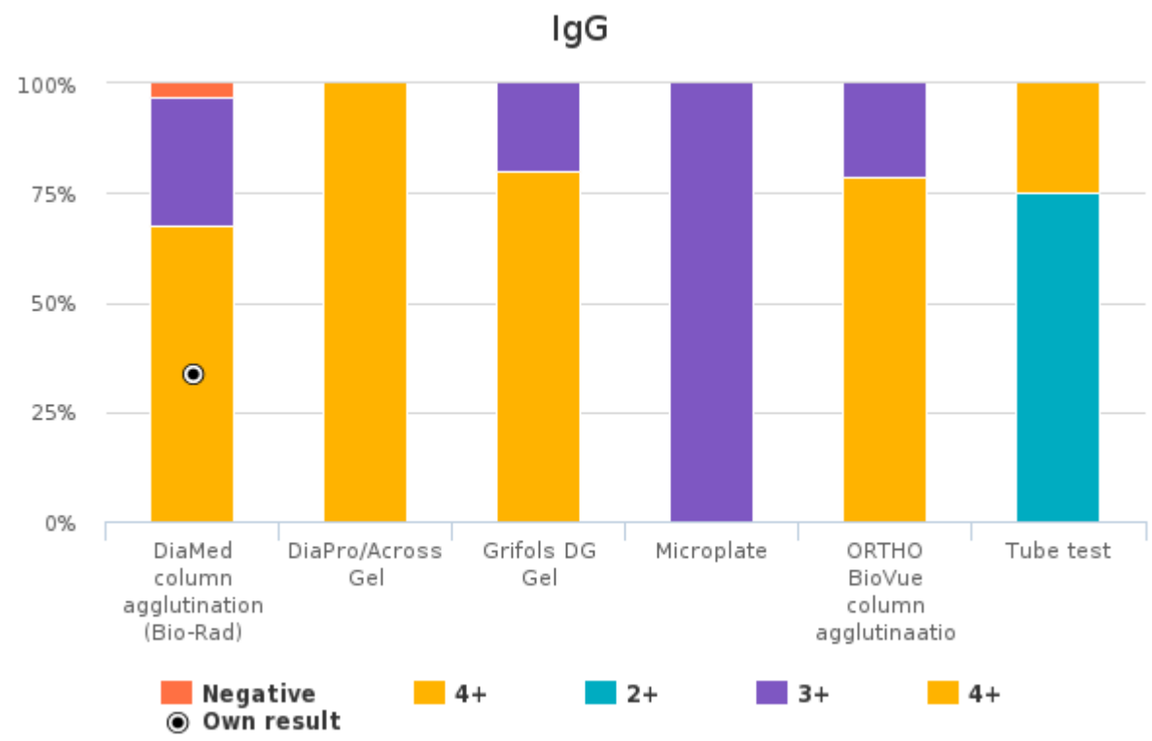
Summary	Own score	Max score	Own success rate
Sample S001	5	5	100 %
Sample S002	6	6	100 %
Average:			100 %

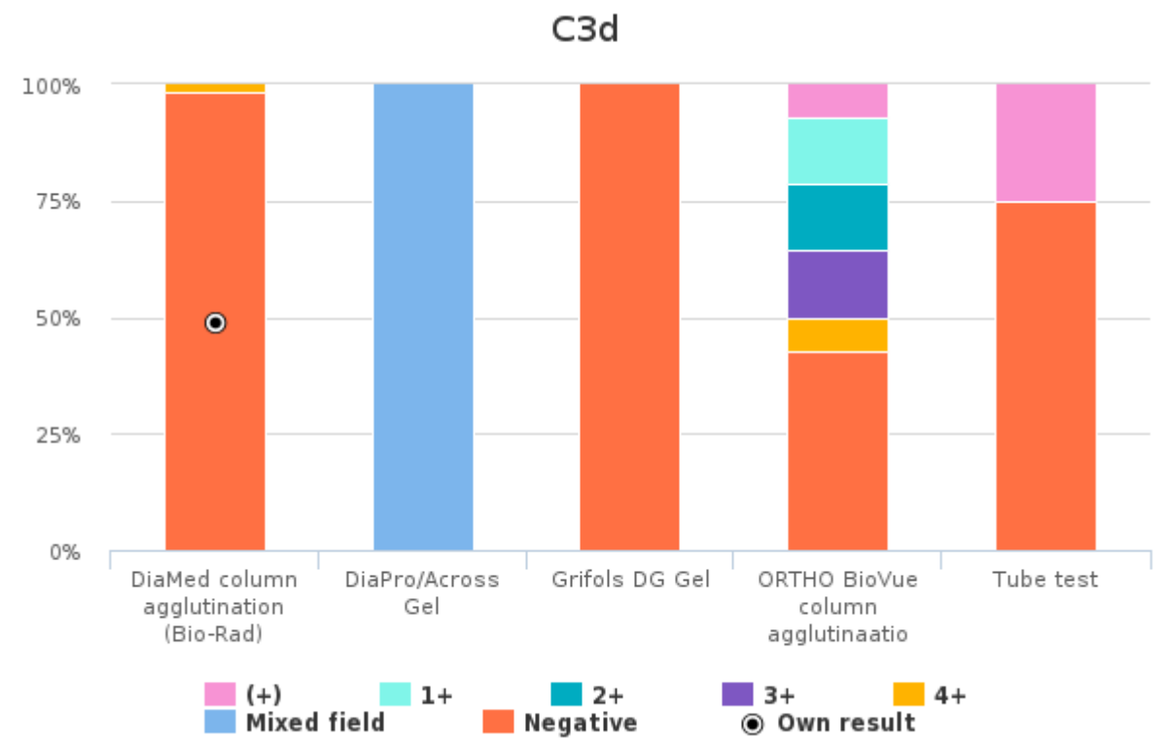
Sample S001 | DAT pos (IgG)



Result interpretation	Method	Interpretation	Interpretation count	%	Interpretation Score
	DiaMed column agglutination (Bio-Rad)	Negative	4	4 %	0
		◉ Positive	100	96 %	3
	Total:		104	100 %	







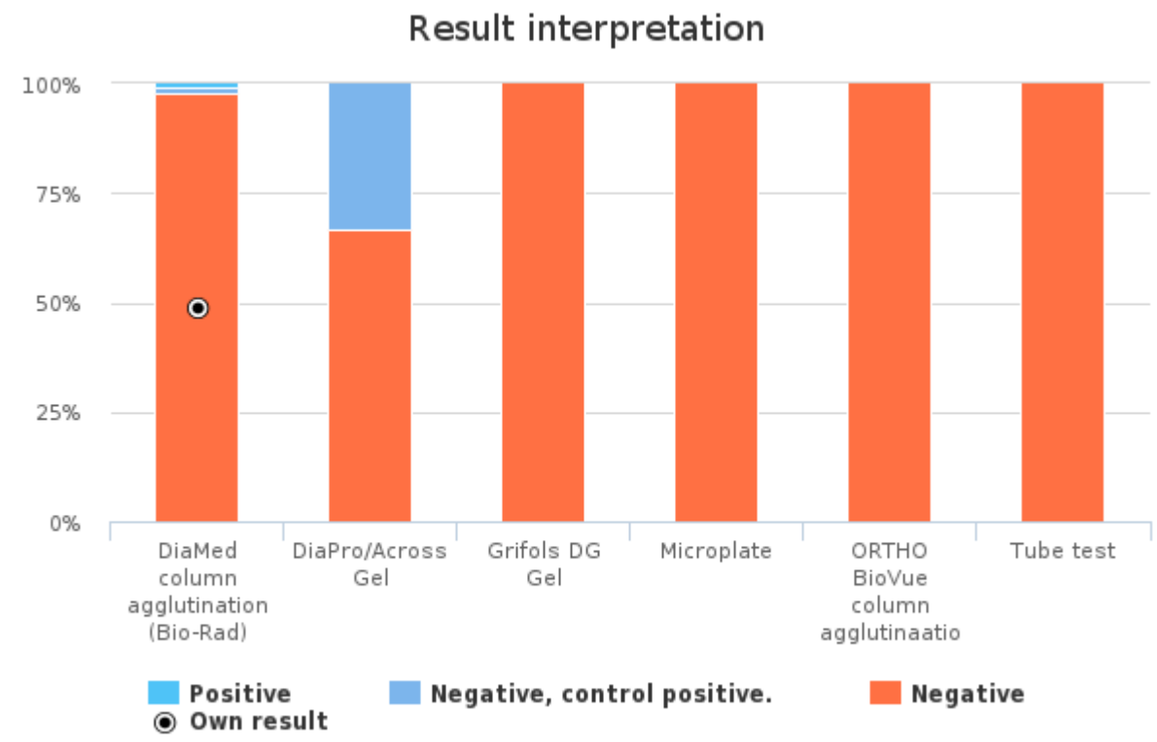
IgG + C3d	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	3+	25	28 %	1
		◉ 4+	63	72 %	1

	Total:		88	100 %	

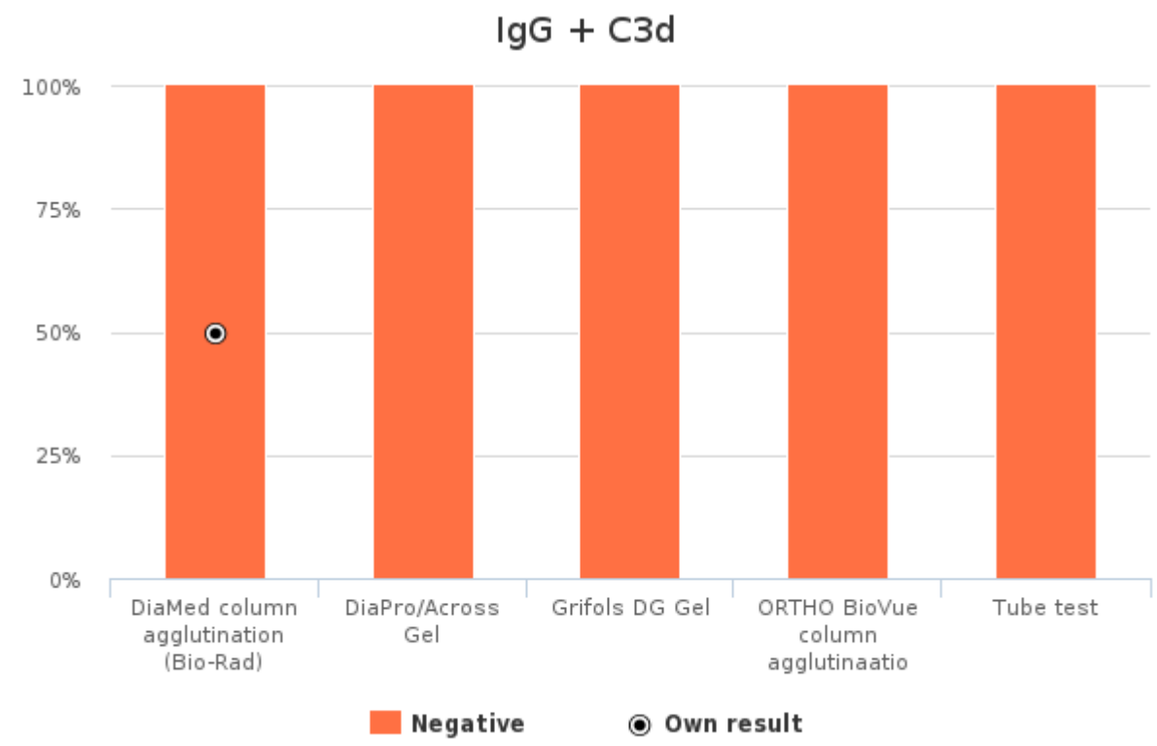
IgG	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	3+	19	29 %	1
		◉ 4+	44	68 %	1
		Negative	2	3 %	0
	Total:		65	100 %	

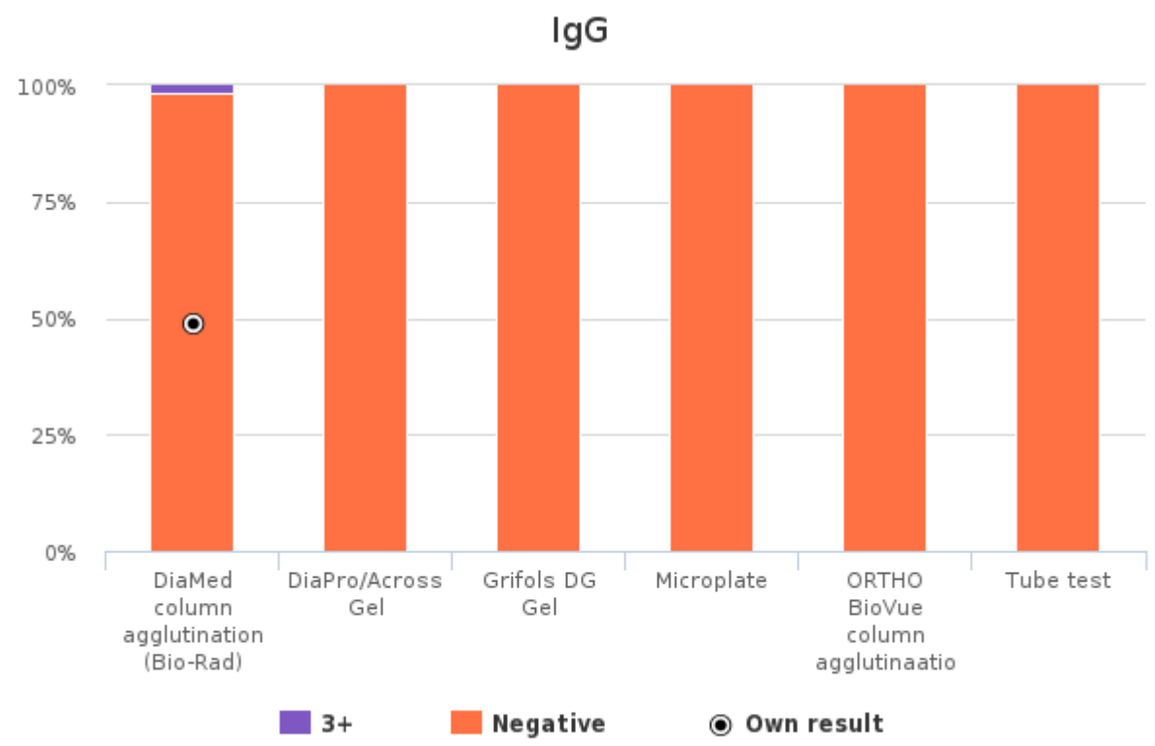
C3d	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	4+	1	2 %	-
		◉ Negative	62	98 %	-
	Total:		63	100 %	

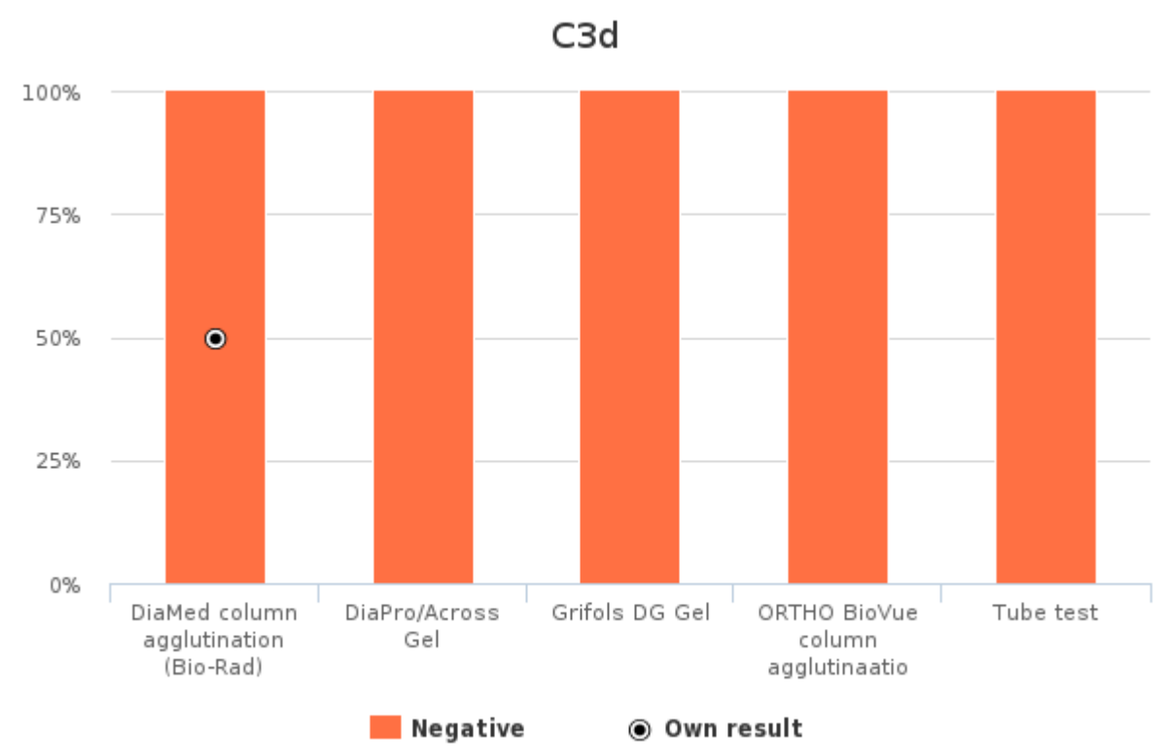
Sample S002 | DAT neg



Result interpretation	Method	Interpretation	Interpretation count	%	Interpretation Score
	DiaMed column agglutination (Bio-Rad)	◉ Negative	97	98 %	3
		Negative, control positive.	1	1 %	3
		Positive	1	1 %	0
	Total:		99	100 %	







IgG + C3d	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	◉ Negative	87	100 %	1

	Total:		87	100 %	

IgG	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	3+	1	2 %	0
		◉ Negative	53	98 %	1
	Total:		54	100 %	

C3d	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	◉ Negative	53	100 %	1
	Total:		53	100 %	

Report Info

PARTICIPANTS

Altogether 154 laboratories from 14 countries participated in this EQA round.

REPORT INFO

The principles of the scoring will be as follows:
Direct antiglobulin test
1. Reaction strengths

Correct agglutination reaction and grade:1 point /reaction, altogether 3 points /specimen
Correct reaction, but large difference in reaction grade from the expected: 0.5 point (eg. + for an expected +++)
Wrong reaction: 0 points /reaction

2. Interpretation

Correct interpretation 3 points / specimen
Wrong interpretation 0 points / specimen, maximum points / specimen = 6

Antiglobulin test, direct, February, 1-2023

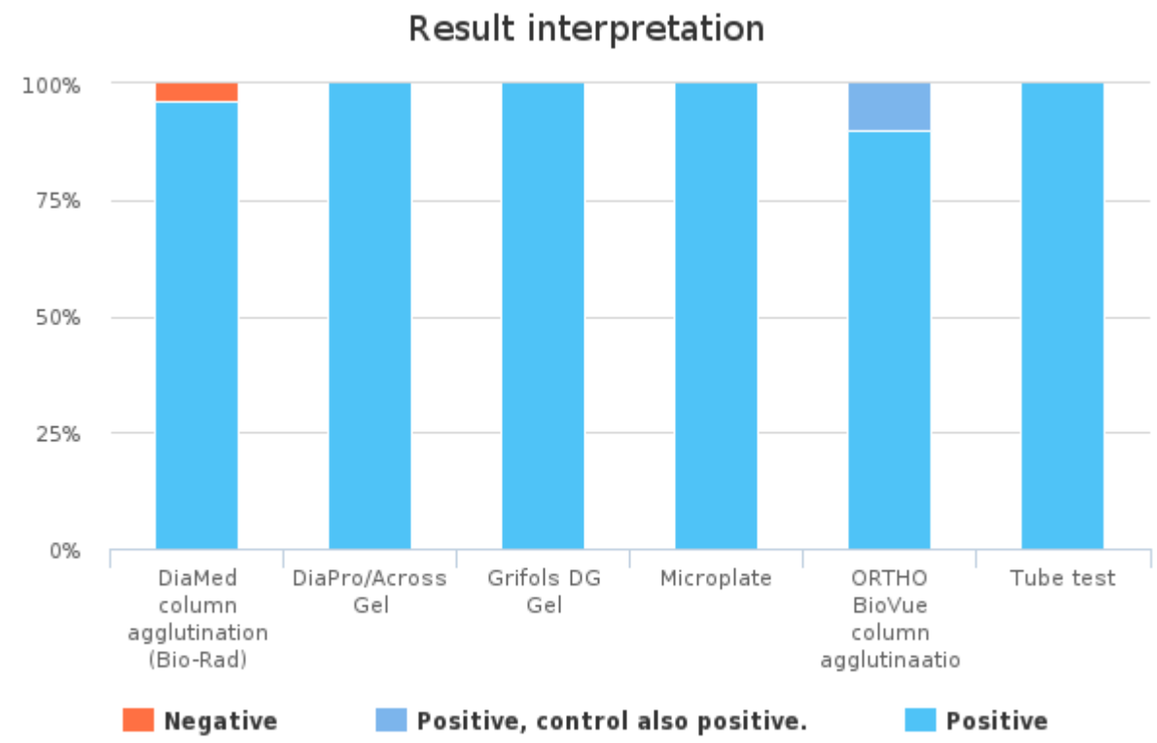
GLOBAL REPORT

	No of participants	No of responded participants	Response percentage
Antiglobulin test, direct, February, 1-2023	154	154	100 %

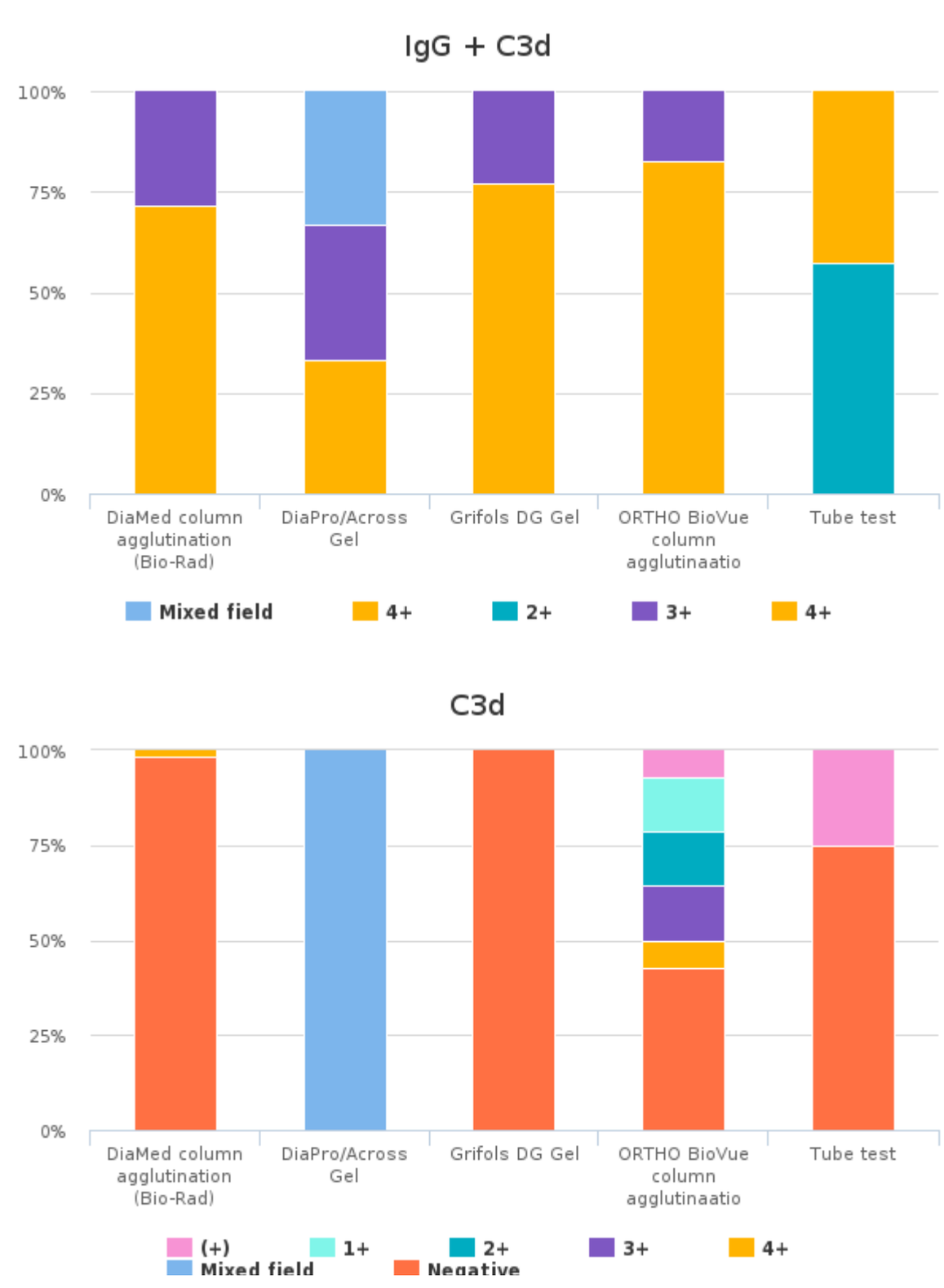
Summary

Summary	AVR success rate
Sample S001	97.6 %
Sample S002	99.5 %
Average:	98.5 %

Sample S001 | DAT pos (IgG)



Result interpretation	Method	Interpretation	Interpretation count	%	Interpretation Score
	DiaMed column agglutination (Bio-Rad)	Negative	4	4 %	0
		Positive	100	96 %	3
	DiaPro/Across Gel	Positive	3	100 %	3
	Grifols DG Gel	Positive	13	100 %	3
	Microplate	Positive	1	100 %	3
	ORTHO BioVue column agglutinaatio	Positive	27	90 %	3
		Positive, control also positive.	3	10 %	3
	Tube test	Positive	7	100 %	3
	Total:		158	100 %	



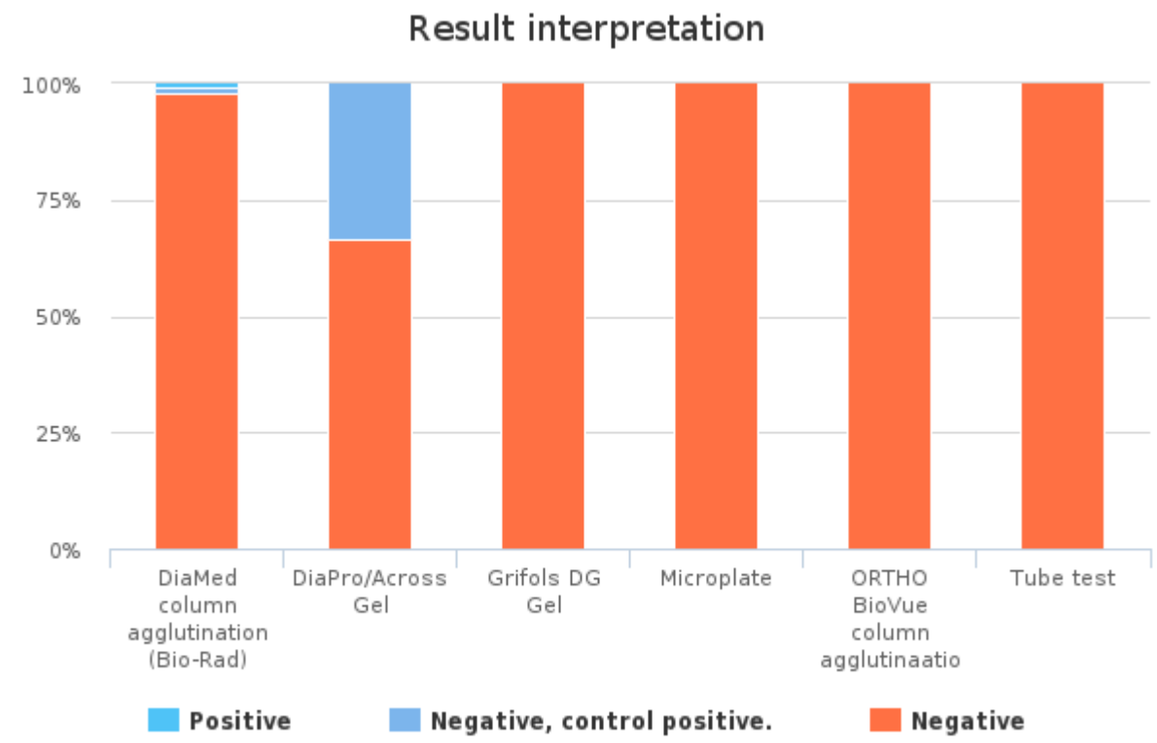
Antiglobulin test, direct, February, 1-2023

IgG + C3d	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	3+	25	28 %	1
		4+	63	72 %	1
	DiaPro/Across Gel	3+	1	33 %	1
		4+	1	33 %	1
		Mixed field	1	33 %	0
	Grifols DG Gel	3+	3	23 %	1
		4+	10	77 %	1
	ORTHO BioVue column agglutinaatio	3+	5	17 %	1
		4+	24	83 %	1
	Tube test	2+	4	57 %	1
		4+	3	43 %	0.5
	Total:		140	100 %	

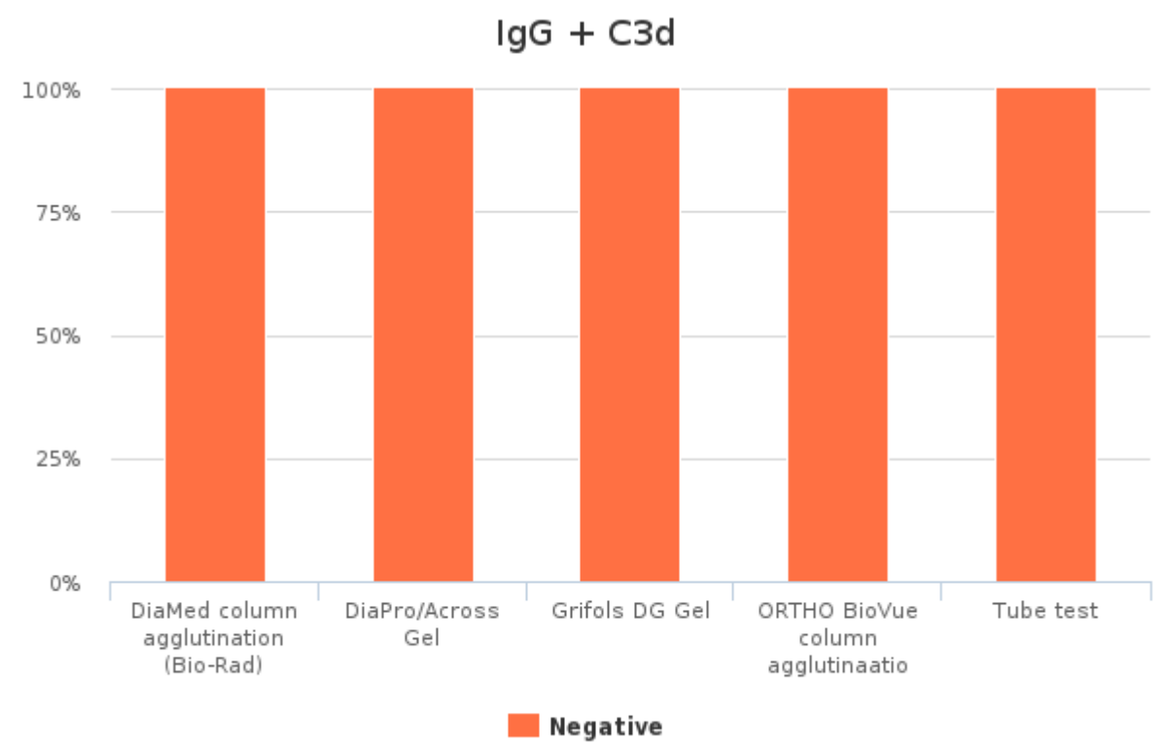
IgG	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	3+	19	29 %	1
		4+	44	68 %	1
		Negative	2	3 %	0
	DiaPro/Across Gel	4+	1	100 %	1
	Grifols DG Gel	3+	2	20 %	1
		4+	8	80 %	1
	Microplate	3+	1	100 %	1
	ORTHO BioVue column agglutinaatio	3+	3	21 %	1
		4+	11	79 %	1
	Tube test	2+	3	75 %	1
		4+	1	25 %	0.5
	Total:		95	100 %	

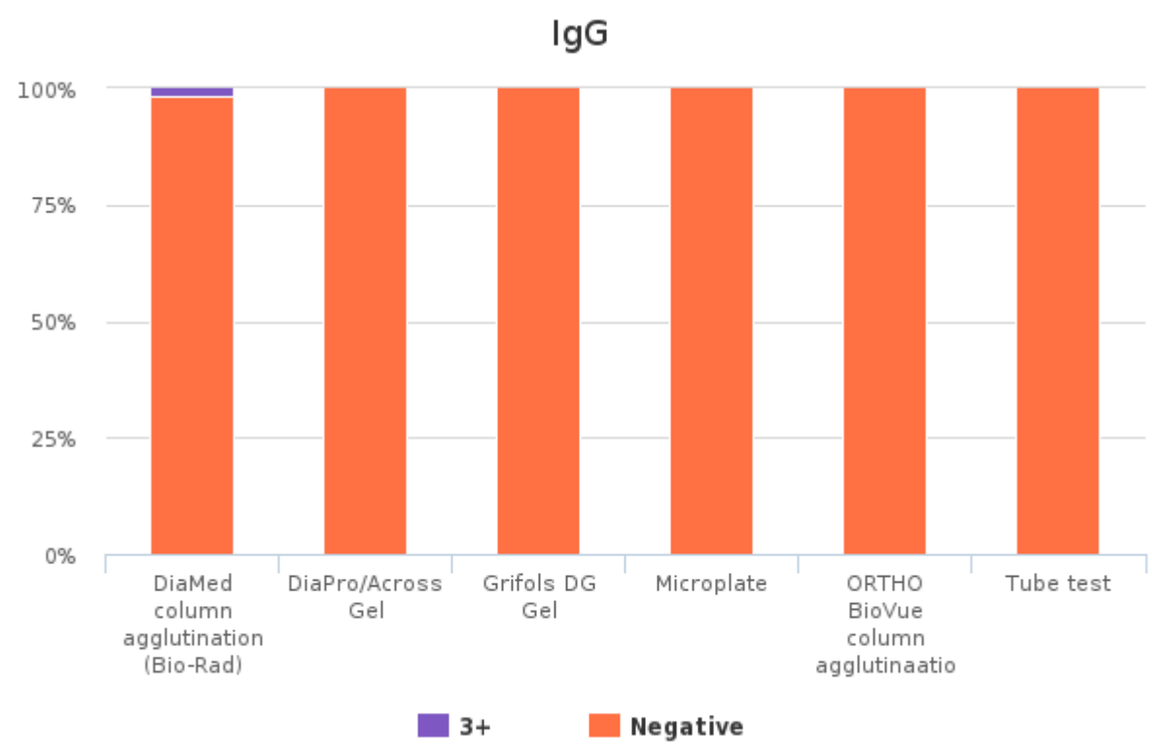
C3d	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	4+	1	2 %	-
		Negative	62	98 %	-
	DiaPro/Across Gel	Mixed field	1	100 %	-
	Grifols DG Gel	Negative	10	100 %	-
	ORTHO BioVue column agglutinaatio	(+)	1	7 %	-
		1+	2	14 %	-
		2+	2	14 %	-
		3+	2	14 %	-
		4+	1	7 %	-
		Negative	6	43 %	-
	Tube test	(+)	1	25 %	-
		Negative	3	75 %	-
	Total:		92	100 %	

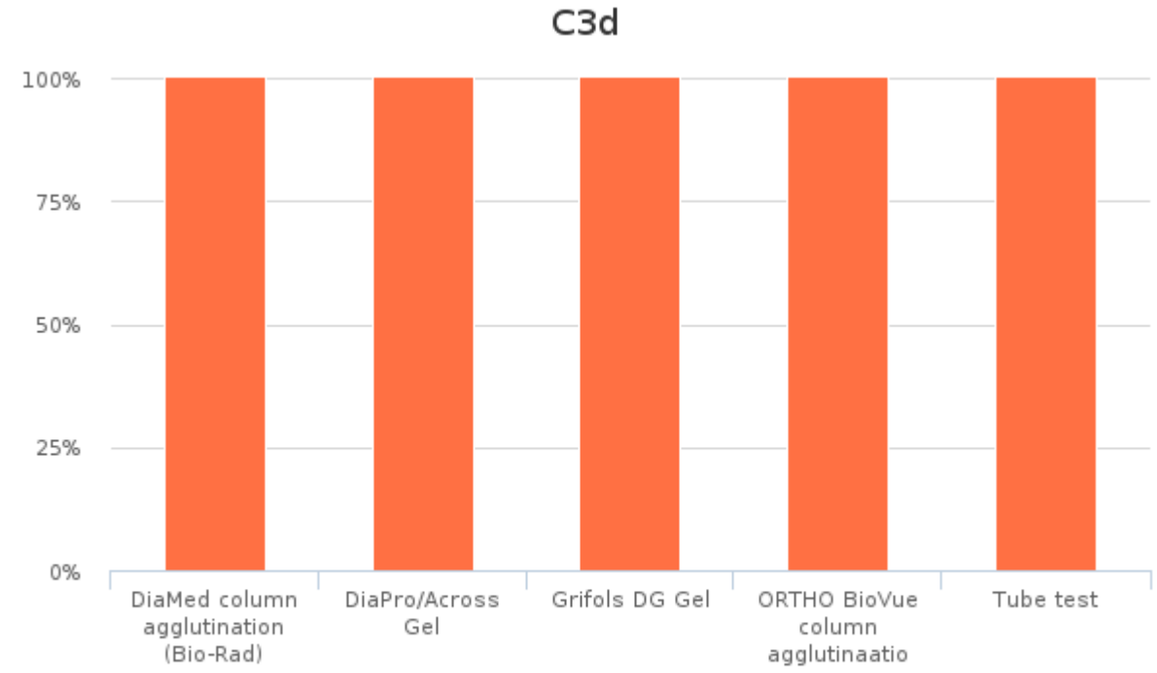
Sample S002 | DAT neg



Result interpretation	Method	Interpretation	Interpretation count	%	Interpretation Score
	DiaMed column agglutination (Bio-Rad)	Negative	97	98 %	3
		Negative, control positive.	1	1 %	3
		Positive	1	1 %	0
	DiaPro/Across Gel	Negative	2	67 %	3
		Negative, control positive.	1	33 %	3
	Grifols DG Gel	Negative	13	100 %	3
	Microplate	Negative	1	100 %	3
	ORTHO BioVue column agglutinaatio	Negative	38	100 %	3
	Tube test	Negative	4	100 %	3
	Total:		158	100 %	







Antiglobulin test, direct, February, 1-2023

IgG + C3d	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	Negative	87	100 %	1
	DiaPro/Across Gel	Negative	3	100 %	1
	Grifols DG Gel	Negative	13	100 %	1
	ORTHO BioVue column agglutinaatio	Negative	31	100 %	1
	Tube test	Negative	4	100 %	1
	Total:		138	100 %	

IgG	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	3+	1	2 %	0
		Negative	53	98 %	1
	DiaPro/Across Gel	Negative	1	100 %	1
	Grifols DG Gel	Negative	9	100 %	1
	Microplate	Negative	1	100 %	1
	ORTHO BioVue column agglutinaatio	Negative	20	100 %	1
	Tube test	Negative	2	100 %	1
	Total:		87	100 %	

C3d	Method	Reaction strength	n	%	Score
	DiaMed column agglutination (Bio-Rad)	Negative	53	100 %	1
	DiaPro/Across Gel	Negative	1	100 %	1
	Grifols DG Gel	Negative	9	100 %	1
	ORTHO BioVue column agglutinaatio	Negative	19	100 %	1
	Tube test	Negative	2	100 %	1
	Total:		84	100 %	

Report Info

PARTICIPANTS

Altogether 154 laboratories from 14 countries participated in this EQA round.

REPORT INFO

The principles of the scoring will be as follows:
Direct antiglobulin test
1. Reaction strengths

Correct agglutination reaction and grade:1 point /reaction, altogether 3 points /specimen
Correct reaction, but large difference in reaction grade from the expected: 0.5 point (eg. + for an expected +++)
Wrong reaction: 0 points /reaction

2. Interpretation

Correct interpretation 3 points / specimen
Wrong interpretation 0 points / specimen, maximum points / specimen = 6

LABQUALITY

External Quality Assessment Scheme

Direct antiglobulin test
Round 1, 2023

Specimens
Sample S001 (LQ714123011) and sample S002 (LQ714123012) were red cell suspensions.

Sample S001 included erythrocytes with a positive (IgG) direct antiglobulin test.

Sample S002 included erythrocytes with a negative direct antiglobulin test.

Based on the previous tests and the results of this round, the samples were homogeneous, stable and suitable for the external quality assessment scheme.

The materials were sent without temperature control packaging.

Report info
Please see the description of the scoring on the last page of the laboratory-specific reports and Numerical Summary 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
Sample S001: The expected results were a positive DAT with anti-IgG and a polyspecific reagent and a negative DAT with anti-C3d. There were few false negative reactions anti-IgG (Diamed). Most of the participants reported the correct negative reaction with anti-C3d. However, participants using BioVue reported varied reactions varying from negative to 4+ reactions. This part of the exercise is non-scoring.

Sample S002: The expected reactions were negative reactions with all the reagents. There was one false positive reaction with Diamed. Few participants using Diamed and DiaPro/Across Gel reported a false positive reaction in the control tube.

Exceptions in scoring
In sample S001 analyte anti-C3d was not scored.

End of Report

2023-04-17

FINAL REPORT

Product no. 4440

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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