Revisione dei risultati VEQ relativi al programma Sieroimmunologia SARS COV2 ciclo 2021

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Serological Assays for SARS-CoV-2 Infectious Disease: Benefits, Limitations and Perspectives

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KEYWORDS: coronavirus, COVID-19, SARS-CoV-2 antibodies, SARS-CoV-2 diagnostic tests, serological tests

IMAJ 2020; 22: 203–210

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which first appeared in Wuhan, China, in December 2019 and is now spreading worldwide.

SARS-CoV-2, formerly known by the provisional name 2019 novel Coronavirus (2019-nCoV), shares some characteristics with two other coronaviruses, which previously caused epidemic respiratory syndromes: severe acute respiratory

multiple copies of the nucleocapsid (N) protein. This protein is bound to the single-stranded RNA genome [9]. The lipid bilayer envelope, membrane proteins, and nucleocapsid protect the virus when it is outside the host cell [10]. Moreover, the first two-thirds of the viral genome encode non-structural proteins (NSPs), and in particular, the RNA polymerase represents the main part of the transcription/replication machinery, well conserved among different CoV species.

Specifically, SARS-CoV and SARS-CoV-2 account for the same receptor used to penetrate into human cells and start replication: angiotensin-converting enzyme 2 (ACE2), which is mostly expressed by type II pneumocytes, as well as by endothelial, myocardial, and gut mucosa cells [11]. It has been hypothesized that the high affinity of CoV-2 Spike (S) Receptor Binding Domain (RBD)

Where there is little or no access to molecular testing, **serology tests** provide a means to quickly triage suspected cases of **COVID**-19

Serological tests confirm the low incidence of COVID-19 in chronic rheumatic inflammatory diseases treated with biological DMARD.
Benucci M, Damiani A, Giannasi G, Li Gobbi F, Quartuccio L, Grossi V, Infantino M, Manfredi M. Ann Rheum Dis. 2020 Jul 6:annrheumdis-2020-218214.

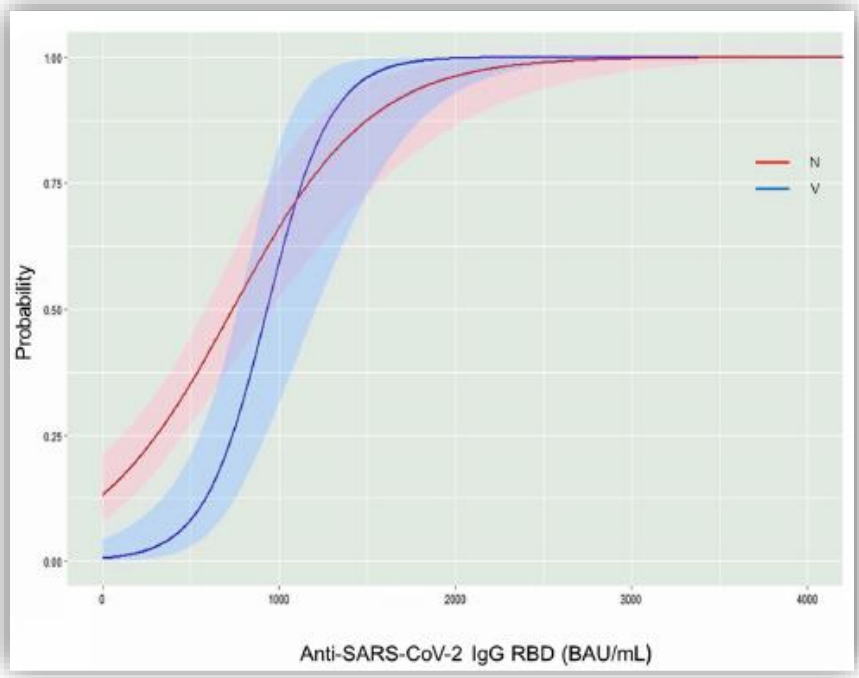
Prevention and control of COVID-19 in the penitentiary of Florence
Mirco Capacci, Maria Infantino, Valentina Grossi, Barbara Lari, Sergio Fabbri, Alessio Bellucci, Patrizia Sani, Alessandro Perri, Maurizio Benucci, Lorenza Cristiano, Luciana Amendola, Francesca Veneziani, Patrizia Casprini, Sandra Rogialli, Mariangela Manfredi. Clin Chem Lab Med. 2021;59:e239-e241.

The role of serological testing combined with RT-PCR to support diagnosis of COVID-19: a real-life report
Annamaria Grazia Gelli, Maria Infantino, Mariangela Manfredi, Roberta Lamanna, Patrizia Casprini, Valentina Grossi, Barbara Lari, , Maurizio Benucci, Silvia Pancani, Benedetta Ciambotti, Elisa Grifoni, Marianna Mannini, Stefania Di Martino, Eleonora Sisti, Silvia Dolenti, Giulia Vannini, Roberto Tarquini, Simone Vanni, Luca Masotti

SARS-CoV-2 infection serology: a useful tool to overcome lockdown?

Predicting the protective humoral response to SARS-CoV-2 vaccine

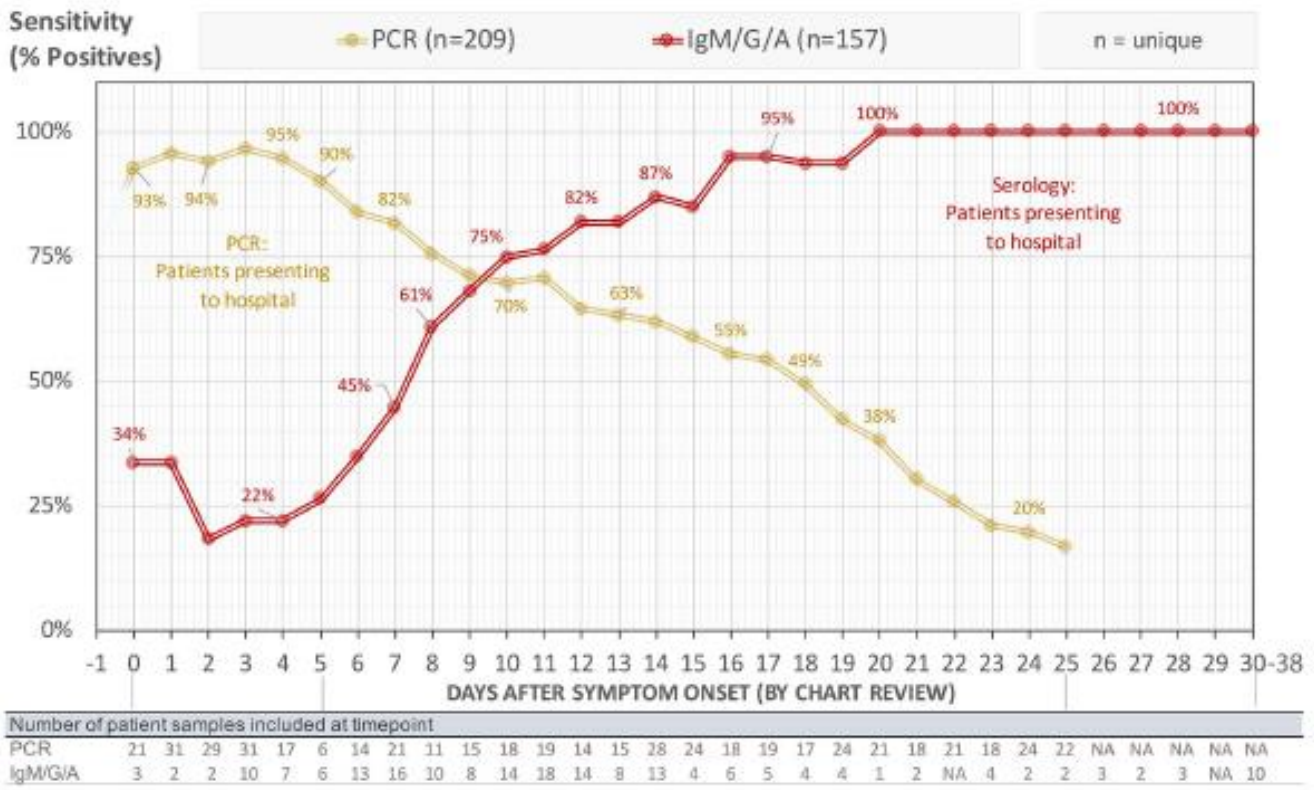
Anti-SARS-CoV-2 IgG (RBD) BAU/mL at 99% probability		
MNT(IC90) dilution	**N [95% CI]**	**V [95% CI]**
1:20	1,109 [745–4,029]	1,197 [822–2,248]
1:40	1,507 [868–3,279]	833 [562–1,014]
1:80	3,564 [1,970–9,471]	1,814 [939–4,393]
1:160	6,285 [3,272–21,358]	4,987 [3,177–8,735]



Levels of anti-SARS-CoV-2 IgG RBD (BAU/mL) calculated by multivariate logistic regression models corresponding to a 99% probability of being at or above different microneutralization IC90 dilution titers

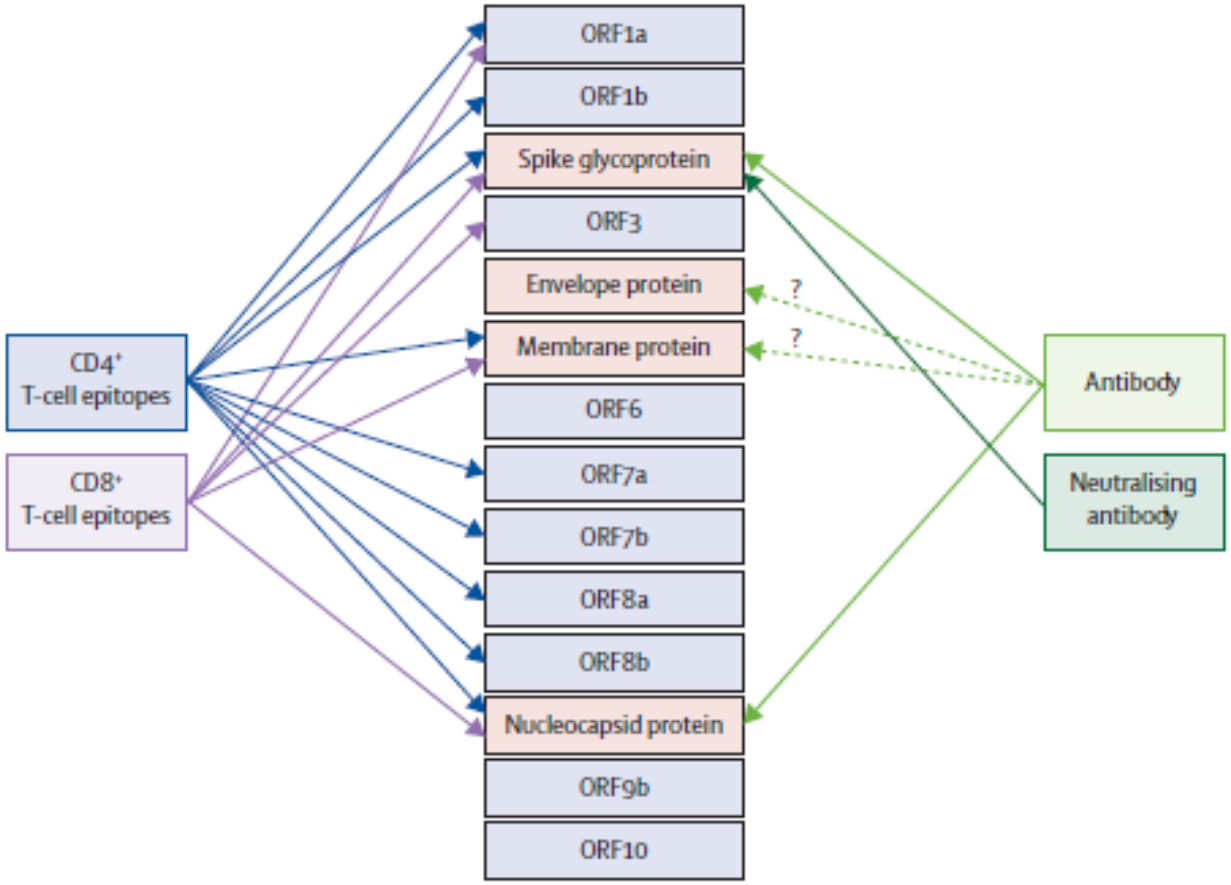
Meschi S, et al. Clin Chem Lab Med. 2021;59:2010-2018

KINETICS



Lei Liu, et al. medRxiv 2020.03.06.20031856

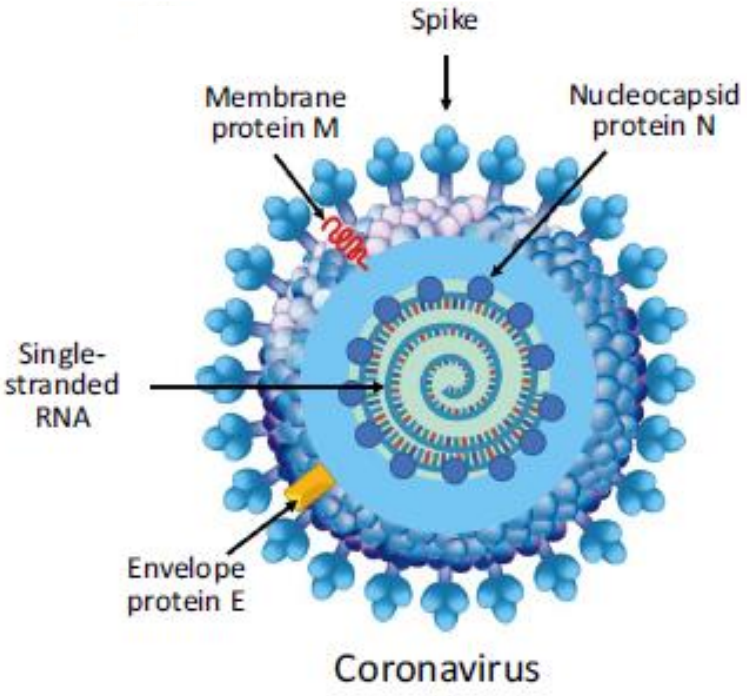
SEROLOGICAL TESTS- Target Antigens

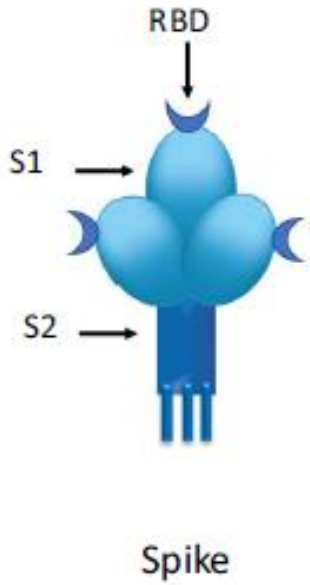


SEROLOGICAL TESTS- Target Antigens

- Nucleocapsid (N)
- Spike (S)
- Receptor Binding Domain(RBD)

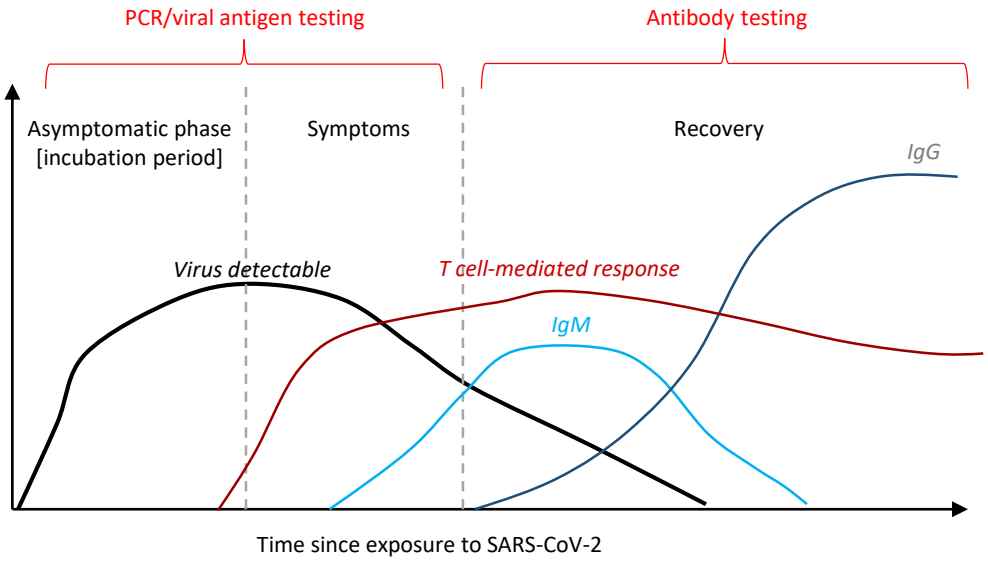
Main target antigens:
RBD, S1, full-length spike, nucleocapsid





Infection (2020) 48:665–669

COVID-19 AND THE PATH TO IMMUNITY



B cell response

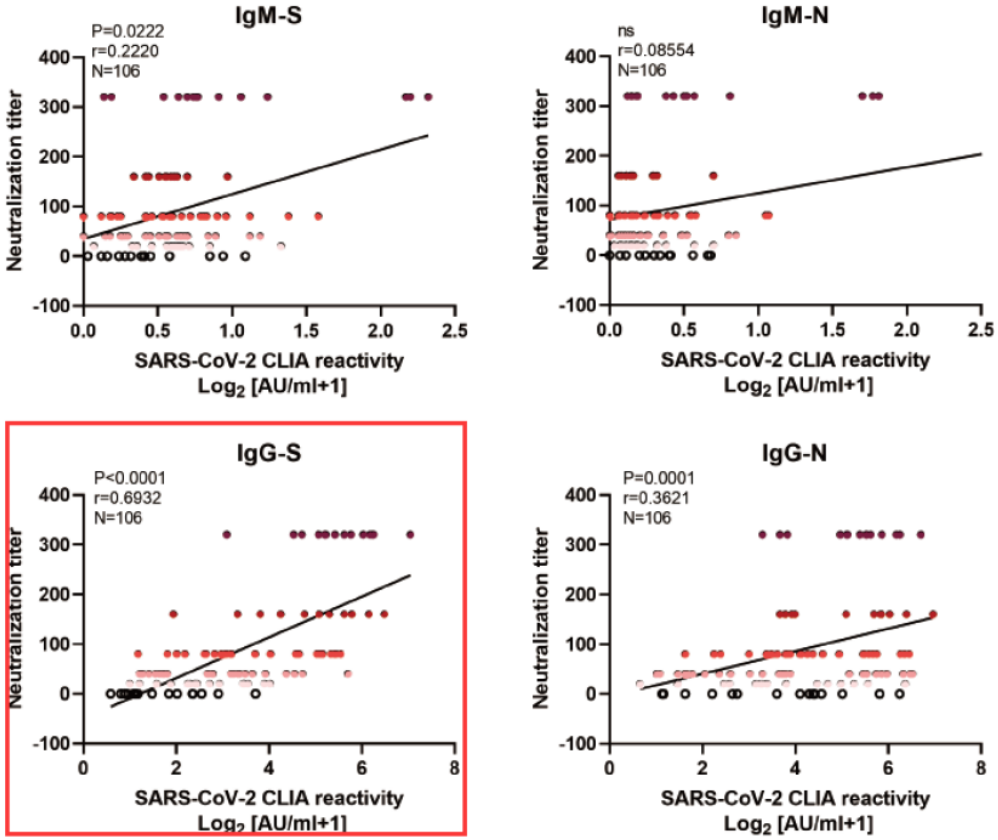
- **Binding antibodies**
- **Neutralising antibodies**

T cell response

Could T cell-based assays be used for immune monitoring as an alternative to antibody tests?

Adapted from the World Health Organisation – EPI-WiN webinar COVID-19 immunity

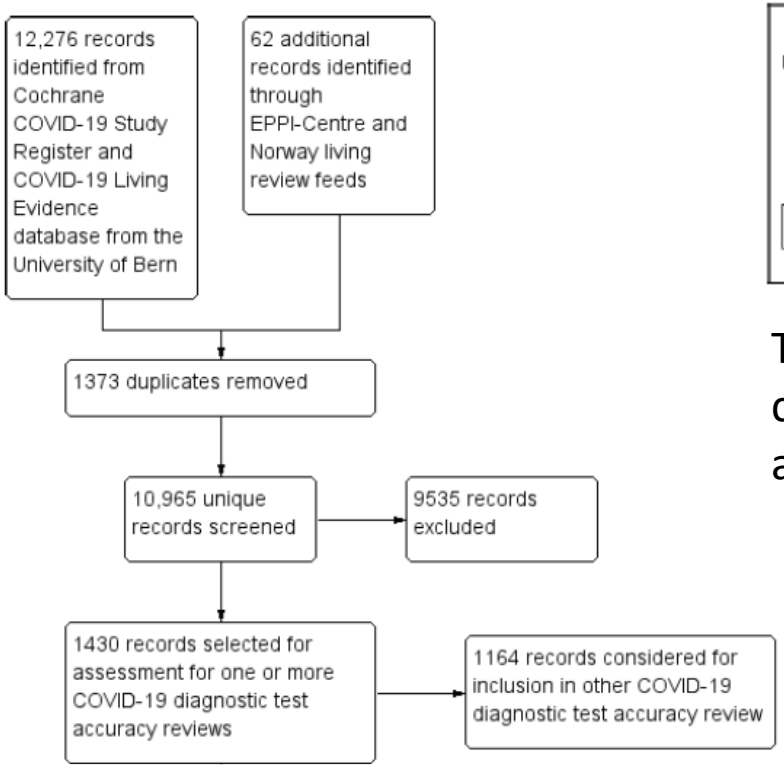
NEUTRALISING ANTIBODIES

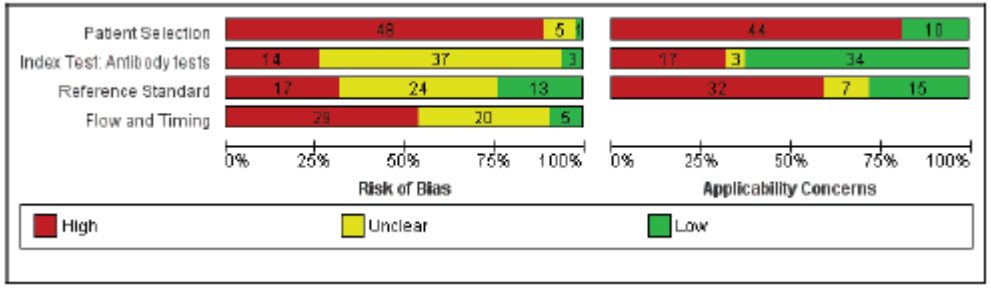


- To further determine which antibody subclasses and specificities may exert the neutralizing effect, correlations between the titers of the four antibodies and the neutralizing activity were analyzed.
- The IgG-RBD-S titer demonstrated by far the highest positive correlation with antibody neutralization activity ($r=0.6932$, $p<0.0001$), compared to IgM-S ($r=0.2220$, $p<0.05$) and IgG-N ($r=0.3621$, $p=0.0001$)

Courtesy of L.Subissi

THE LACK OF HARMONIZATION OF TEST RESULTS





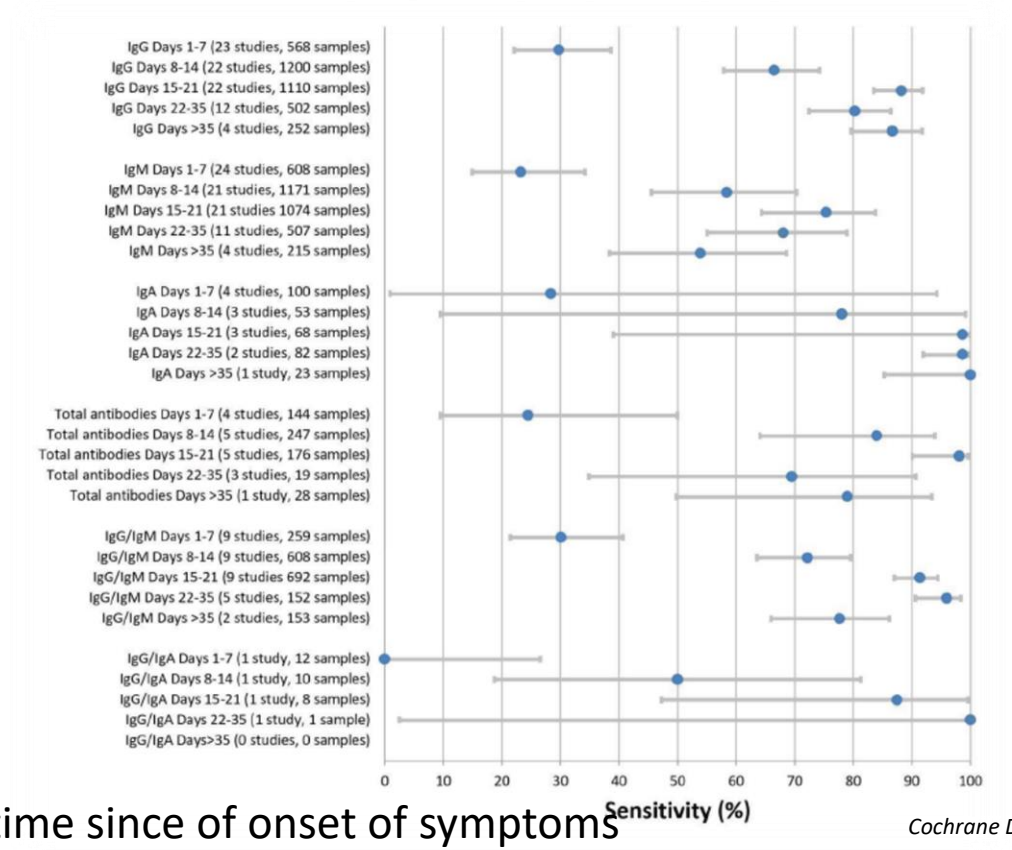
This review has evaluated data from 25 commercial tests and numerous in-house assays

Cochrane Library

Cochrane Database of Systematic Reviews

Antibody tests for identification of current and past infection with SARS-CoV-2 (Review)

THE LACK OF HARMONIZATION OF TEST RESULTS



Sensitivity varies with the time since of onset of symptoms

Cochrane Database of Systematic Reviews

363 immunoassay

314 commercialized

213 RDT

12 FDA-EUA

61 RUO

FIND
Because diagnosis matters

maglumi

CONTACT US

COVID-19 | WHO WE ARE | WHAT WE DO | NEWSROOM | PARTNERS & DONORS | CALLS FOR PARTNERS

Home > Diagnostics & testing > SARS-CoV-2 diagnostic pipeline

FIND is collating an overview of SARS-CoV-2 tests that are commercially available or in development for the diagnosis of COVID-19. We do not guarantee that this is a comprehensive list, since the information below has been submitted voluntarily by test suppliers and is not independently verified. If you have any queries or wish for us to make updates in the pipeline, please contact us.

If you would like your test to be included in the pipeline, please click on this button to download the form. SUBMISSION FORM

To know more about the FIND evaluations of submitted SARS-CoV-2 tests, click here. ONGOING TEST EVALUATIONS

***EUA**: Emergency Use Authorization — **HSA**: Health & Safety/Sciences Authority — **MFDS**: Ministry of Food & Drug Safety — **MoH**: Ministry of Health — **MHRA**: Medicines & Health Care Products Regulatory Agency — **NRA**: National Regulatory Authority — **RUO**: Research Use Only — **TGA**: Therapeutic Goods Administration — **WHO EUL**: World Health Organization Emergency Use Listing*

SHOW ALL | IMMUNOASSAYS | MOLECULAR ASSAYS | SAMPLE COLLECTION / INACTIVATION | DIGITAL SOLUTIONS | OTHER DIAGNOSTICS

Status | Test format | Test target | Regulatory | FILTER | EXPORT TO XLS

914 RESULT(S)

- **1drop Inc.** 1copy™ COVID-19 qPCR Multi Kit (Korea MFDS EUA - US FDA EUA - Health Canada - Saudi FDA - Sri Lanka NMRA - CE-IVD) Contact
- **3B BlackBio Biotech India Ltd** TRUPCR®SARS-CoV-2 RT qPCR Kit (India CDSCO - US FDA EUA) Contact
- **3D Medicines** 3DMed 2019-nCoV RT-qPCR Detection Kit (CE-IVD) Contact
- **3D Medicines** ANDiS® SARS-CoV-2 RT-qPCR Detection Kit (US FDA EUA - CE-IVD) Contact
- **A*ccelerate Technology** A*STAR Fortitude Kit 2.0 (Singapore HSA) Contact
- **AAZ-LMB** COVID-PRESTO® (CE-IVD) Contact
- **AB ANALITICA srl** REALQUALITY RQ-2019-nCoV (CE-IVD) Contact
- **AB ANALITICA srl** REALQUALITY RQ-SARS-CoV-2 (CE-IVD) Contact
- **AB Dianostic Systems GmbH** abia SARS-CoV-2 IgG/IgM (CE-IVD) Contact
- **Abace Biotechnology** COVID-19 IgG / IgM Antibody Test Kit (CE-IVD) Contact
- **Abace Biotechnology** Virus Sampling Kit (CE-IVD) Contact

EUA Authorized Serology Test Performance | FDA

www.fda.gov › medical-devices

Test Performance

Test:
Techn CMIA
Targe

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgG	Sensitivity (PPA)	100% (34/34)	(89.9%; 100%)
IgG	Specificity (NPA)	99.0% (99/100)	(94.6%; 99.8%)
IgG	PPV at prevalence = 5%	84.0%	(46.5%; 96.8%)
IgG	NPV at prevalence = 5%	100%	(99.4%; 100%)

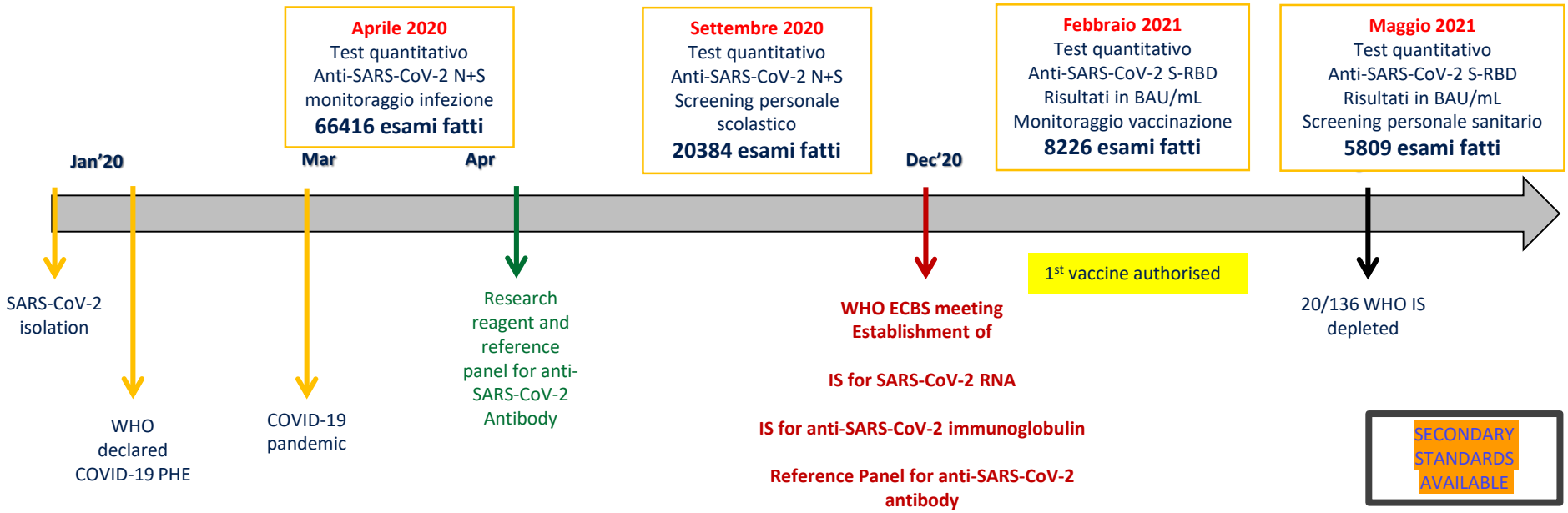
Test Facts:

- Information for Healthcare Providers
- Information for Recipients
- Instructions for Use

G

Developer:
Test:
Techn CMIA
Targe

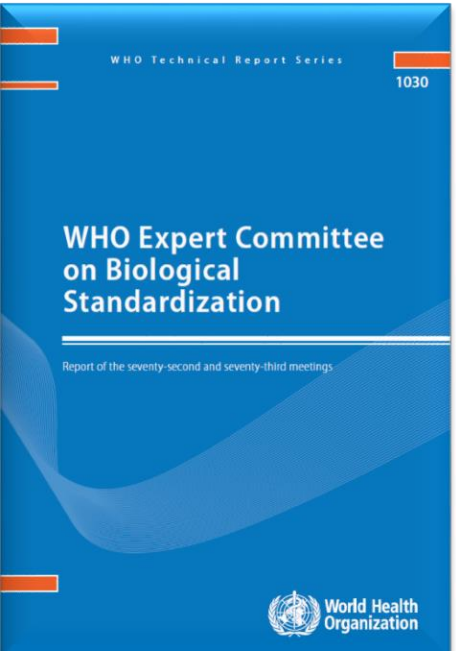
Timelines of COVID-19 serology

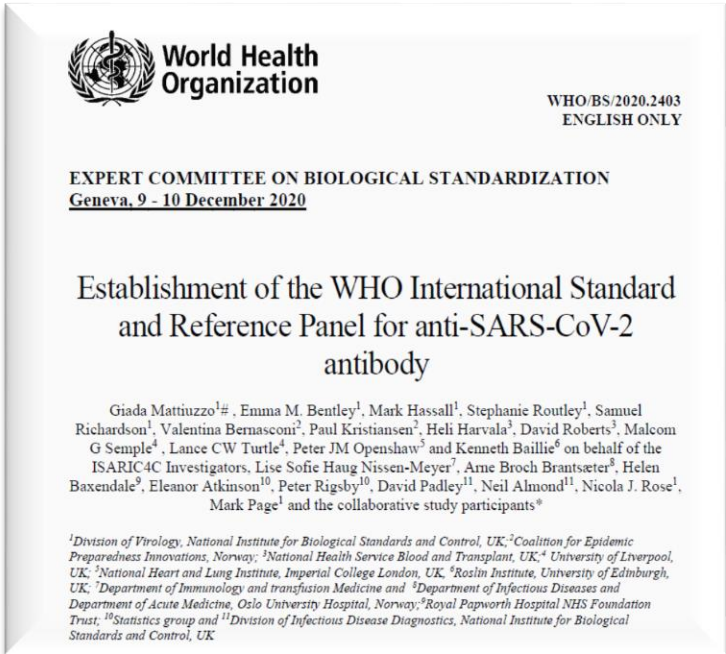


Courtesy of Giada Mattiuzzo

The establishment of WHO international reference standards for SARS-CoV-2 antibodies would facilitate the standardization of such assays thus strengthening the comparability and harmonization of datasets obtained by different laboratories worldwide.

In turn, this would help to establish the protective antibody levels needed to develop efficacious vaccines and therapeutics, while also improving the comparability of data collected during epidemiological and immunological surveillance studies.




World Health Organization

WHO/BS/2020.2403
ENGLISH ONLY

EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION
Geneva, 9 - 10 December 2020

Establishment of the WHO International Standard and Reference Panel for anti-SARS-CoV-2 antibody

Giada Mattiuzzo[1]# , Emma M. Bentley[1], Mark Hassall[1], Stephanie Routley[1], Samuel Richardson[1], Valentina Bernasconi[2], Paul Kristiansen[2], Heli Harvala[3], David Roberts[3], Malcom G Semple[4] , Lance CW Turtle[4], Peter JM Openshaw[5] and Kenneth Baillie[6] on behalf of the ISARIC4C Investigators, Lise Sofie Haug Nissen-Meyer[7], Arne Broch Brantsæter[8], Helen Baxendale[9], Eleanor Atkinson[10], Peter Rigsby[10], David Padley[11], Neil Almond[11], Nicola J. Rose[1], Mark Page[1] and the collaborative study participants*

[1]Division of Virology, National Institute for Biological Standards and Control, UK; [2]Coalition for Epidemic Preparedness Innovations, Norway; [3]National Health Service Blood and Transplant, UK; [4] University of Liverpool, UK, [5]National Heart and Lung Institute, Imperial College London, UK, [6]Roslin Institute, University of Edinburgh, UK; [7]Department of Immunology and transfusion Medicine and [8]Department of Infectious Diseases and Department of Acute Medicine, Oslo University Hospital, Norway; [9]Royal Papworth Hospital NHS Foundation Trust; [10]Statistics group and [11]Division of Infectious Disease Diagnostics, National Institute for Biological Standards and Control, UK

- Primary calibrant – no a validation tool nor a positive control for routine use
- Sets a common language does not standardised assays
- Use of the standard WON'T make a bad assay good

World Health Organization

WHO/BS/2020.2403
ENGLISH ONLY

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Methods: 125 data sets

NEUTRALISATION ASSAY (27)

LIVE SARS-CoV-2* (15)

PRNT/FRNT

CPE

MN

PSEUDOTYPED VIRUS(12)

VSV(Luc)

HIV(Luc)

ELISA (78)

IgG:

In house (44)

Commercial kit * (18)

IgM (7), IgA (9)

RBD, S1, Spike, N, M, E and S2

OTHERS (20)

Flow cytometry-based binding Ab assay

Lateral flow immunoassay

Fusion inhibitory assay

ACE2 binding inhibitory assay

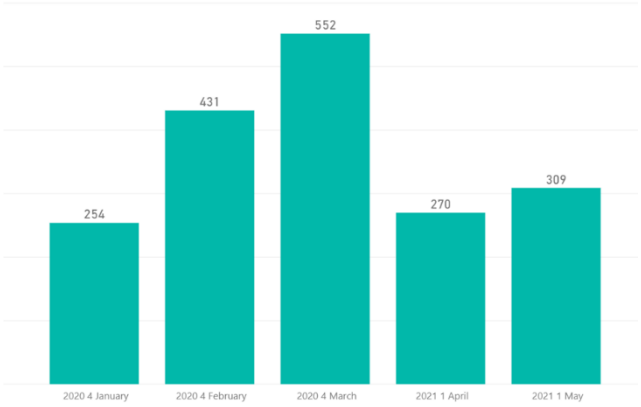
* 9 different isolates

* 13 different kits

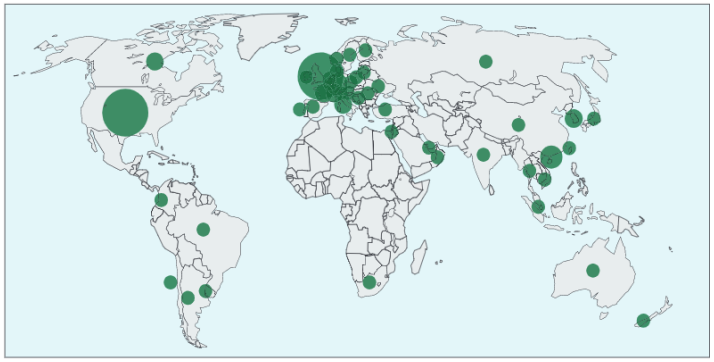
Courtesy of Giada Mattiuzzo

Uptake WHO IS for anti-SARS-CoV-2 immunoglobulin

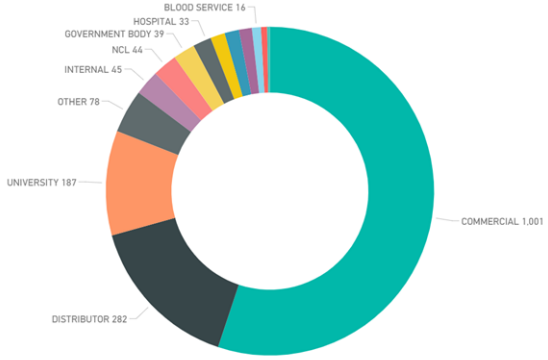
Over 2400 units 20/136 were shipped to 581 individual customers



Data/graphs kindly provided by Hanvir Klair and Assam Rassol



Knezevic et al. *Lancet Microbe* 2021



Courtesy of Giada Mattiuzzo

ThermoFisher SCIENTIFIC

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D-79111 Freiburg
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www.thermoscientific.com/phadia/de

thermoscientific

March 11th, 2021

Correlation of the EliA SARS-CoV-2-Sp1 IgG test units (EliA U/mL) to the *binding antibody units* (BAU) of the first WHO International Standard for anti-SARS-CoV-2 immunoglobulins NIBSC code: 20/136

Dear valued customers,

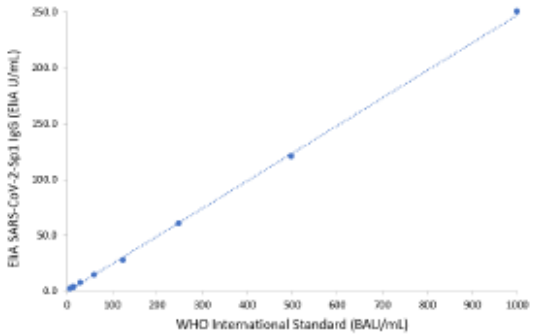
Thank you for using EliA™ SARS-CoV-2-Sp1 IgG test (Art. No. 14-6663-01) to measure IgG antibodies to SARS-CoV-2 spike 1 in human serum and plasma as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

The EliA SARS-CoV-2-Sp1 IgG test was developed before an International Standard for anti-SARS-CoV-2 immunoglobulins was available. As a result, manufacturer specific arbitrary EliA U/mL were assigned to the concentrations obtained, making it difficult to compare numerical results from different assays.

Recently, the NIBSC (National Institute for Biological Standards and Control, UK) launched the first WHO International Standard for anti-SARS-CoV-2 immunoglobulins NIBSC code: 20/136[1,2]. A total of 1000 binding antibody units/mL (BAU/mL) were assigned to the pure sample.

We correlated EliA units (EliA U/mL) of the EliA SARS-CoV-2-Sp1 IgG assay to the BAUs of the WHO International Standard (results are shown below).

ThermoFisher
SCIENTIFIC



Linear regression

Best fit values
Slope CI (95%): 0.2448 to 0.2545
Equation: y = 0.2467 * x

Pearson correlation
r : 1.000
r CI (95%): 0.999 to 1.000
r^2 : 0.9992
p < 0.0001
n = 8 values
1:2 dilution series ranging from pure sample (1000 BAU/mL) to 0.781% (7.81 BAU/mL)

Conclusions

The first WHO International Standard for anti-SARS-CoV-2 immunoglobulins correlates very well with the EliA SARS-CoV-2-Sp1 IgG test (Pearson r = 1.0000, Fisher 95% CI 0,999-1,000). The standard shows a linear dilution from the pure sample (1000 BAU/mL) down to 7,81 BAU/mL.

A mathematical transposition from EliA U/mL to the BAU/mL of the WHO International Standard would follow this equation:

1 EliA U/mL = 4 BAU/mL

We expect that the excellent correlation initially observed with the WHO International Standard will be confirmed by additional data in an extended study.

Please do not hesitate to contact us in case you have further questions.

Sincerely,

Dr. Raimund Fiedler, Director R&D AI
Speciality Diagnostics group

International Immunopharmacology 100 (2021) 108095

Contents lists available at ScienceDirect

International Immunopharmacology

journal homepage: www.elsevier.com/locate/intimp

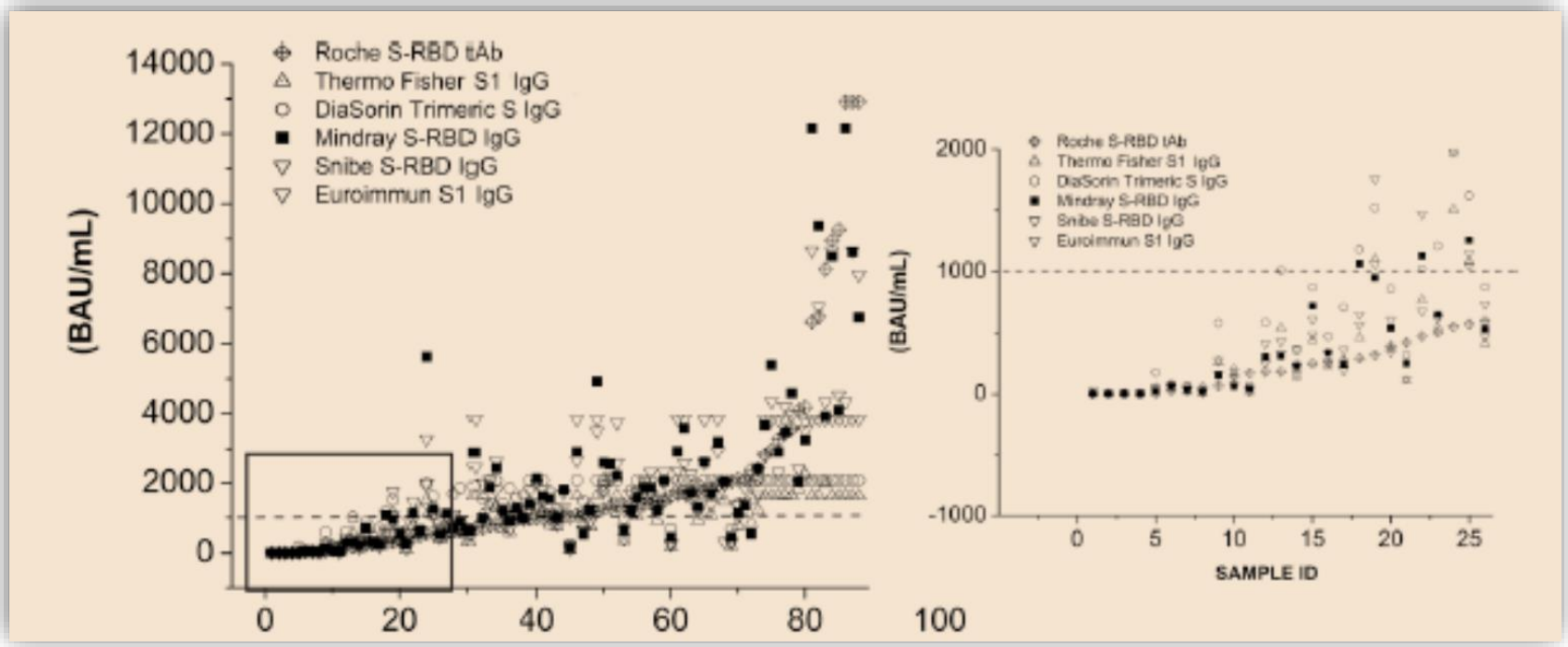
The WHO International Standard for COVID-19 serological tests: towards harmonization of anti-spike assays

Maria Infantino [a,*], Massimo Pieri [b,c,d], Marzia Nuccetelli [c], Valentina Grossi [a], Barbara Lari [a], Flaminia Tomassetti [d], Graziella Calugi [d], Silvia Pancani [a], Maurizio Benucci [e], Patrizia Casprini [f], Mariangela Manfredi [a], Sergio Bernardini [b,c,g]

[a] Immunology and Allergology Laboratory, S. Giovanni di Dio Hospital, Florence, Italy
[b] Department of Experimental Medicine, University of Tor Vergata, Rome, Italy
[c] Department of Laboratory Medicine, Tor Vergata University Hospital, Rome, Italy
[d] Lifebrain srl; Viale Roma 190/A, Guidonia Montecelio, Rome, Italy
[e] Rheumatology Department, S. Giovanni di Dio Hospital, Florence, Italy
[f] Clinical Pathology Laboratory, S. Giovanni di Dio Hospital, Florence, Italy
[g] Emerging Technologies Division, International Federation Clinical Chemistry and Laboratory Medicine, Milan, Italy

CV 0,68 AU/ mL a CV 0,38 BAU/mL

RESULTS



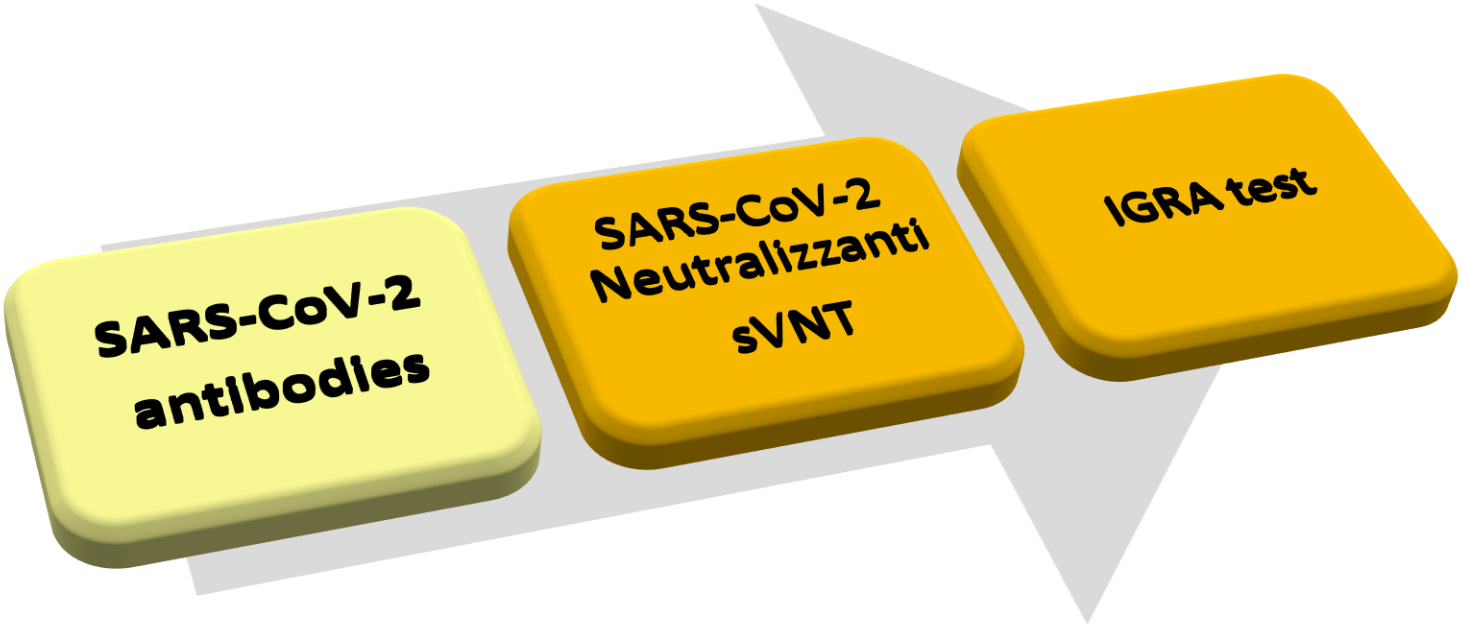
Infantino M,. Int Immunopharmacol. 2021;100:108095

RESULTS

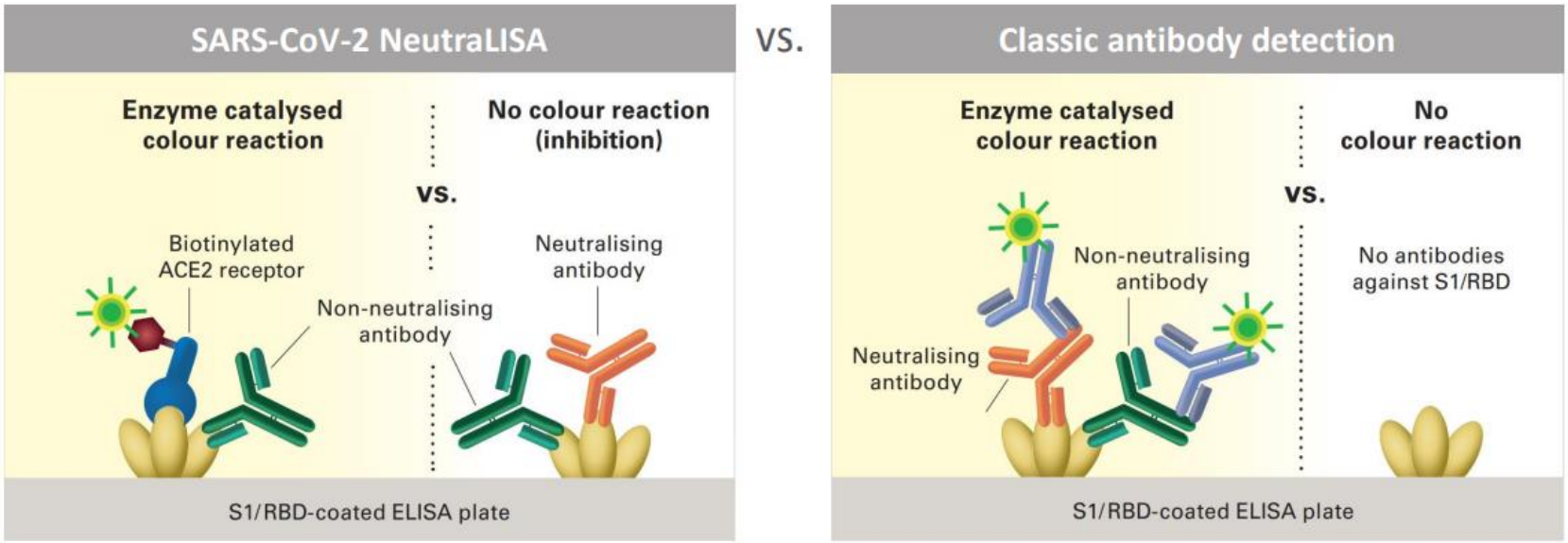
		Thermo Fisher S1 IgG	Mindray S RBD IgG	Roche S RBD tAb	Snibe S RBD IgG	DiaSorin Trimeric S IgG
Mindray S RBD IgG	(r)	0.847				
	(n)	63				
Roche S RBD tAb	(r)	0.634	0.729			
	(n)	66	82			
Snibe S RBD IgG	(r)	0.867	0.940	0.771		
	(n)	65	80	81		
DiaSorin Trimeric S IgG	(r)	0.910	0.687	**0.513**	0.813	
	(n)	46	48	48	48	
Euroimmun S1 IgG	(r)	**0.942**	0.796	0.689	0.893	0.762
	(n)	63	66	66	66	46

Infantino M,. Int Immunopharmacol. 2021;100:108095

DIAGNOSI COVID19
L'evoluzione dei test



Neutralizing antibodies (Nabs)

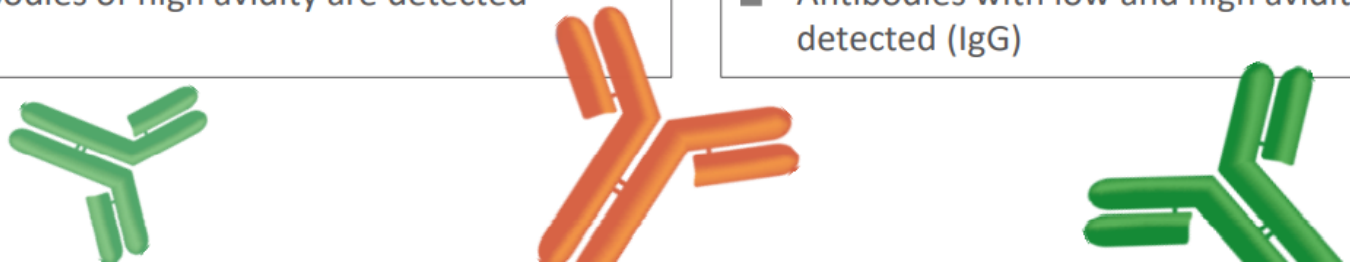


Neutralisation Test (NT)

- Detects functional antibodies that inhibit the binding between S1/RBD and ACE2 and thus virus entry
- All immunoglobulin classes are detected – functional antibodies are mainly of type IgG
- Antibodies of high avidity are detected

ELISA

- Detects all antibodies against a specific antigen that is coated on the plate (e.g. anti-S1/RBD)
- Differentiation of IgG, IgA, IgM depending on enzyme conjugate possible
- Antibodies with low and high avidity are detected (IgG)



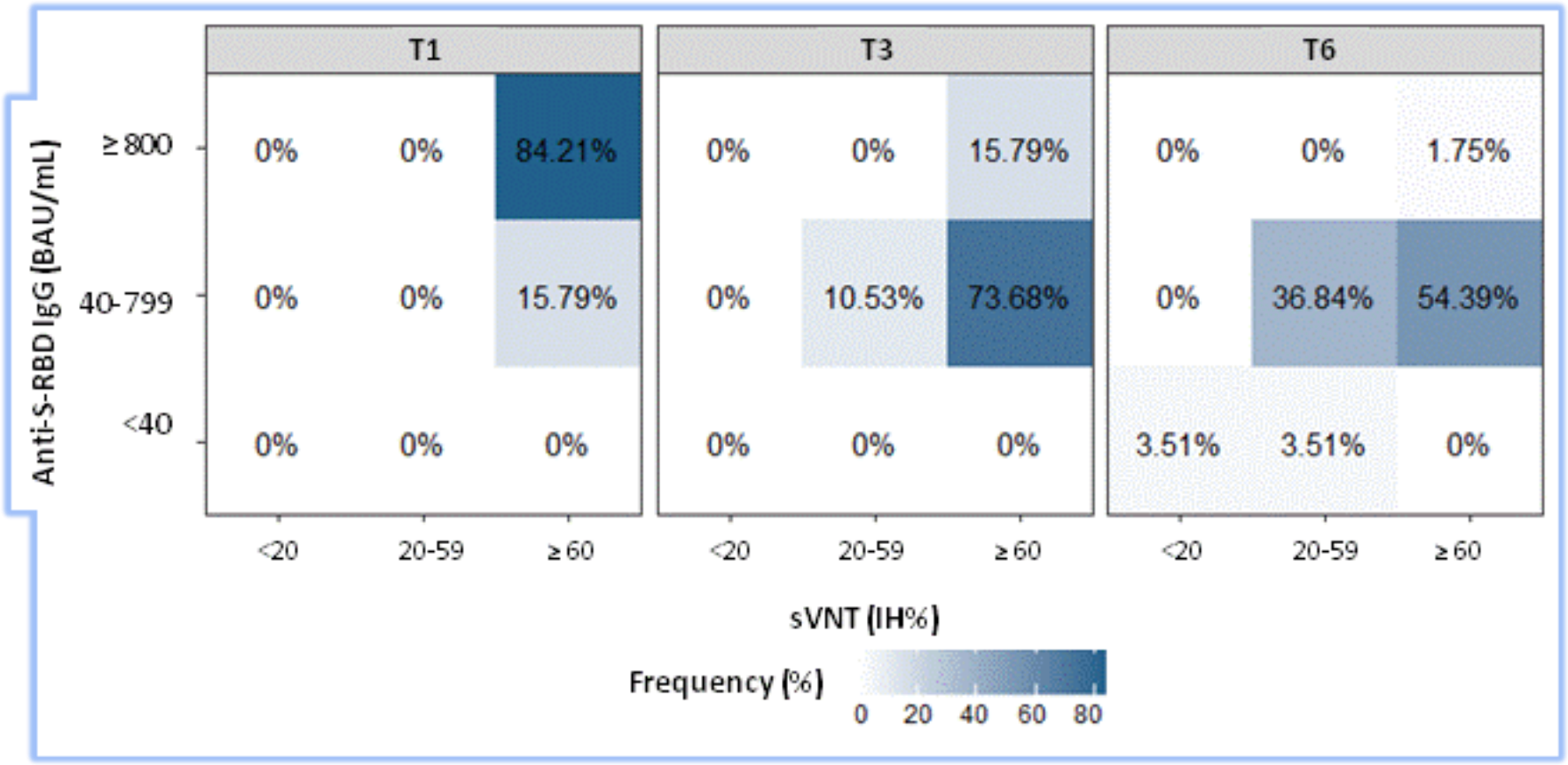
Test surrogati di neutralizzazione: quale supporto nelle indagini sierologiche?

Manufacturer	Kit assay	Method	Cut-off	Conversion factor	Dynamic range	Assay principle
Mindray	*SARS-CoV-2 Neutralizing Antibodies*	CLIA	10 AU/mL	1 AU = 3.6547 IU/mL	2 AU/mL to 400 AU/mL	Neutralizing antibody in the sample competes with ACE2-ALP conjugate for binding sites of SARS-CoV-2 S-RBD immobilized in the para-magnetic microparticles
Snibe	*Maglumi SARS-CoV-2 Neutralizing Antibody*	CLIA	0.05 µg/mL	1 µg/mL = 405 IU/mL	0.050–30 µg/mL	Neutralizing antibody in the sample competes with recombinant SARS-CoV-2 S-RBD antigen labeled with ABEI for binding ACE2 antigen immobilized on magnetic microbeads
Euroimmun	*SARS-CoV-2 NeutraLISA*	ELISA	% IH <20: negative ≥20% IH <35: borderline % IH ≥35: positive	n.a.	% IH 0–100	Neutralizing antibody in the sample competes with the receptor biotinylated ACE2 (sample buffer) for the binding sites of the SARS-CoV-2 S1 /RBD proteins immobilized on the plate
Diesse	*Chorus SARS-CoV-2 "Neutralizing" Ab*	ELISA	<20 BAU/mL	n.a.	20–1500 BAU/mL	Neutralizing antibody in the sample competes with the peroxidase-conjugated SARS-CoV-2 anti-S1 therapeutic monoclonal antibodies to bind S1 subunit fixed on the solid phase support

ABEI, N-(aminobutyl)-N-(ethylisoluminol); ALP, alkaline phosphatase; CLIA, chemiluminescence immunoassay; ELISA, enzyme-linked immunosorbent assay; IH, percentage of inhibition; n.a., not available.

Pieri M, Front Biosci (Landmark Ed). 202221;27:74

The role of neutralizing antibodies following the BNT162b2 mRNA vaccine in a cohort of Italian healthcare workers



(submitted 2021)

SIEROIMMUNOLOGIA SARS-CoV-2 - Ciclo 2021

Centro di Riferimento Sicurezza e Qualità

Valutazione esterna di qualità

Azienda Ospedaliero Universitaria Careggi

- **Laboratori partecipanti**: 132
  (di cui 68 centri Regione Toscana)

- **18 Regioni**

- **Valutazione dei risultati**:

✓qualitativa

✓quantitativa

SIEROIMMUNOLOGIA SARS-CoV-2 - Ciclo 2021

Centro di Riferimento Sicurezza e Qualità

Valutazione esterna di qualità

Azienda Ospedaliero Universitaria Careggi

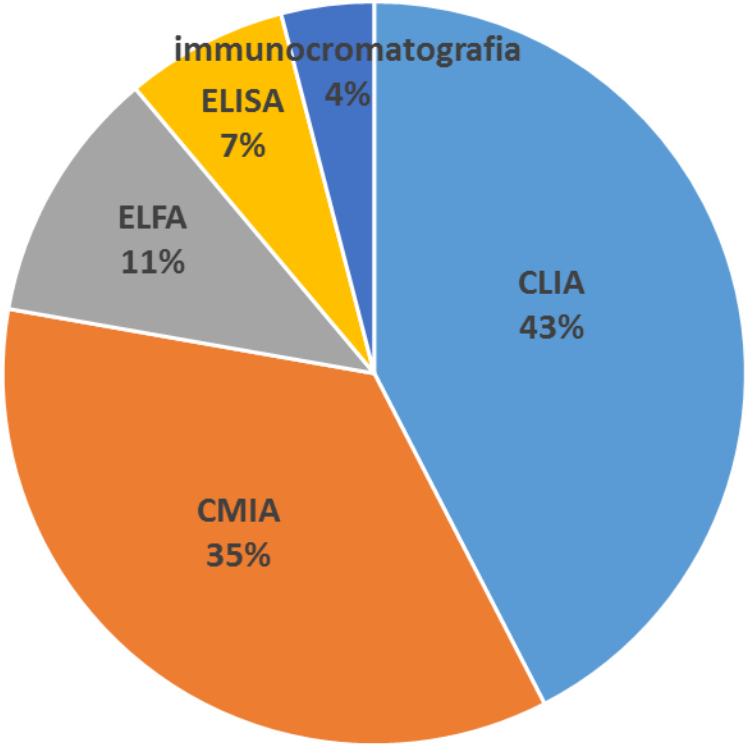
DISTRIBUZIONE DEI METODI

anti-SARS-CoV-2	
Ig TOTALI	4 CLIA (n=36)
IgG	7 CLIA (n=42), 1 CMIA (n=35), 1 ELFA (=11), 1 ELISA (=7), 1 IMMUNOCROMATOGRAFIA (=4)
IgM	5 CLIA (n=33), 1 CMIA (n=28), 1 ELFA (=12), 1 ELISA (=6), 1 IMMUNOCROMATOGRAFIA (=4)

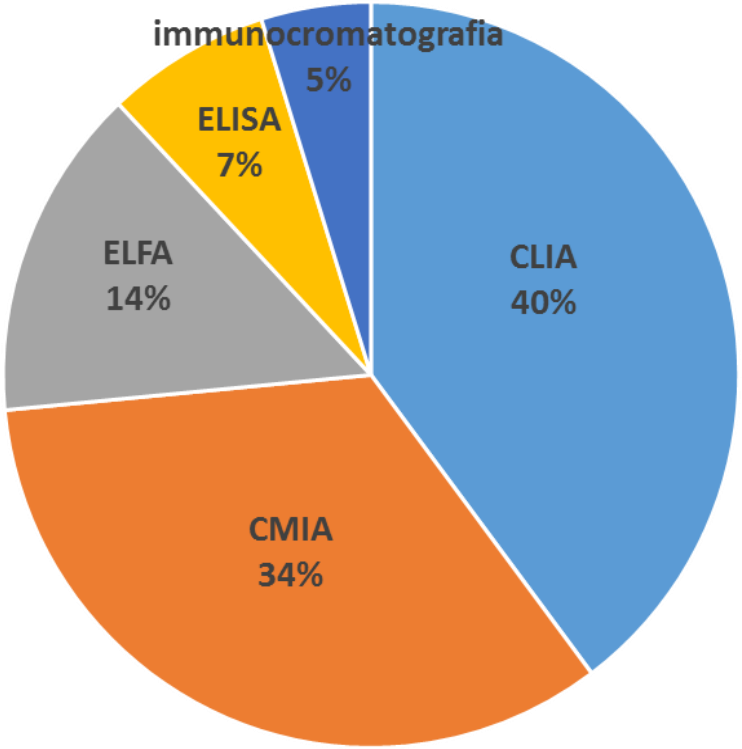
- ✓ Alcuni partecipanti hanno inviato sia i dati delle totali che IgG e IgM
- ✓ Alcuni partecipanti hanno espresso i risultati in BAU/mL e altri in UA/mL

DISTRIBUZIONE DEI METODI

Anti-SARS-CoV-2 IgG



Anti-SARS-CoV-2 IgM



ANALISI QUALITATIVA

Campione N°6

A.C. Anti SARS Cov2 IgG
Valore Atteso:
Positivo

Risultato inviato: POSITIVO

Risultato	Numero	%	Score
POSITIVO	98	99.0	2
DUBBIO	0	0.0	
NON ESEGUITO	0		
NEGATIVO	1	1.0	-1

n.a. = non assegnato

ANALISI QUANTITATIVA

Azienda Ospedaliero Universitaria Careggi

Centro di Riferimento Sicurezza e Qualità
Valutazione esterna di qualità
SIEROIMMUNOLOGIA SARS-CoV-2 - Ciclo 2021

REGIONE TOSCANA
Centro n. 00015

Analita: *A.C. Anti SARS Cov2 IgG*
Risultato atteso: Positivo

N° Risposte totali: 99

Sottogruppo: *A.C. Anti SARS Cov2 IgG (DIASORIN-prot S e/o RBD-BAU)* | BAU

	N.	Out	Media	C.V.	S.D.	Med.na
Tutti	11	0	98.291	8.58	8.24	98.70
Tuo Metodo	11	0	98.291	8.58	8.24	98.70

Campione	6 *(Scad. 15/10/2021)*
Valore Atteso	Positivo
Tuo risultato	91.80 - POSITIVO

	Diff. S	Diff. %
Tutti	-0.53	-4.68
Tuo Metodo	-0.53	-4.68

N. risultati numerici	11
N. risultati semiquantitativi/qualitativi	1

Riepilogo x Metodo risultati numerici (> 7 Centri)

Metodo	N.	Out	M.	C.V.	Pos.	Neg.	Dub.
CLIA DIASORIN-prot S e/o RBD-BAU	11	0	98.291	8.58	11		
CMIA-prot S e/o RBD-UA	18	1	496.70	3.89	18		
CMIA-prot N-UA	9	0	6.427	24.71	9		

Tuo Metodo
CLIA DIASORIN-prot S e/o RBD-BAU

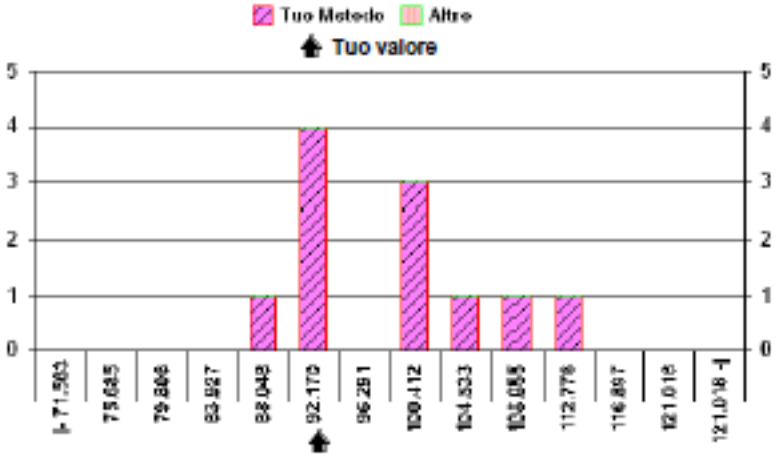


Grafico dati semiquantitativi/qualitativi	Tuo Metodo
POSITIVO	1/1

Azienda Ospedaliero Universitaria Careggi

Risultato atteso

1 Positivo anti-SARS-CoV-2 IgG

2 Negativo

3 Positivo anti-SARS-CoV-2 IgG +IgM

4 Positivo anti-SARS-CoV-2 IgG+IgM

5 Positivo anti-SARS-CoV-2 IgG

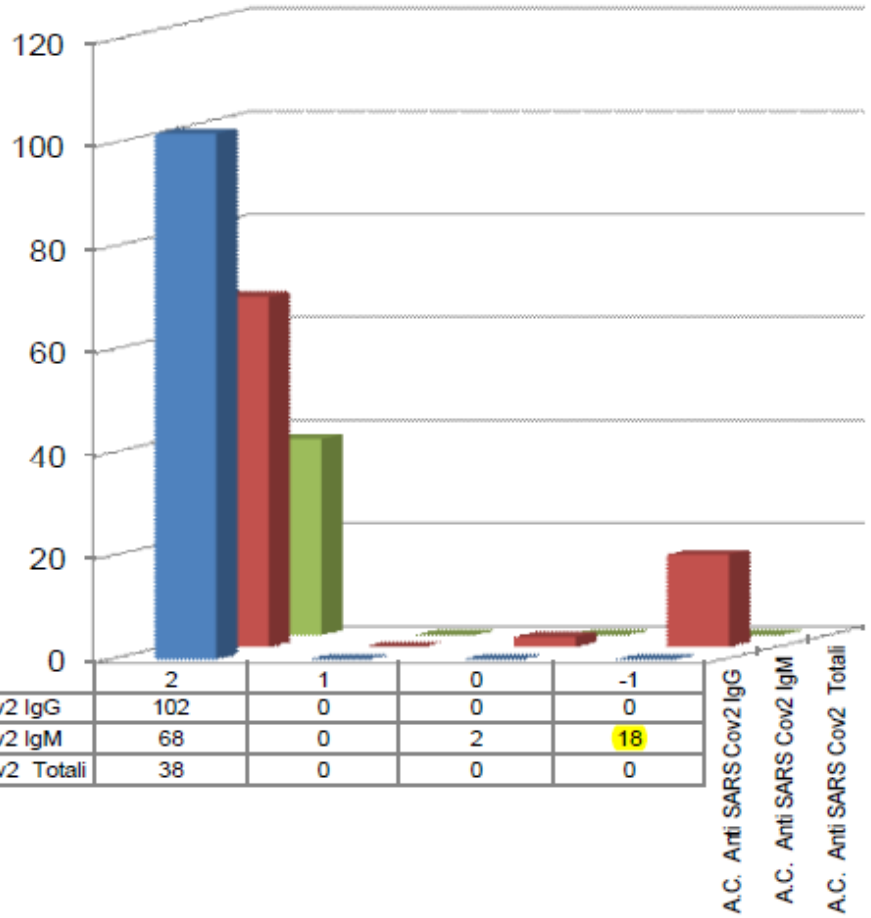
6 Positivo anti-SARS-CoV-2 IgG +IgM

7 Positivo anti-SARS-CoV-2 IgG +IgM

8 Positivo anti-SARS-CoV-2 IgG

Campione n° 1

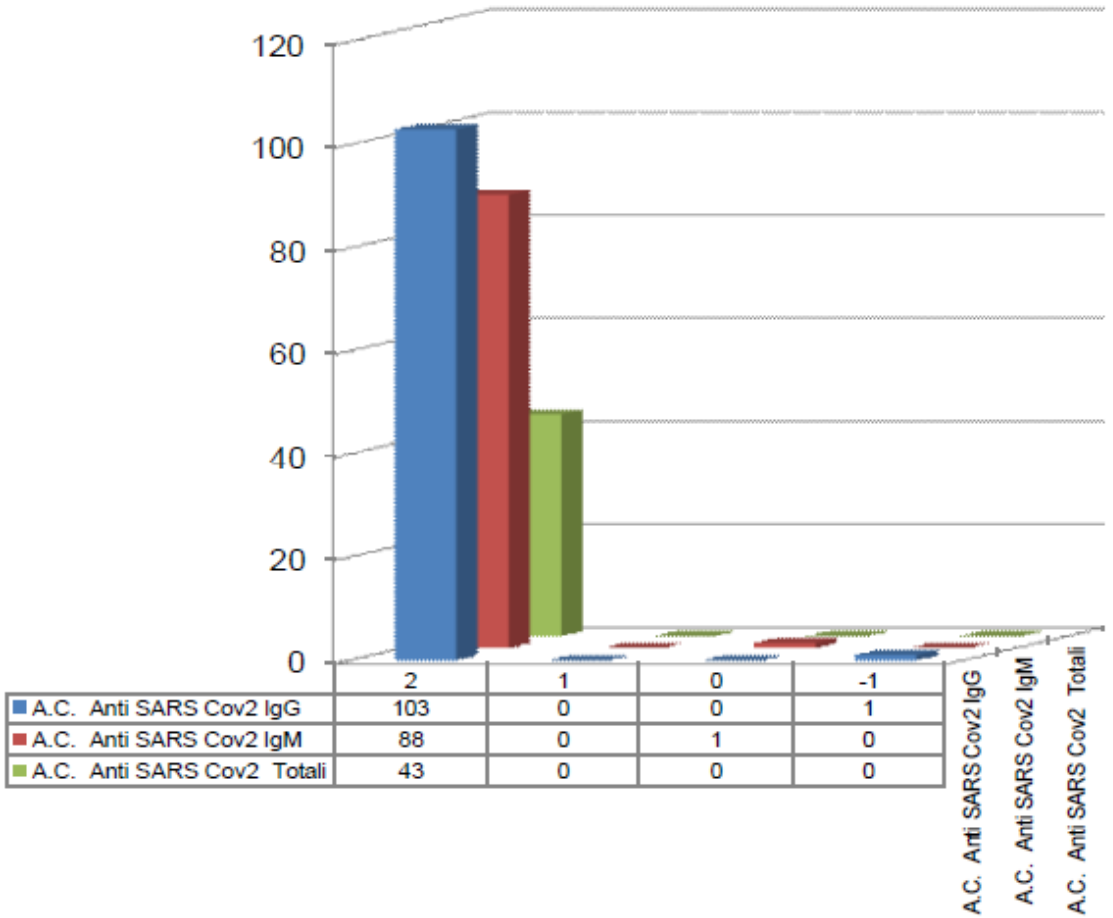
Positivo anti-SARS-CoV-2 IgG



	2	1	0	-1
A.C. Anti SARS Cov2 IgG	102	0	0	0
A.C. Anti SARS Cov2 IgM	68	0	2	18
A.C. Anti SARS Cov2 Totali	38	0	0	0

Campione n° 2

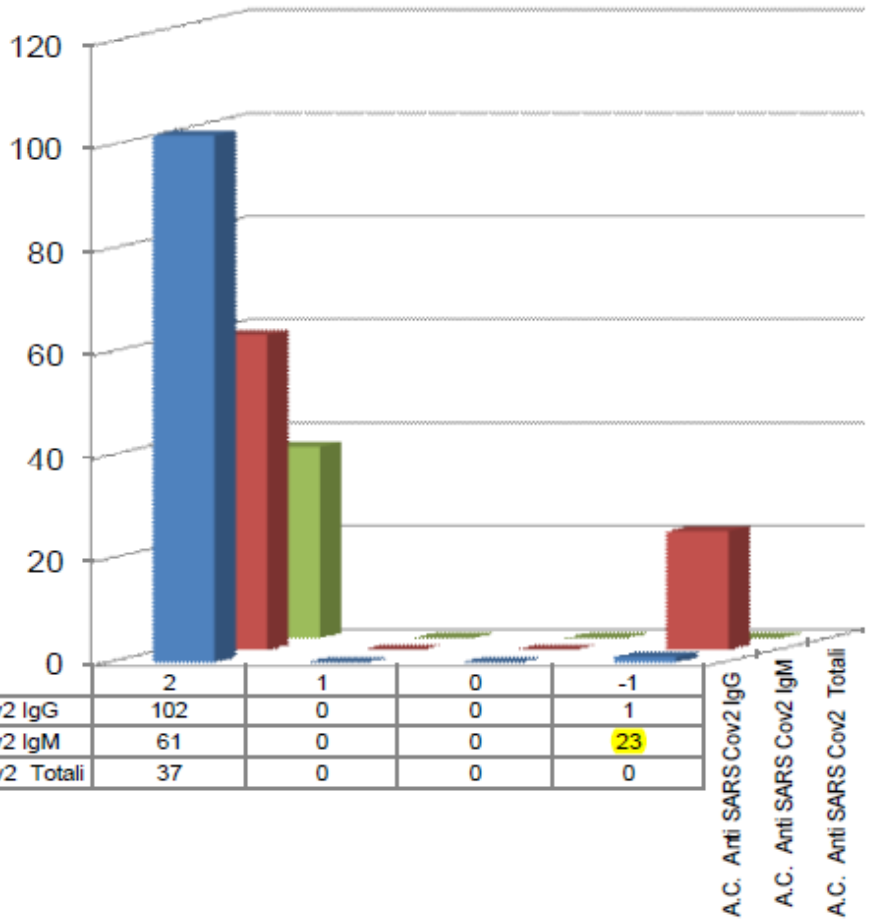
Negativo



	2	1	0	-1
A.C. Anti SARS Cov2 IgG	103	0	0	1
A.C. Anti SARS Cov2 IgM	88	0	1	0
A.C. Anti SARS Cov2 Totali	43	0	0	0

Campione n° 3

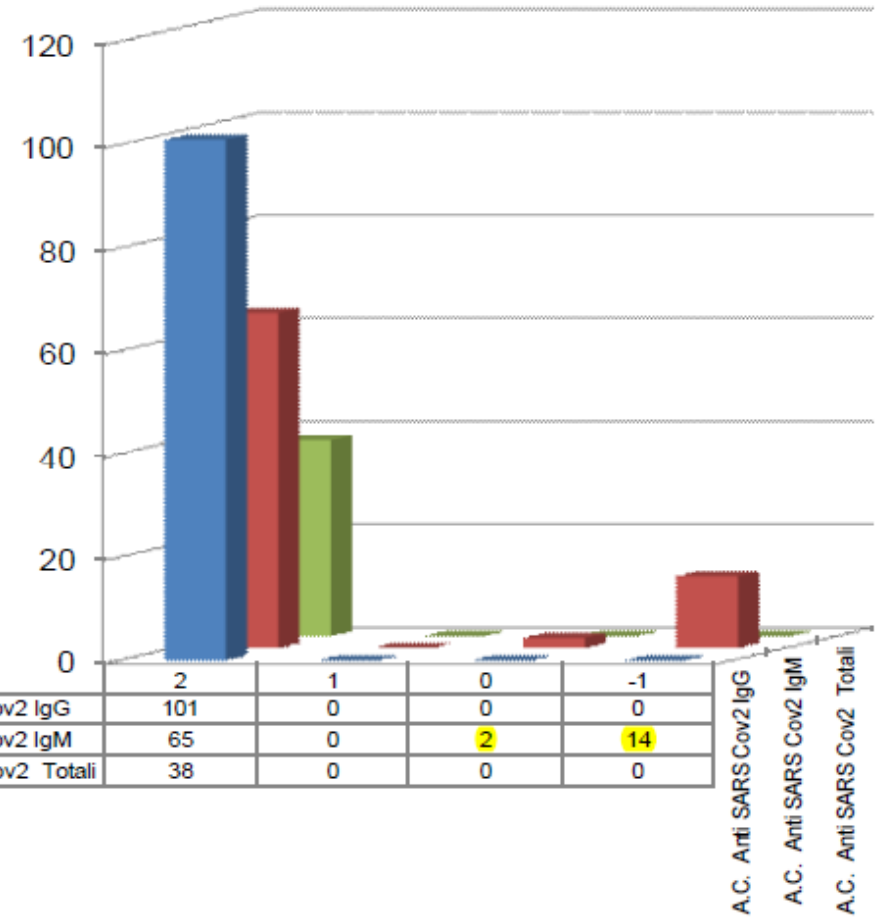
Positivo anti-SARS-CoV-2 IgG +IgM



	2	1	0	-1
A.C. Anti SARS Cov2 IgG	102	0	0	1
A.C. Anti SARS Cov2 IgM	61	0	0	23
A.C. Anti SARS Cov2 Totali	37	0	0	0

Campione n° 4

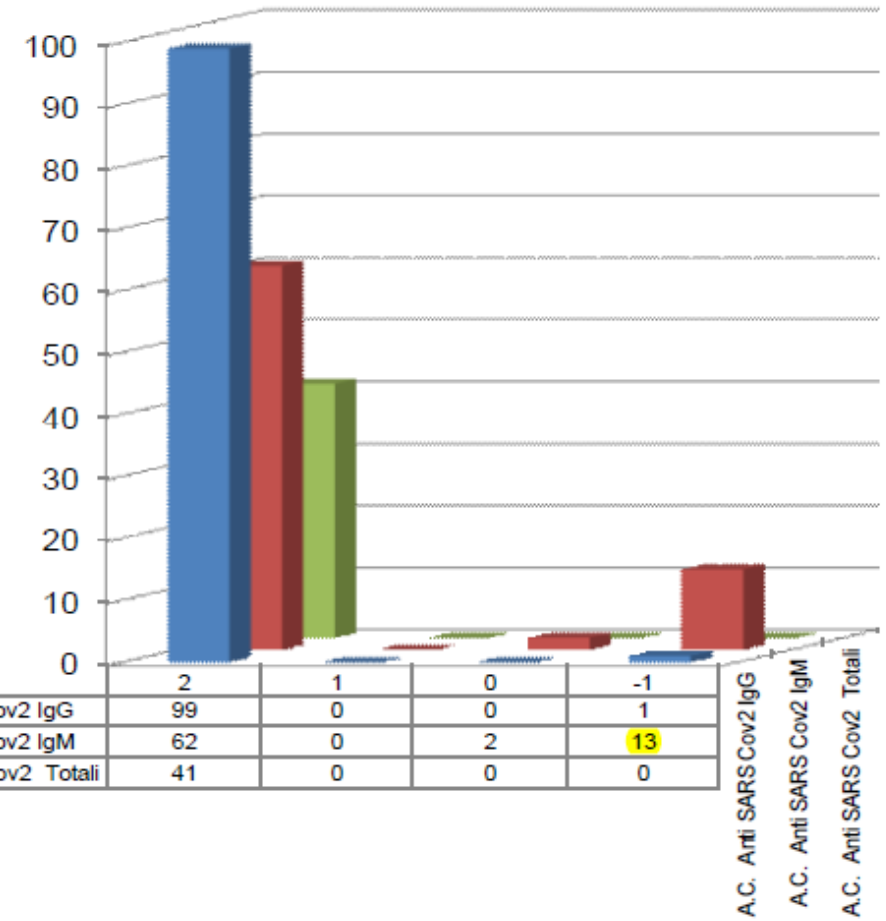
Positivo anti-SARS-CoV-2 IgG+IgM



	2	1	0	-1
A.C. Anti SARS Cov2 IgG	101	0	0	0
A.C. Anti SARS Cov2 IgM	65	0	2	14
A.C. Anti SARS Cov2 Totali	38	0	0	0

Campione n° 5

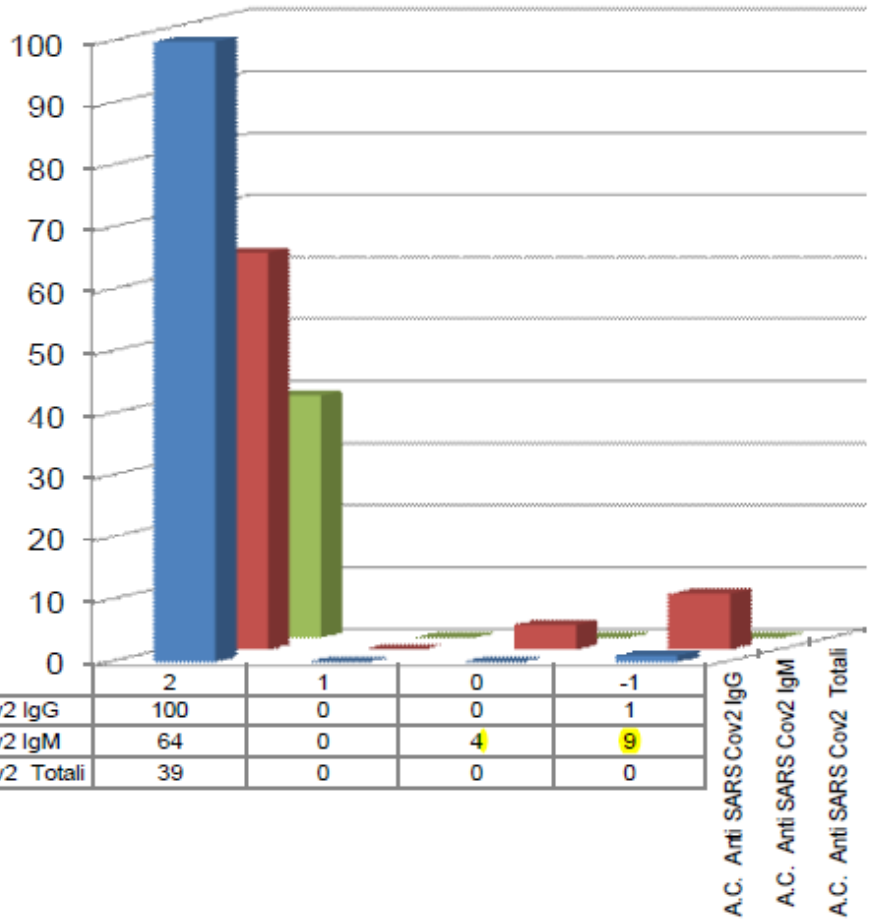
Positivo anti-SARS-CoV-2 IgG



	2	1	0	-1
A.C. Anti SARS Cov2 IgG	99	0	0	1
A.C. Anti SARS Cov2 IgM	62	0	2	13
A.C. Anti SARS Cov2 Totali	41	0	0	0

Campione n° 6

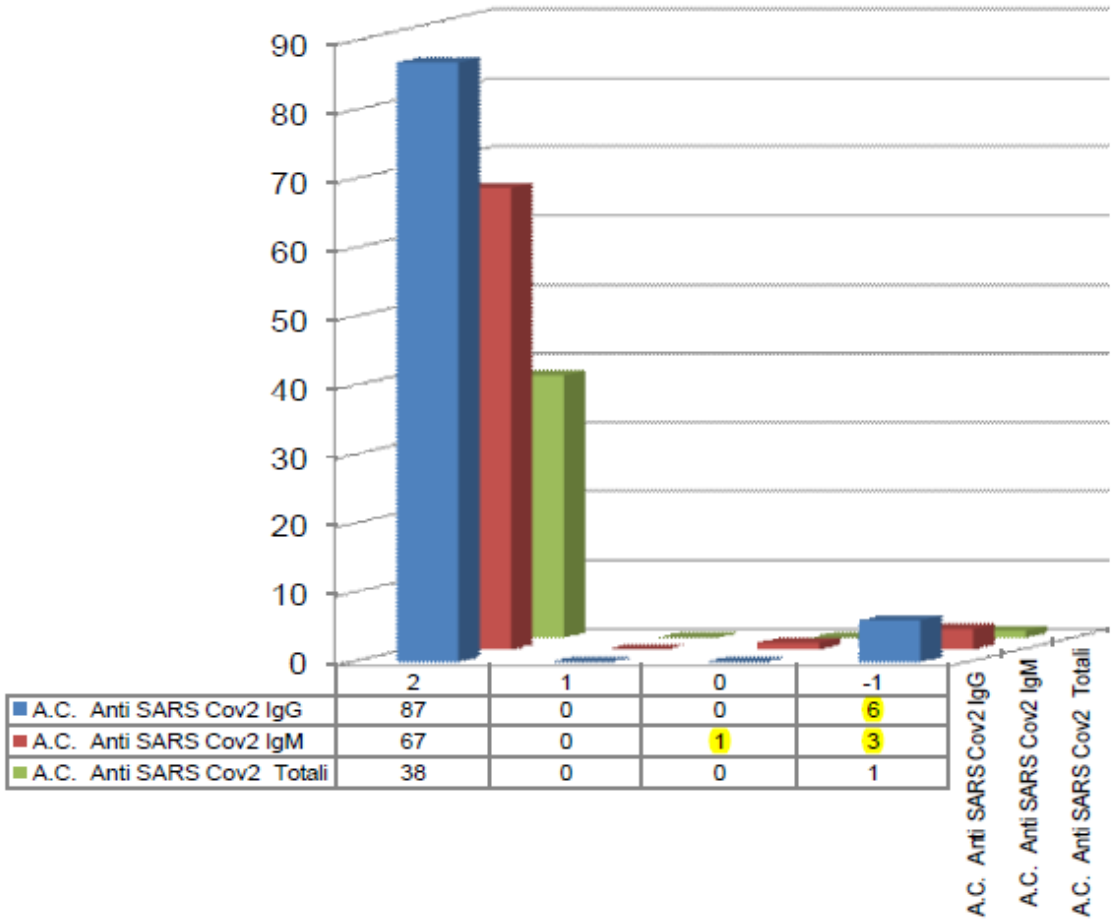
Positivo anti-SARS-CoV-2 IgG +IgM



	2	1	0	-1
A.C. Anti SARS Cov2 IgG	100	0	0	1
A.C. Anti SARS Cov2 IgM	64	0	4	9
A.C. Anti SARS Cov2 Totali	39	0	0	0

Campione n° 7

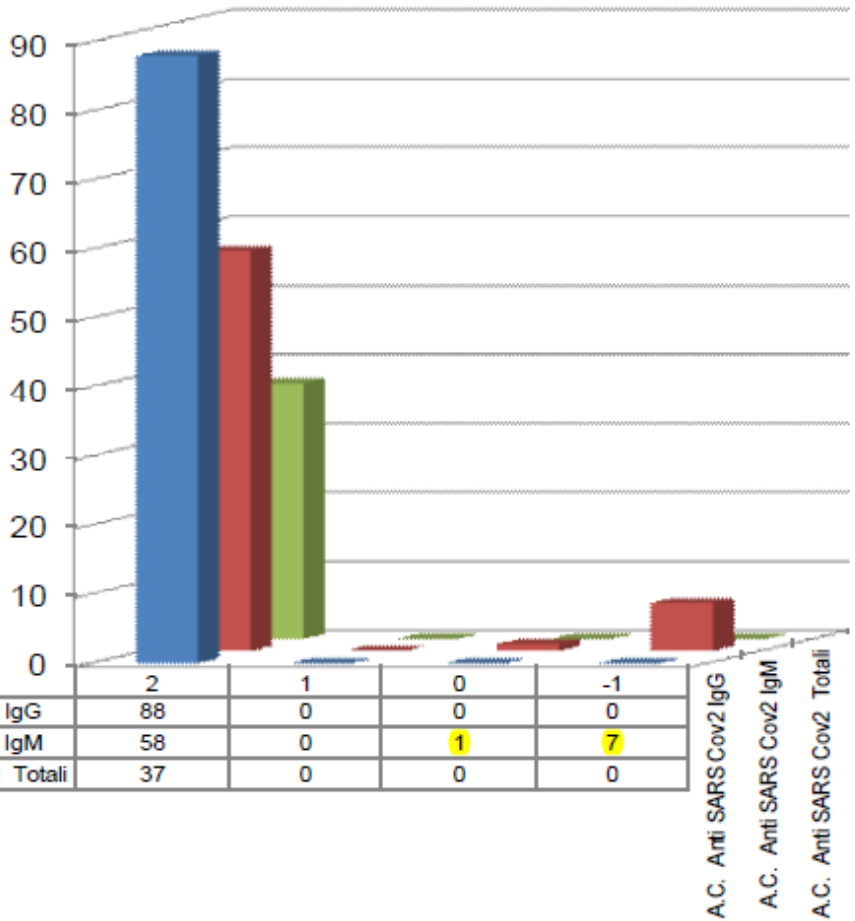
Positivo anti-SARS-CoV-2 IgG +IgM



	2	1	0	-1
A.C. Anti SARS Cov2 IgG	87	0	0	6
A.C. Anti SARS Cov2 IgM	67	0	1	3
A.C. Anti SARS Cov2 Totali	38	0	0	1

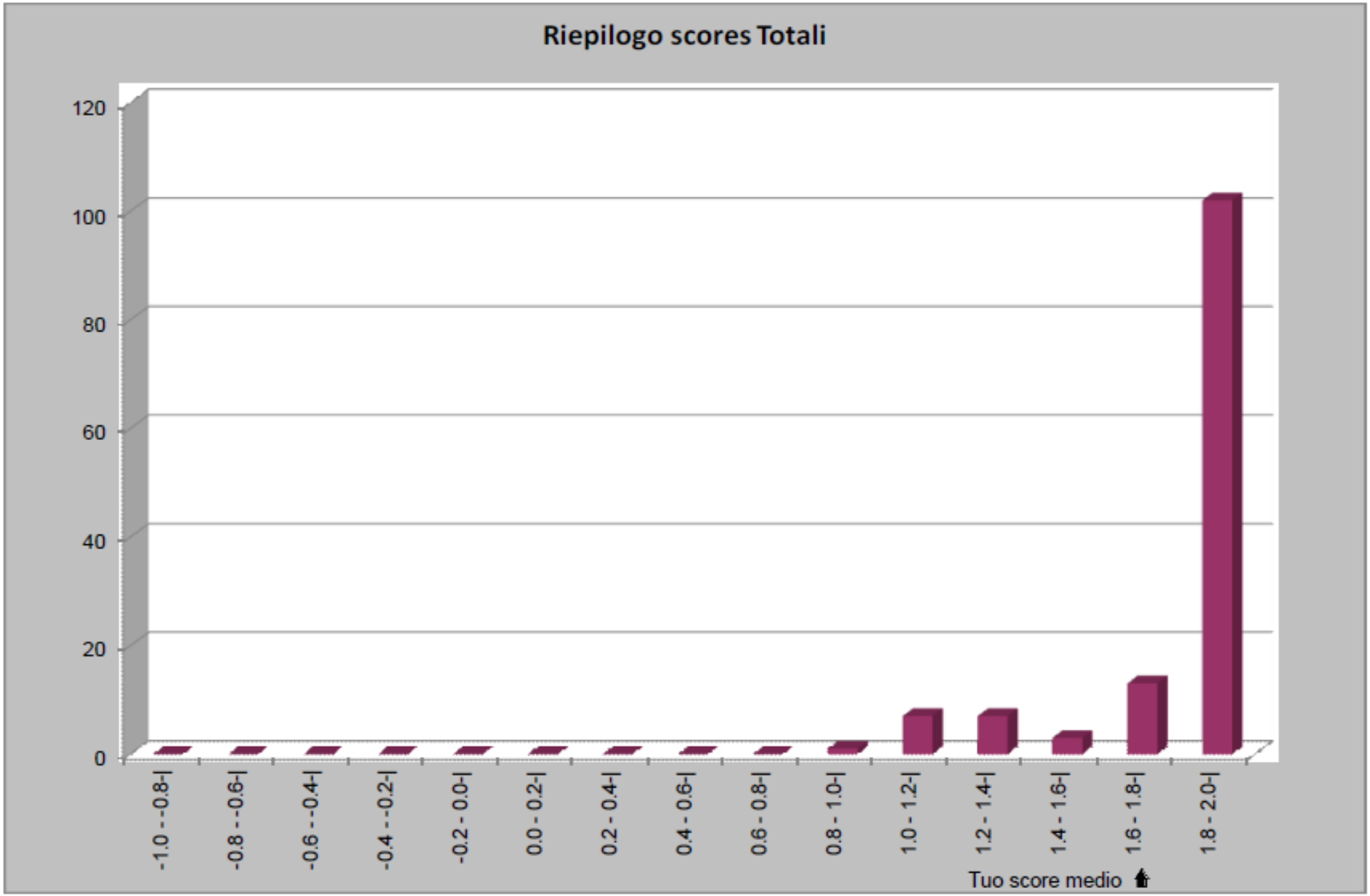
Campione n° 8

Positivo anti-SARS-CoV-2 IgG



	2	1	0	-1
A.C. Anti SARS Cov2 IgG	88	0	0	0
A.C. Anti SARS Cov2 IgM	58	0	1	7
A.C. Anti SARS Cov2 Totali	37	0	0	0

V.E.Q. in SIEROIMMUNOLOGIA SARS-CoV-2 Ciclo 2021 Riepilogo Score



UK NEQAS
Immunology, Immunochemistry & Allergy

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

UK NEQAS for SARS-CoV-2/COVID-19 Antibodies

Distribution : 203 Date : 11-Aug-2020

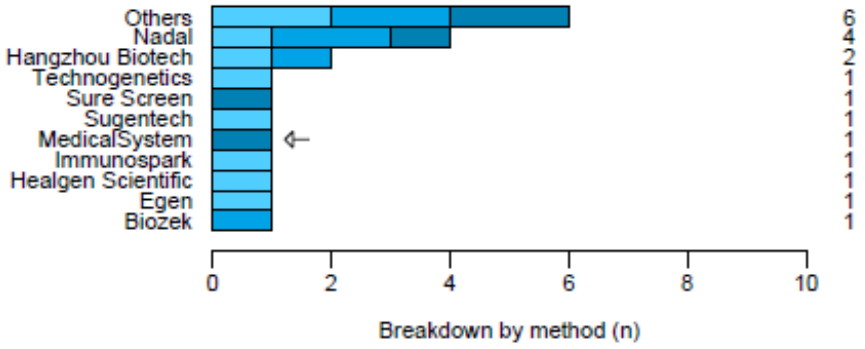
Specimen 203-2 - Qualitative

259 / 338 (77%) laboratories returned results for this distribution.
Sample 203-2 produced IgG positive results within all lateral flow devices utilised by participants. Results submitted for the IgM antibody did not however produce a clear consensus. Sample 203-2 will not be subject to MI scoring for the lateral flow section of this report.

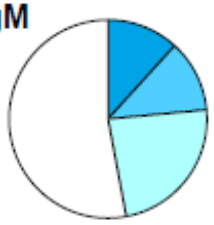
IgG

Strong Positive	25.0%	(5)
Moderate Positive	30.0%	(6)
Positive	45.0%	(9)
Equivocal	0.0%	(0)
Negative	0.0%	(0)

Your result: Strong Positive



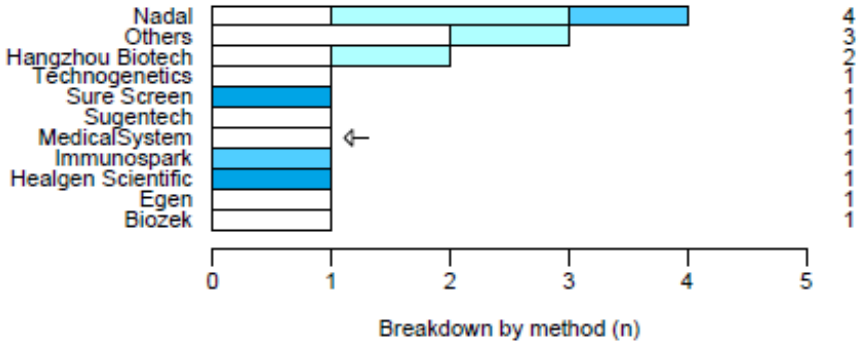
IgM



Strong Positive	0.0%	(0)
Moderate Positive	11.8%	(2)
Positive	11.8%	(2)
Equivocal	23.5%	(4)
Negative	52.9%	(9)

Your result: Negative

47.1% Positive
52.9% Negative

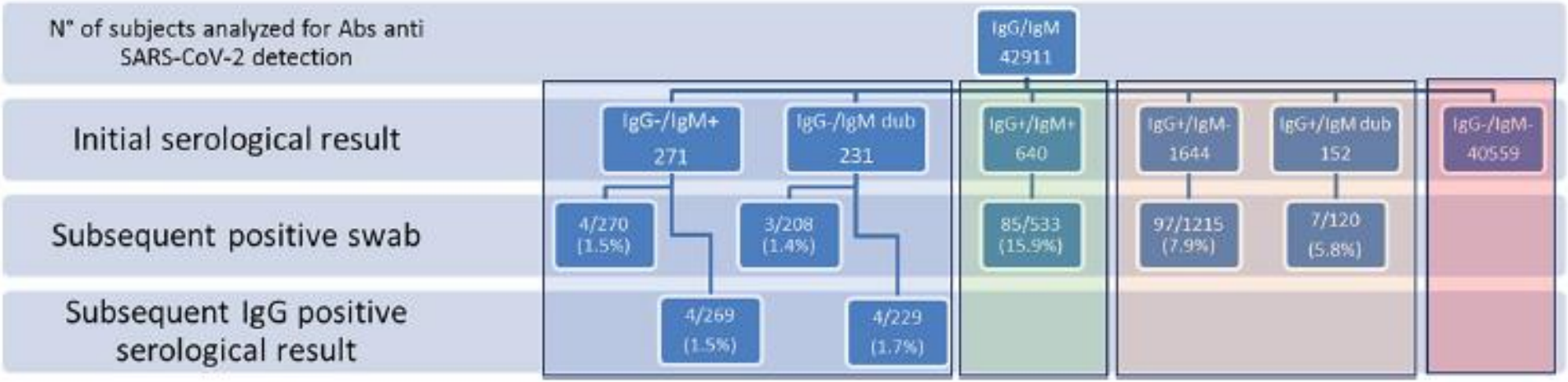


Internal and Emergency Medicine (2021) 16:2327–2330
https://doi.org/10.1007/s11739-021-02747-3

CE - LETTER TO THE EDITOR

IgM anti-SARS-CoV-2-specific determination: useful or confusing? Big Data analysis of a real-life scenario

Tommaso Trenti[1] · Valentina Pecoraro[1] · Tommaso Pirotti[1] · Mario Plebani[2]



Impact Factor 4.862

Clinical and Experimental
RHEUMATOLOGY

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Brief Paper

Lack of cross-reactivity between rheumatoid factor IgM and anti-S1 receptor binding domain of SARS-CoV-2 IgM: a case-control study

G. Pellegrino[1], S. Mancuso[2], T. Colasanti[3], S. Mieli[4], C. Gioia[5], R. Izzo[6], P. Pignatelli[7], M.R. Ciardi[8], C. Alessandri[9], F. Conti[10], V. Riccieri[11]

This study confirmed the lack of cross-reactivity between RF and anti-S1 RBD IgM, offering to clinicians a valuable tool for a better management of RA patients undergoing SARSCoV-2 serological tests

Main concepts

- Important to acknowledge differences between Ab response (interassays variability) against the different viral antigens.
- Anti-Spike Ab correlate better than anti-N Ab with neutralising activity
- Reliable serological assays are needed to understand the real impact of COVID-19 through sero-epidemiological studies.
- Development and harmonisation of serological assays for COVID-19 antibodies are important to evaluate the vaccine and treatment responses and to compare the multiple candidates.


Thank You
For Your Attention