

# INSTAND EQA Schemes for Anti-SARS-CoV-2 in 2020

**Heinz Zeichhardt<sup>1,2,3,4</sup>, Martin Kammel<sup>2,3</sup> and Hans-Peter Grunert<sup>4</sup>**

<sup>1</sup>Professor of Virology (i.R.)  
Charité – University Medicine Berlin

<sup>2</sup>INSTAND e.V. - Gesellschaft zur Förderung der Qualitätssicherung  
in medizinischen Laboratorien e.V, Düsseldorf

<sup>3</sup>IQVD GmbH - Institut für Qualitätssicherung in der Virusdiagnostik

<sup>4</sup>GBD Gesellschaft für Biotechnologische Diagnostik mbH, Berlin

Coronavirus Standards Working Group Meeting  
05 March 2021

# EQA Network

## Scientific umbrella

German Association for Prevention of Virus Diseases (DVV e.V.)

Society of Virology (GfV e.V.)

German Society for Hygiene and Microbiology (DGHM e.V.)

## Partners

### Berlin

Teams of

GBD Gesellschaft für Biotechnologische Diagnostik mbH, Berlin

Hans-Peter Grunert

Wolfgang Güthoff

Ulf Dühring

and

IQVD GmbH

Institut für Qualitätssicherung in der Virusdiagnostik, Berlin

and

### Düsseldorf

INSTAND-Team

and

38 INSTAND Expert Laboratories

incl.

Robert Koch-Institut

Paul-Ehrlich-Institut

National Reference and Consiliary Labs

and

**EMPIR**  
**AntiMicroResist**

**EMRP**  
European Metrology Research Programme  
Programme of EURAMET  
The EMRP is jointly funded by the EMRP participating countries within EURAMET and the European Union



**JRC – Joint Research Centre (BE)**

**LGC – National Measurement Laboratory (UK)**

**NIB – National Institute of Biology (SI)**

**PTB - Physikalisch-Technische Bundesanstalt (DE)**

and

**NIST - National Institute of Standards and Technology (USA)**

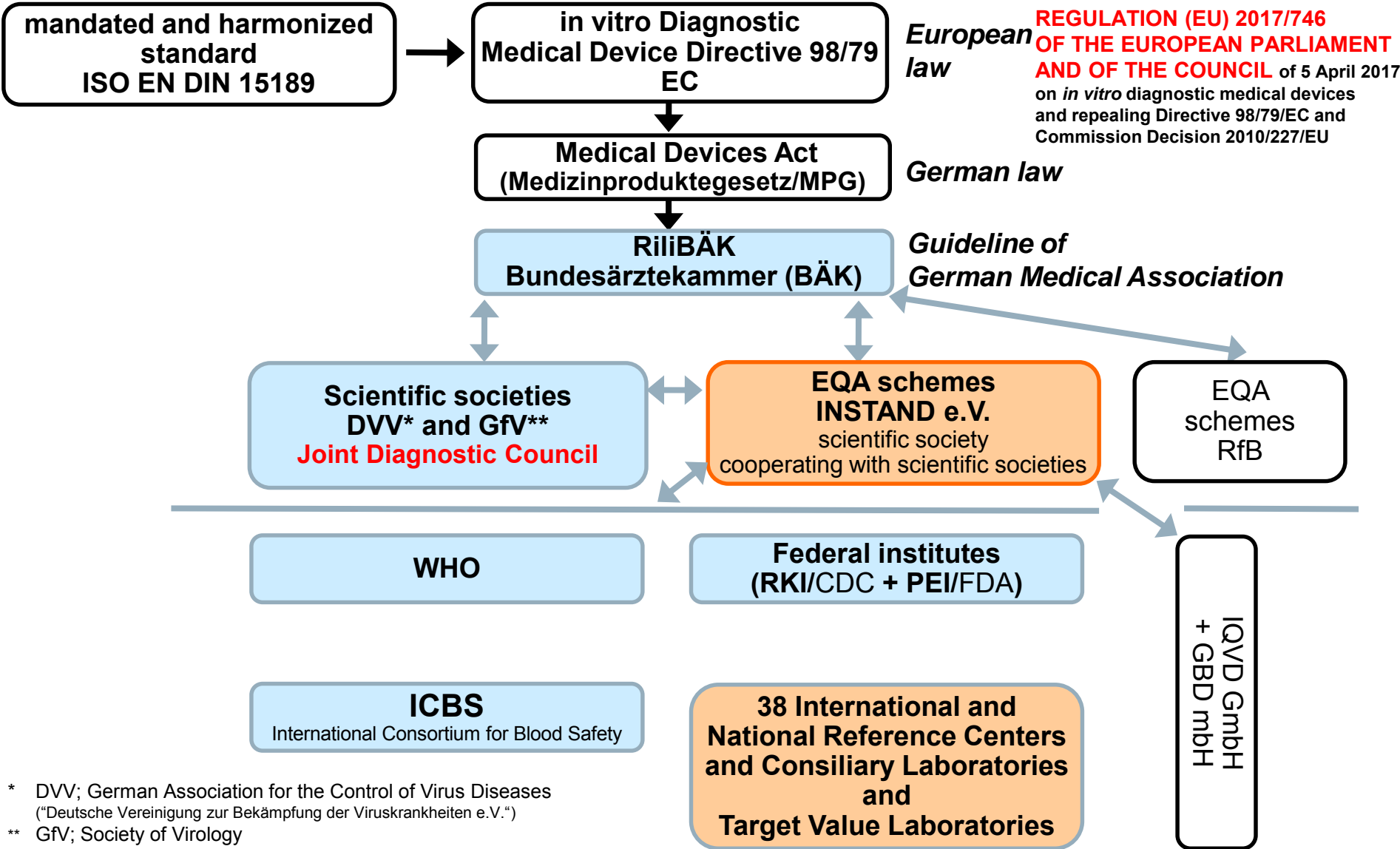
# Disclosure

Heinz Zeichhardt is share-holder and CEO  
of  
GBD Gesellschaft für Biotechnologische Diagnostik mbH, Berlin  
and  
IQVD GmbH - Institut für Qualitätssicherung in der Virusdiagnostik, Berlin

# Outlook

- INSTAND External Quality Assessment (EQA) Schemes
- EQAS for SARS-CoV-2 antibody detection
  - qualitative results - performance of laboratories with different tests
  - follow-up sera of the same patient with individual immune response
    - tests for IgG
    - antibodies against S and/or N antigen
    - tests for total ab
    - tests for IgA and/or IgM
- Pre-characterization of convalescent sera and sera of vaccinees
  - comparative results of qualitative and quantitative tests

# INSTAND e.V. - Quality Assurance in (Virus) Diagnostics



**REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

\* DVV; German Association for the Control of Virus Diseases ("Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V.")

\*\* GfV; Society of Virology ("Gesellschaft für Virologie e.V.")



# INSTAND e.V.

Gesellschaft zur Förderung der Qualitätssicherung  
in medizinischen Laboratorien e.V.

accredited by:



## INSTAND E.V. – A SCIENTIFIC SOCIETY COOPERATING WITH INTERNATIONAL AND NATIONAL SOCIETIES AND ORGANISATIONS

### International

14 Organisations / Scientific Societies

#### INTERNATIONAL

- Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS)
- EQAS/PT-Provider, QualiCont, Hungary
- European Committee for Standardization (CEN)
- European Organisation For External Quality Assurance Providers in Laboratory Medicine (EQALM)
- International Consortium for Blood Safety (ICBS)
- International Organisation for Standardisation (ISO)
- Joint Committee for Traceability in Laboratory Medicine (JCTLM)
- MQ Zürich Schweiz
- National Institute of Standards and Technology (NIST)
- Österreichische Gesellschaft für Qualitätssicherung und Standardisierung medizinisch-diagnostischer Untersuchungen (ÖQUASTA)
- Working Group HbA1c (IFCC)
- Working Group HbA2 (IFCC)
- World Association of Pathology and Laboratory Medicine (WASPaLM)
- World Health Organisation

- Deutsche Akkreditierungsstelle (DAkkS)
- Deutsche Dermatologische Gesellschaft e.V. (DDG)
- Deutsche Gesellschaft für Hämatologie und Onkologie e.V. (DGHO)
- Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V. (DGHM)
- Deutsche Gesellschaft für Immunogenetik e.V. (DGI)
- Deutsche Gesellschaft für Innere Medizin e.V. (DGIM)
- Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)
- Deutsche Gesellschaft für Liquordiagnostik und Klinische Neurochemie e.V. (DGLN)
- Deutsche Gesellschaft für Mineralstoffe und Spurenelemente e.V. (GMS)
- Deutsche Gesellschaft für Parasitologie e.V. (DGP)
- Deutsche Gesellschaft für Transfusionsmedizin und Immunhämatologie e.V. (DGTI)
- Deutsche Gesellschaft für Urologie e.V. (DGU)
- Deutsche Gesellschaft für Zytologie e.V. (DGZ)
- Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV)
- Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin e.V. (DGKL)
- Deutschsprachige Mykologische Gesellschaft e.V. (DMyKG)
- DIN - Deutsches Institut für Normung with special activities in „Normenausschuss Medizin“
- Gesellschaft für Thrombose und Hämostaseforschung e.V. (GTH)
- Gesellschaft für Virologie e.V. (GFV)
- National organisations for technical assistants and continuous education (dvta and diw-mta e.V.)
- Physikalisch-Technische Bundesanstalt (PTB)
- Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)

### National

28 Organisations / Scientific Societies

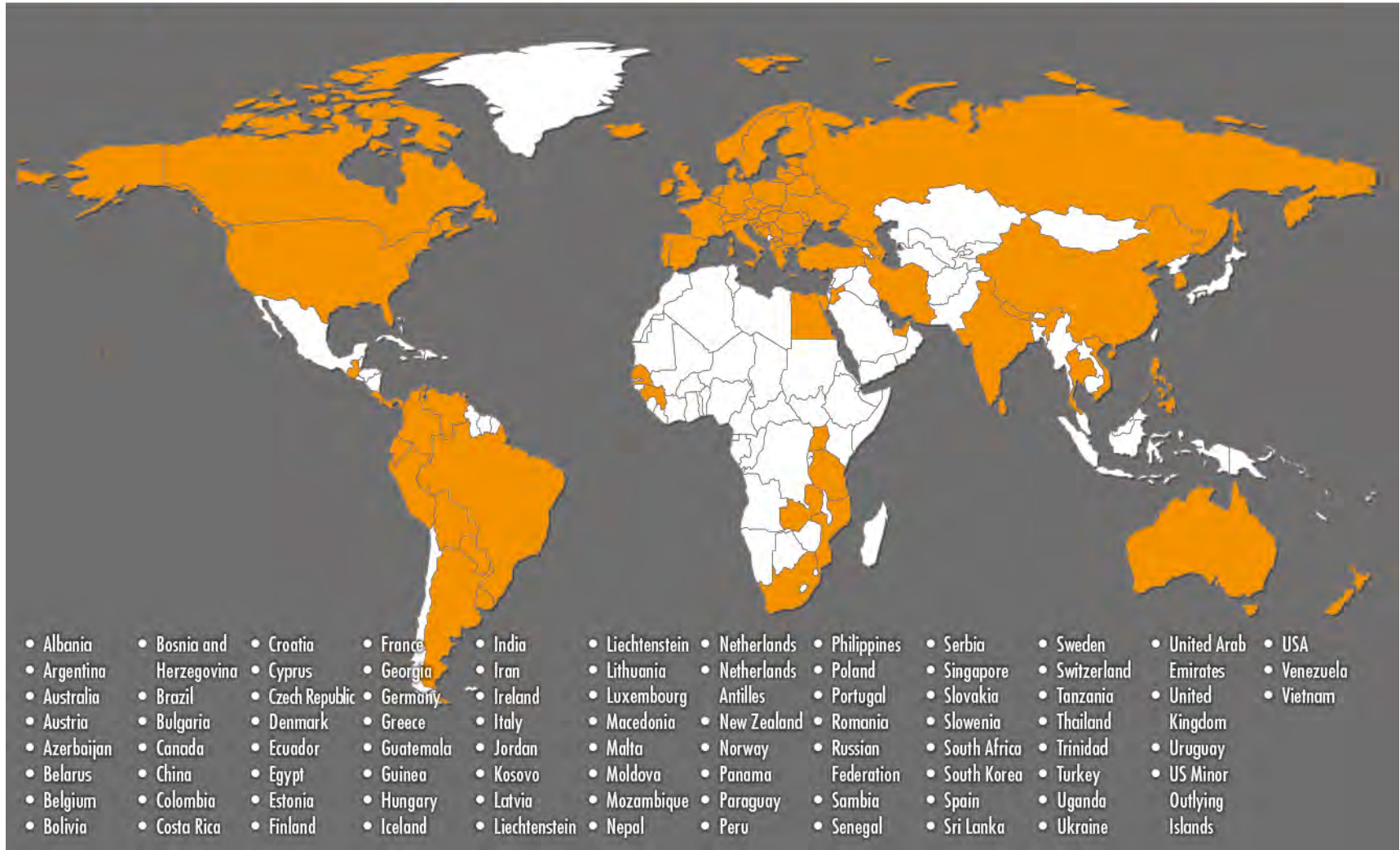
#### NATIONAL

- Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (AWMF)
- Arbeitsgruppe Therapeutisches Drug Monitoring (AGTDM) der Arbeitsgemeinschaft Neuropsychopharmakologie und Pharmakopsychiatrie e.V. (AGNP e.V.)
- Arbeitskreis Mykobakterien (AKM)
- Ärzteverband Deutscher Allergologen e.V. (AeDA)
- Berufsverband Deutscher Dermatologen e.V. (BVDD)
- Bundesärztekammer (BÄK, German Medical Association)



# INSTAND e.V.

## Cooperation with participants from more than 80 Countries



# INSTAND e.V.

Immunohaematology  
(41)

Autoimmune diseases (57)

Haemostasis  
(54)

Haematology  
(54)

Clinical chemistry  
(43)

Trace elements  
(50)

Pharmaceuticals and drugs  
(152)

> 350

Programs

Virtual EQA schemes  
(3)

Virology  
(81)

Bacteriology / serology  
(47)

Bacterial genome detection  
(19)

Parasitology  
(8)

Mycology  
(7)

Molecular diagnostics  
(90)

POCT  
(34)

EQAS in virus diagnostics – 2020/2021:

- > 2200 participating laboratories
- from approx. 70 countries worldwide



# INSTAND EQA Schemes (81 Schemes) in Virus Immunology and Genome Detection 2020/2021

Serology and Antigen Detection		Virus Genome Detection and Typing	
HIV-1/2	Herpes simplex Viruses	HIV-1 (RNA) HIV-2 (RNA)	Measles Rubella Mumps Viruses
HIV-1 p24 Ag	Varicella Zoster Virus	HIV-1 Resistance + Tropism	Adenoviruses
HTLV-1/2	Epstein Barr Virus	Hepatitis A Virus	Norovirus Rotavirus
Hepatitis A Virus	Resp. Sync. Virus Ag	Hepatitis B Virus + Genotyping + Resistance	CoV incl. MERS CoV, <b>SARS-CoV-2 incl. VOC NEW</b>
Hepatitis B Virus, Prg. I	Influenza A and B Ag + A/H1N1 pdm 2009 + A/H5N1+A/H7N9	Hepatitis C Virus + Genotyping + Resistance	Enteroviruses + Enterovirus (WHO/RKI) Parechovirus <b>NEW</b>
Hepatitis B Virus, Prg. II	Rubella Virus Measles Virus Mumps Virus	Hepatitis D Virus Hepatitis E Virus	Human Rhinoviruses Resp. Syncytial Virus Hum. Metapneumovirus Parainfluenza viruses
Hepatitis C Virus	TBE Virus	Torque Teno Virus <b>NEW</b>	Influenza A and B incl avian
Hepatitis D Virus	Hantavirus	Cytomegalovirus + Resistance	BK Virus JC Virus
Hepatitis E Virus	Dengue Virus Chikungunya Virus Zika Virus	Epstein-Barr Virus Herpes simplex Viruses HHV-6 <b>NEW</b> HHV-8 <b>NEW</b>	Dengue Virus West Nile Virus Chikungunya Virus Zika Virus
Parvovirus B19	Rabies Virus	Varicella Zoster Virus	Hum. Papilloma Viruses
Cytomegalovirus	Borna Virus <b>NEW</b>	Parvovirus B19	Rabies Virus
<b>SARS-CoV-2 (Ab) NEW</b>	BSE (PrPsc) (2002-2007)	Multiplex: Respiratory Viruses (2 programs)	Multiplex: <b>NEW</b> Viral Meningitis/Encephalitis
<b>SARS-CoV-2 (Ag) NEW =&gt; 2021</b>		Multiplex: Gastrointestinal Viruses	Borna Viruses <b>NEW</b>

# INSTAND EQA Schemes - SARS-CoV-2 Diagnostics

	2020	2021
(340) Virus genome detection - SARS-CoV-2	Apr	
(340) Virus genome detection - coronaviren incl. differentiation SARS-CoV-2 / MERS / different HCoVs	Jun + Nov	Jun + Nov
(409) Virus genome detection - SARS-CoV-2		Mrz + Jun + Sep + Nov <b>NEW</b> with VOC differentiation by point mutation analysis and sequencing
(431 und 432) Virus genome detection – respiratory virus panel 1 and panel 2 for multiplex tests incl. SARS-CoV-2	Jun + Nov	Jun + Nov
(410) <b>NEW</b> – Antigen detection - SARS-CoV-2 for rapid tests and automated immuno assays		Mrz + Jun + Sep + Nov
(416) Detection of anti-SARS-CoV-2 (total, IgG, avidity, IgA and IgM)	Jun + Sep + Nov	Mrz + Jun + Sep + Nov
(7340) Cooperation RKI – Charité Consultant Lab CoV and INSTAND e.V. Quantitative comparison samples (QS) für SARS-CoV-2 QS 1 – 10E7 copies/ml, QS 2 – 10E6 copies/ml	3. Nov + 17. Nov	15. Jan + 17. Feb. + ...

# Outlook

- INSTAND External Quality Assessment (EQA) Schemes
- EQAS for SARS-CoV-2 antibody detection
  - qualitative results - performance of laboratories with different tests
  - follow-up sera of the same patient with individual immune response
    - tests for IgG
    - antibodies against S and/or N antigen
    - tests for total ab
    - tests for IgA and/or IgM
- Pre-characterization of convalescent sera and sera of vaccinees
  - comparative results of qualitative and quantitative tests

# INSTAND EQA Scheme (416)

## Virus Immunology - SARS-CoV-2 (ab)

### Cooperation partner

National Consultant Laboratory for Coronaviruses  
Institute of Virology, Charité – University Medicine Berlin, Campus Charité Mitte  
Christian Drosten  
Victor M. Corman  
Daniela Niemeyer

### Expert Laboratories

Medizinisches Infektiologiezentrum  
Berlin - MIB (DE)  
Martin Obermeier  
Robert Ehret

Medizinisches  
Versorgungszentrum Labor 28,  
Berlin (DE)  
Ralf Ignatius  
Heike Kietzmann

Paul-Ehrlich-Institut  
Bundesinstitut für Impfstoffe und  
biomedizinische Arzneimittel  
Prüflabor für IVD, Langen (DE)  
Heiner Scheiblauer

Uniklinik Köln,  
Institut für Virologie  
Nationales Referenzzentrum für  
Papillom- und Polyomaviren (DE)  
Florian Klein  
Rolf Kaiser  
Ulrike Wieland  
Steffi Silling  
Eva Heger  
Elena Knops

Universität Würzburg  
Institut für Virologie und  
Immunbiologie (DE)  
Benedikt Weißbrich

Universitätsklinikum Frankfurt,  
Institut für Medizinische Virologie (DE)  
Sandra Ciesek  
Holger F. Rabenau  
Annemarie Berger

Universitätsklinikum Regensburg  
Institut für Medizinische  
Mikrobiologie und Hygiene  
André Gessner

# INSTAND EQA Scheme (416)

## Virus Immunology - SARS-CoV-2 (ab)

### Overview EQA schemes performed 2020

EQAS term	number of subgroups	28 panel members	number of laboratories having reported results*	number of countries
May/June 2020	3	12	385	27
September 2020	2	8	279	23
November 2020	2	8	327	21

\*each lab assigned to one subgroup with 4 panel members

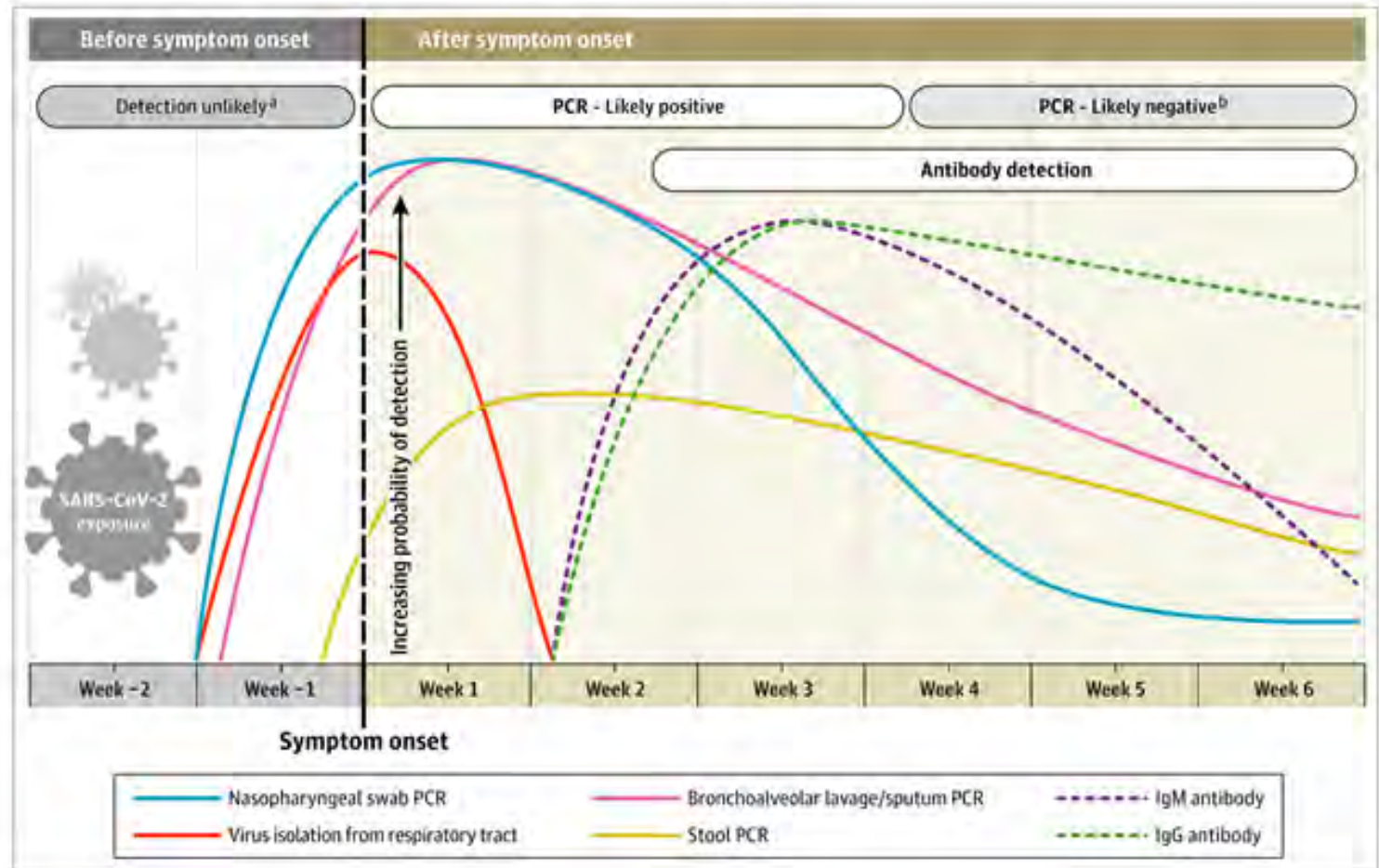
#### for each of the 28 panel members:

native patient serum or patient plasma (not re-calcified) from one individual donor only

- serum from patients after SARS-CoV-2 infection (PCR confirmed)
- serum/plasma from patients after HCoV infection (PCR confirmed)
- serum from healthy blood donors from 2015 and earlier

# From: Interpreting Diagnostic Tests for SARS-CoV-2

JAMA. Published online May 06, 2020. doi:10.1001/jama.2020.8259



Published online May 06, 2020.

<http://jamanetwork.com/article.aspx?doi=10.1001/jama.2020.8259>



# INSTAND EQA Scheme (416) Anti-SARS-CoV-2

## Results for Specificity Samples

### Blood Donations 2011 - 2015

EQA scheme	Sample	Sample source	Time after onset of disease	Success rate for the detection of anti-SARS-CoV-2			
				Ab total	IgG	IgA	IgM
May/June 20	416002	healthy blood donor from 2015	----	negative 98.2% (55/56)	negative 98.2% (168/171)	negative 100% (62/62)	negative 100% (35/35)
May/June 20	416008	healthy blood donor from 2015	----	negative 100% (45/45)	negative 99.4% (155/156)	negative 98.0% (48/49)	negative 100% (51/51)
May/June 20	416009	healthy blood donor from 2015	----	negative 100% (46/46)	negative 97.9% (143/146)	negative 100% (46/46)	negative 100% (43/43)
Sep 20	416015	healthy blood donor from 2015	----	negative 98.5% (64/65)	negative 98.9% (174/176)	negative 98.5% (67/68)	negative 100% (27/27)
Sep 20	416017	healthy blood donor from 2015	----	negative 95.2% (40/42)	negative 97.0% (130/134)	negative 100% (25/25)	negative 93.1% (67/72)
Nov 20	416026	healthy blood donor from 2011	----	negative 98.4% (62/63)	negative 99.0% (191/193)	negative 98.7% (74/75)	negative 100% (39/39)
Nov 20	416032	healthy blood donor from 2013	----	negative 100% (59/59)	negative 97.3% (142/146)	negative 92.5% (37/40)	negative 100% (64/64)

7 sera of German healthy blood donors (2011 – 2015):  
Specificity (negative for anti-SARS-CoV-2) shown in 98 tests of 45 manufacturers

# INSTAND EQA Scheme (416) Anti-SARS-CoV-2

## Results for Specificity Samples

### Anti-Human CoVs - 229E, OC43 and HKU1

EQA scheme	Sample	Sample source	Time after onset of disease	Success rate for the detection of anti-SARS-CoV-2			
				Ab total	IgG	IgA	IgM
May/June 20	416004	patient 3 after HCoV 229E infection	3 months	negative 100% (56/56)	negative 99.4% (170/171)	negative 95.2% (59/62)	negative 97.1% (34/35)
May/June 20	416006	patient 5 after HCoV OC43 and HCoV HKU1, respectively	2 years and 5 years, respectively	negative 100% (45/45)	negative 99.4% (155/156)	negative 83.7% (41/49)	negative 90.2% (46/51)
May/June 20	416012	patient 9 after HCoV HKU1 infection	3 months	negative 97.8% (45/46)	negative 97.9% (143/146)	negative 89.1% (41/46)	negative 97.7% (42/43)

3 sera of donors previously infected with HCoVs:

Specificity (negative for anti-SARS-CoV-2) shown in 48 tests of 27 manufacturers

# INSTAND EQA Scheme (416) Anti-SARS-CoV-2 – Nov 2020

## individual patient response – example patient 16 (N > S)

EQA scheme	Sub-group (SG)	Sample	Sample source all infections PCR confirmed	Time after onset of disease	Success rate for the detection of anti-SARS-CoV-2			
					Ab total	IgG	IgA	IgM
Nov 20	SG 1	416028	<b>patient 16 after SARS-CoV-2 infection (1st blood collection)</b>	<b>65 days</b>	<b>positive 96.8% (61/63)</b>	<b>positive 96.4% (186/193)</b>	<b>positive/ borderline 85.3% (64/75)</b>	<b>not evaluated</b>
Nov 20	SG 1	416025	<b>patient 16 after SARS-CoV-2 infection (2nd blood collection)</b>	<b>169 days</b>	<b>positive/ borderline 95.2% (60/63)</b>	<b>not evaluated</b>	<b>not evaluated</b>	<b>not evaluated</b>
Nov 20	SG 1	416027	patient 17 after SARS-CoV-2 infection	49 days	positive 100% (63/63)	positive 99.5% (192/193)	positive/ borderline 93.3% (70/75)	not evaluated
Nov 20	SG 1	416026	healthy blood donor from 2011	----	negative 98.4% (62/63)	negative 99.0% (191/193)	negative 98.7% (74/75)	negative 100% (39/39)
Nov 20	SG 2	416031	patient 18 after SARS-CoV-2 infection (1st blood collection)	75 days	positive 100% (59/59)	positive 97.9% (143/146)	positive 85.0% (34/40)	not evaluated
Nov 20	SG 2	416029	patient 18 after SARS-CoV-2 infection (2nd blood collection)	154 days	positive 100% (59/59)	positive 88.4% (129/146)	positive 85.0% (34/40)	not evaluated
Nov 20	SG 2	416030	patient 19 after SARS-CoV-2 infection	65 days	positive 100% (59/59)	positive 99.3% (145/146)	positive 82.5% (33/40)	negative 93.8% (60/64)
Nov 20	SG 2	416032	healthy blood donor from 2013	----	negative 100% (59/59)	negative 97.3% (142/146)	negative 92.5% (37/40)	negative 100% (64/64)

# INSTAND EQA Scheme (416) Anti-SARS-CoV-2 – Nov 2020

## individual patient response – example patient 16 (N > S)

EQA scheme	Sub-group (SG)	Sample	Sample source all infections PCR confirmed	Time after onset of disease	Success rate for the detection of anti-SARS-CoV-2			
					Ab total	IgG	IgA	IgM
Nov 20	SG 1	416028	<u>patient 16 after SARS-CoV-2 infection (1st blood collection)</u>	<u>65 days</u>	positive 96.8% (61/63)	positive 96.4% (186/193)	positive/ borderline 85.3% (64/75)	not evaluated
Nov 20	SG 1	416025	<u>patient 16 after SARS-CoV-2 infection (2nd blood collection)</u>	<u>169 days</u>	positive/ borderline 95.2% (60/63)	not evaluated	not evaluated	not evaluated

# INSTAND EQA Scheme (416) Anti-SARS-CoV-2 – Nov 2020

## individual patient response – example patient 16 (N > S)

patient 16 - 1st blood collection **65 days** after SARS-CoV-2 infection

patient 16 - 2nd blood collection **169 days** after SARS-CoV-2 infection

Parameter 10: Anti-SARS-CoV-2 IgG

Reagent	Testkit	Total (N=193)	negative (N=3)	borderline (N=4)	positive (N=186)	Quota (96,4%)
<b>Immuno fluorescence</b>						
IN-HOUSE PRODUCTION						
		1	0	0	1	100,00%
		1	0	0	1	100,00%
<b>Immunoblot</b>						
TEST-LINE						
	Microblot-Array COVID-19 IgG	1	0	0	1	100,00%
VIRAMED						
	SARS-CoV-2 ViraChip IgG	3	0	1	2	66,67%
		4	0	1	3	75,00%
<b>Immunological test (CLIA)</b>						
DIASORIN	LIAISON SARS-CoV-2 S1/S2 IgG	30	0	0	30	100,00%
SHENZHEN YHLO BIOTECH CO	iFlash-SARS-CoV-2 IgG	2	0	0	2	100,00%
SIEMENS MED.SOLUT.DIAG	ADVIA Centaur SARS-CoV-2 IgG	2	1	0	1	50,00%
SNIBE DIAGNOSTICS	Maglumi 2019-nCov IgG	2	0	0	2	100,00%
SNIBE DIAGNOSTICS	Maglumi SARS-CoV-2 S-RBD IgG	3	0	0	3	100,00%
VIRCELL	COVID-19 VirClia IgG Monotest	3	0	0	3	100,00%
		42	1	0	41	97,62%
<b>Immunological test (CMIA)</b>						
ABBOTT	ARCHITECT SARS-CoV-2 IgG	23	0	0	23	100,00%
ABBOTT	Alinity i SARS-CoV-2 IgG	5	0	0	5	100,00%
		28	0	0	28	100,00%

■  
■  
■

Parameter 10: Anti-SARS-CoV-2 IgG not evaluated

Reagent	Testkit	Total (N=193)	negative (N=105)	borderline (N=13)	positive (N=75)	Quota
<b>Immuno fluorescence</b>						
IN-HOUSE PRODUCTION						
		1	0	0	1	
		1	0	0	1	
<b>Immunoblot</b>						
TEST-LINE						
	Microblot-Array COVID-19 IgG	1	0	0	1	
VIRAMED						
	SARS-CoV-2 ViraChip IgG	3	1	1	1	
		4	1	1	2	
<b>Immunological test (CLIA)</b>						
DIASORIN	LIAISON SARS-CoV-2 S1/S2 IgG	30	28	1	1	
SHENZHEN YHLO BIOTECH CO	iFlash-SARS-CoV-2 IgG	2	0	0	2	
SIEMENS MED.SOLUT.DIAG	ADVIA Centaur SARS-CoV-2 IgG	2	2	0	0	
SNIBE DIAGNOSTICS	Maglumi 2019-nCov IgG	2	0	0	2	
SNIBE DIAGNOSTICS	Maglumi SARS-CoV-2 S-RBD IgG	3	0	0	3	
VIRCELL	COVID-19 VirClia IgG Monotest	3	0	0	3	
		42	30	1	11	
<b>Immunological test (CMIA)</b>						
ABBOTT	ARCHITECT SARS-CoV-2 IgG	23	0	0	23	
ABBOTT	Alinity i SARS-CoV-2 IgG	5	0	0	5	
		28	0	0	28	

■  
■  
■



# INSTAND EQA Scheme (416) Anti-SARS-CoV-2 – Nov 2020

## individual patient response – example patient 16 (N > S)

patient 16 - 1st blood collection **65 days** after SARS-CoV-2 infection

patient 16 - 2nd blood collection **169 days** after SARS-CoV-2 infection

Parameter 10: Anti-SARS-CoV-2 IgG

Reagent	Testkit	Total (N=193)	negative (N=3)	borderline (N=4)	positive (N=186)	Quota (96,4%)
<b>Immuno fluorescence</b>						
IN-HOUSE PRODUCTION						
		1	0	0	1	100,00%
		1	0	0	1	100,00%
<b>Immunoblot</b>						
TEST-LINE						
	Microblot-Array COVID-19 IgG	1	0	0	1	100,00%
VIRAMED						
	SARS-CoV-2 ViraChip IgG	3	0	1	2	66,67%
		4	0	1	3	75,00%
<b>Immunological test (CLIA)</b>						
DIASORIN	LIAISON SARS-CoV-2 S1/S2 IgG	30	0	0	30	100,00%
SHENZHEN YHLO BIOTECH CO	iFlash-SARS-CoV-2 IgG	2	0	0	2	100,00%
SIEMENS MED.SOLUT.DIAG	ADVIA Centaur SARS-CoV-2 IgG	2	1	0	1	50,00%
SNIBE DIAGNOSTICS	Maglumi 2019-nCov IgG	2	0	0	2	100,00%
SNIBE DIAGNOSTICS	Maglumi SARS-CoV-2 S-RBD IgG	3	0	0	3	100,00%
VIRCELL	COVID-19 VirClia IgG Monotest	3	0	0	3	100,00%
		42	1	0	41	97,62%
<b>Immunological test (CMIA)</b>						
ABBOTT	ARCHITECT SARS-CoV-2 IgG	23	0	0	23	100,00%
ABBOTT	Alinity i SARS-CoV-2 IgG	5	0	0	5	100,00%
		28	0	0	28	100,00%

Parameter 10: Anti-SARS-CoV-2 IgG not evaluated

Reagent	Testkit	Total (N=193)	negative (N=105)	borderline (N=13)	positive (N=75)	Quota
<b>Immuno fluorescence</b>						
IN-HOUSE PRODUCTION						
		1	0	0	1	
		1	0	0	1	
<b>Immunoblot</b>						
TEST-LINE						
	Microblot-Array COVID-19 IgG	1	0	0	1	
VIRAMED						
	SARS-CoV-2 ViraChip IgG	3	1	1	1	
		4	1	1	2	
<b>Immunological test (CLIA)</b>						
DIASORIN	LIAISON SARS-CoV-2 S1/S2 IgG	30	28	1	1	
SHENZHEN YHLO BIOTECH CO	iFlash-SARS-CoV-2 IgG	2	0	0	2	
SIEMENS MED.SOLUT.DIAG	ADVIA Centaur SARS-CoV-2 IgG	2	2	0	0	
SNIBE DIAGNOSTICS	Maglumi 2019-nCov IgG	2	0	0	2	
SNIBE DIAGNOSTICS	Maglumi SARS-CoV-2 S-RBD IgG	3	0	0	3	
VIRCELL	COVID-19 VirClia IgG Monotest	3	0	0	3	
		42	30	1	11	
<b>Immunological test (CMIA)</b>						
ABBOTT	ARCHITECT SARS-CoV-2 IgG	23	0	0	23	
ABBOTT	Alinity i SARS-CoV-2 IgG	5	0	0	5	
		28	0	0	28	



NCP and S protein  
S protein  
NCP





# INSTAND EQA Scheme (416) Anti-SARS-CoV-2 – Nov 2020

## individual patient response – example patient 16 (N > S)

patient 16 - 1st blood collection **65 days**  
after SARS-CoV-2 infection

patient 16 - 2nd blood collection **169 days**  
after SARS-CoV-2 infection



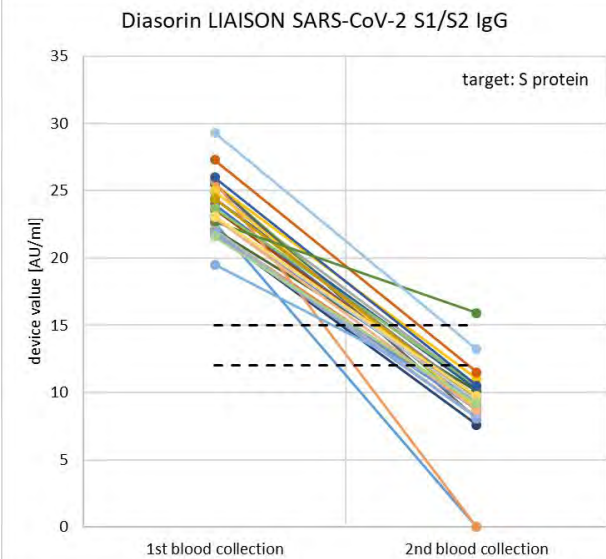
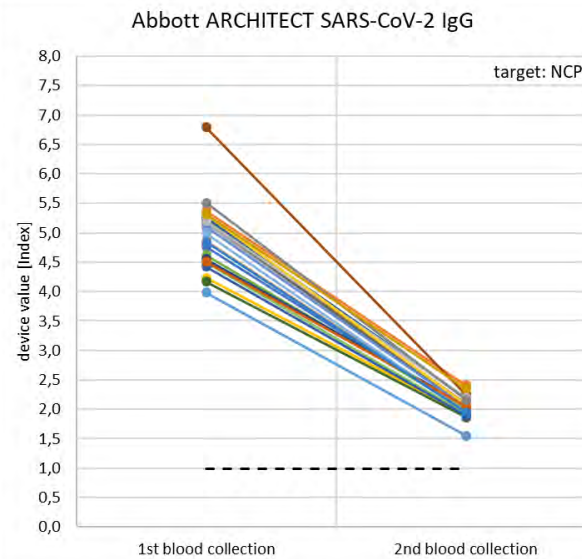
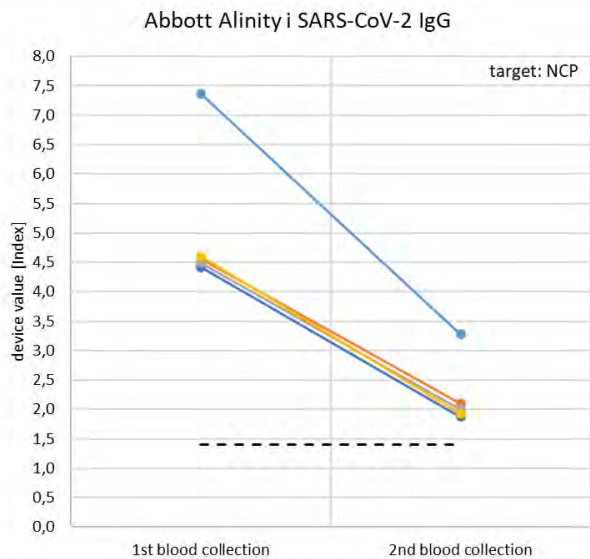
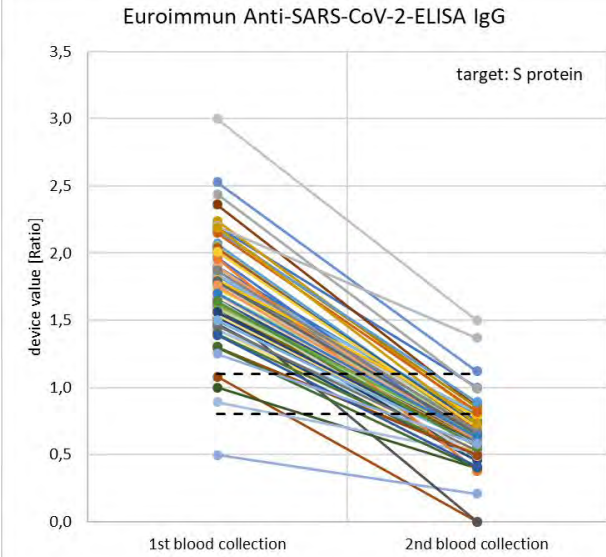
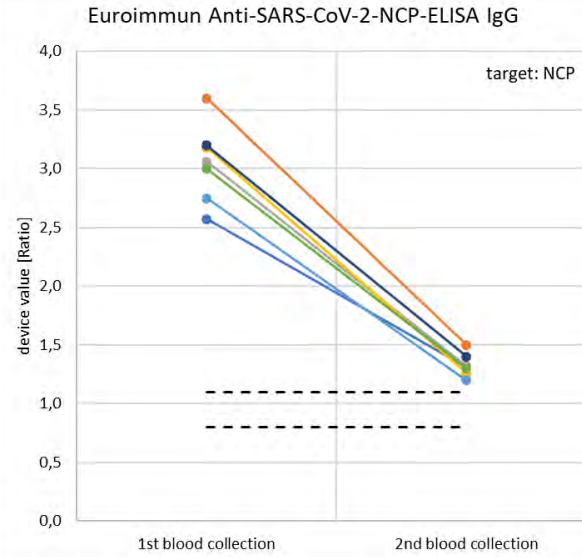
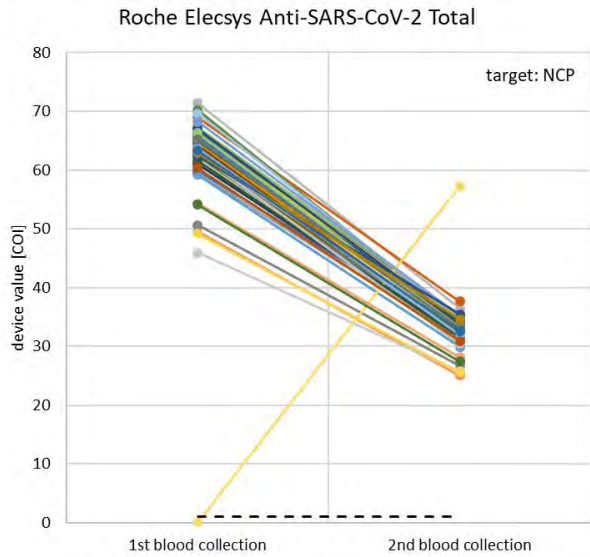
test target protein	Total	negative	border-line	positive
all tests	193	3	4	186
NCP	44	1	0	43
NCP and S protein	20	0	1	19
S protein	120	2	3	115
unknown	9	0	0	9



test target protein	Total	negative	border-line	positive
all tests	193	105	13	75
NCP	44	1	0	43
NCP and S protein	20	1	1	18
S protein	120	102	9	9
unknown	9	1	3	5

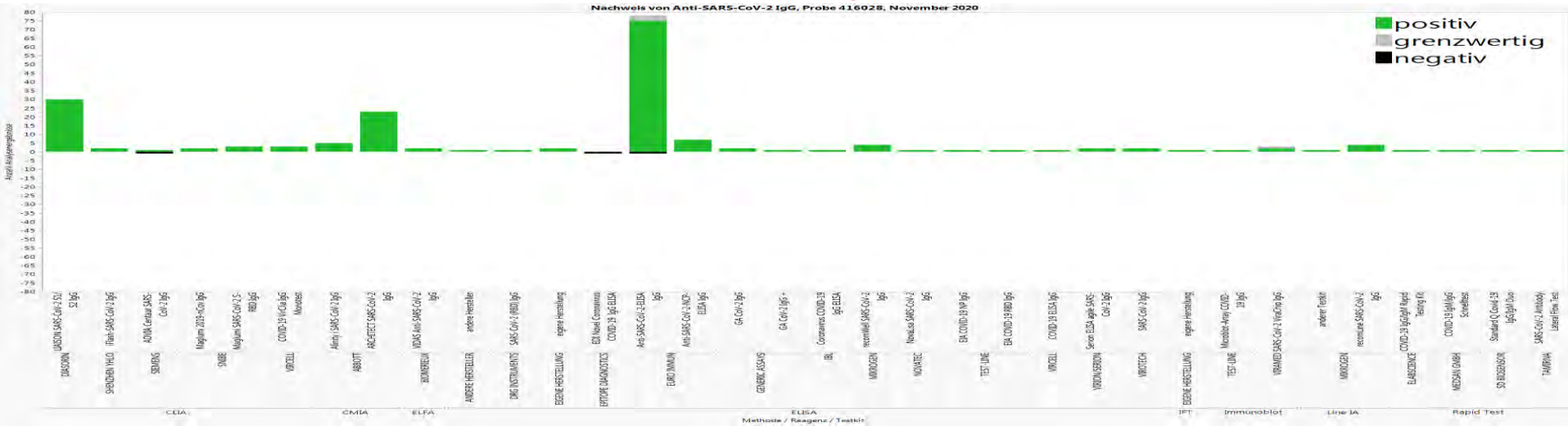
# INSTAND EQA Scheme (416) Anti-SARS-CoV-2 – Nov 2020

## individual patient response – example patient 16 (N > S)

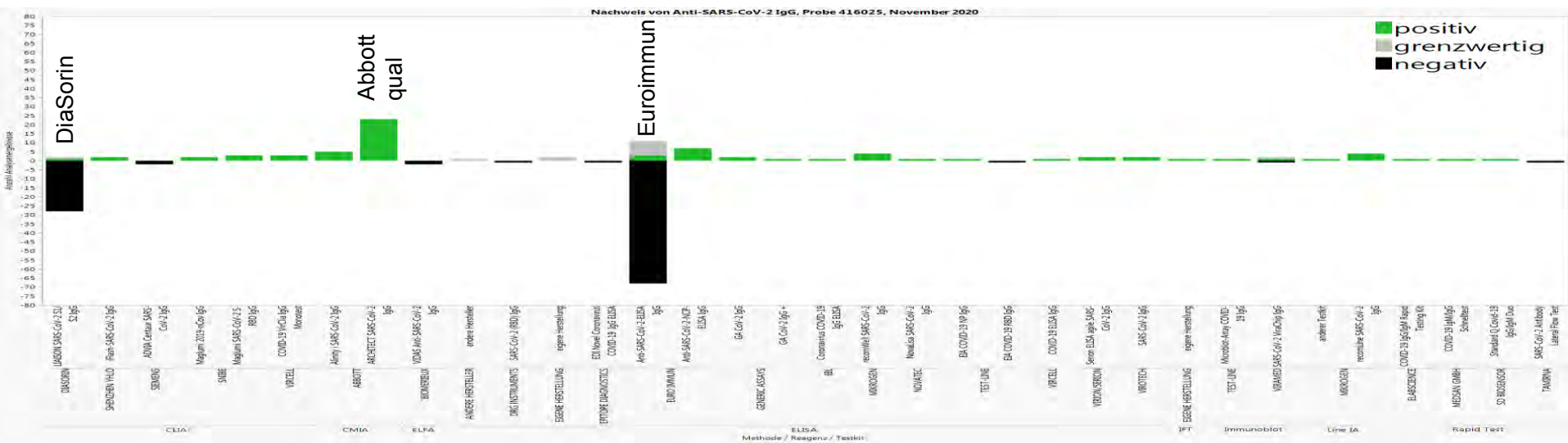


# INSTAND EQA Scheme (416) **Anti-SARS-CoV-2 IgG** – Nov 2020 individual patient response – example patient 16 (N > S)

patient 16 - 1st blood collection **65 days** after SARS-CoV-2 infection

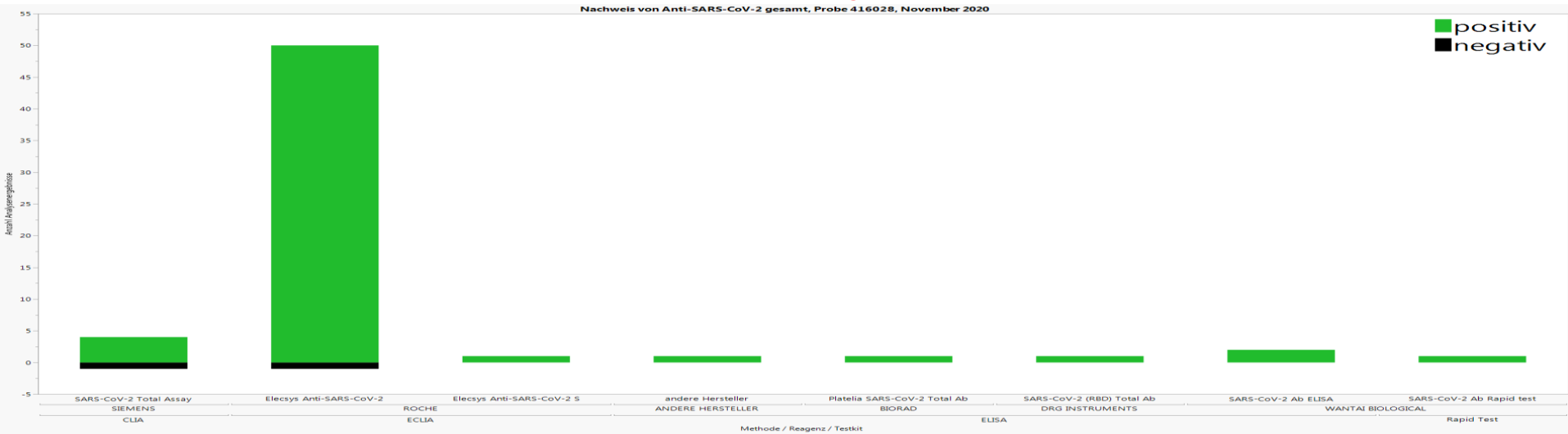


patient 16 - 2nd blood collection **169 days** after SARS-CoV-2 infection

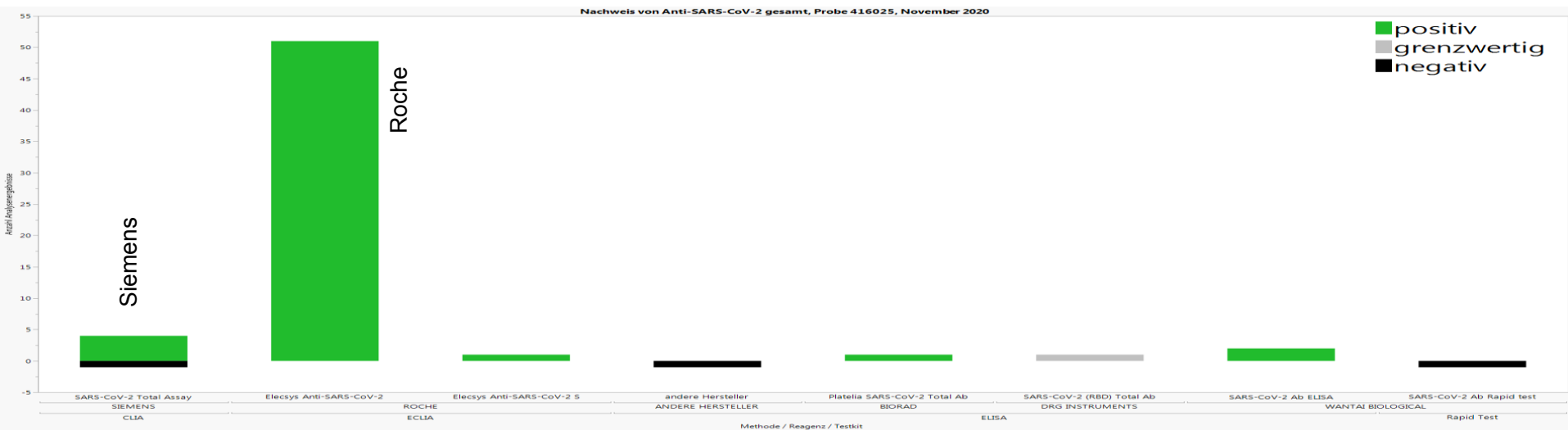


# INSTAND EQA Scheme (416) **Anti-SARS-CoV-2 total** – Nov 2020 individual patient response – example patient 16 (N > S)

patient 16 - 1st blood collection **65 days** after SARS-CoV-2 infection



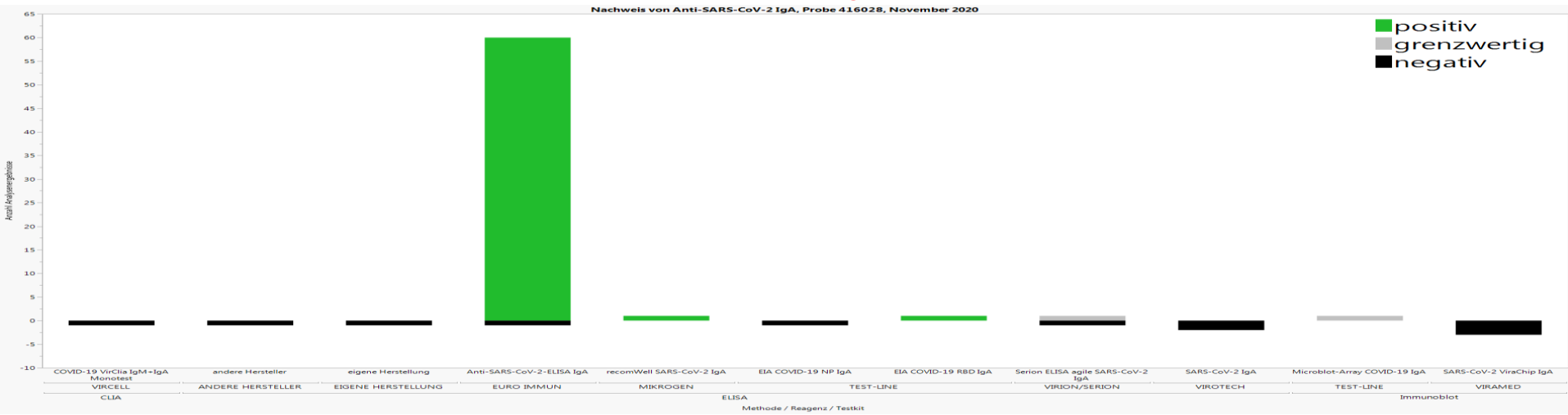
patient 16 - 2nd blood collection **169 days** after SARS-CoV-2 infection



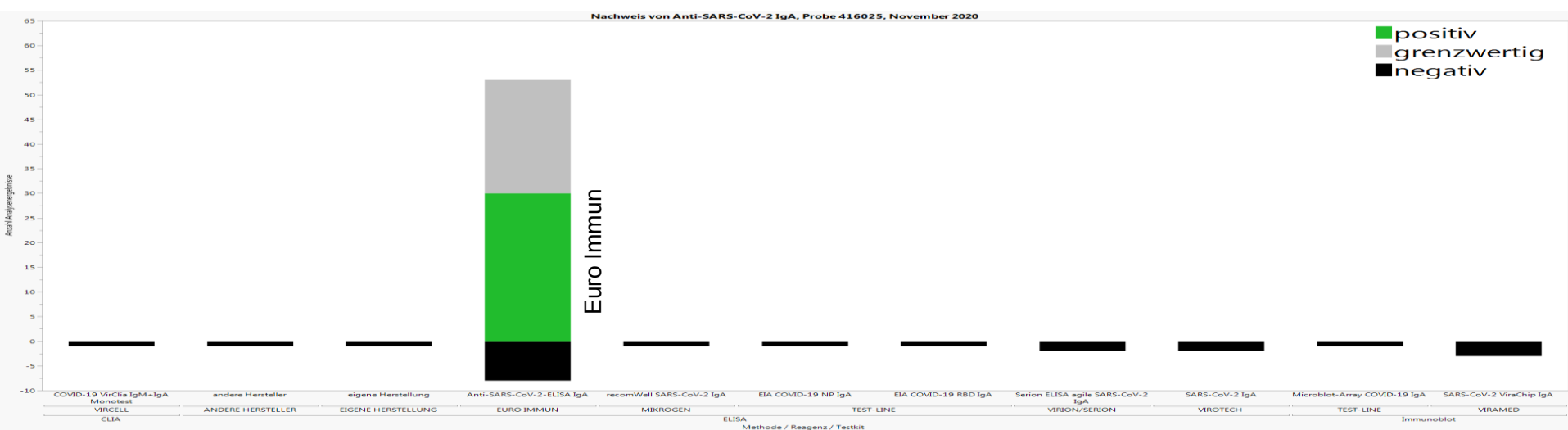
# INSTAND EQA Scheme (416) **Anti-SARS-CoV-2 IgA** – Nov 2020

## individual patient response – example patient 16 (N > S)

patient 16 - 1st blood collection **65 days** after SARS-CoV-2 infection



patient 16 - 2nd blood collection **169 days** after SARS-CoV-2 infection



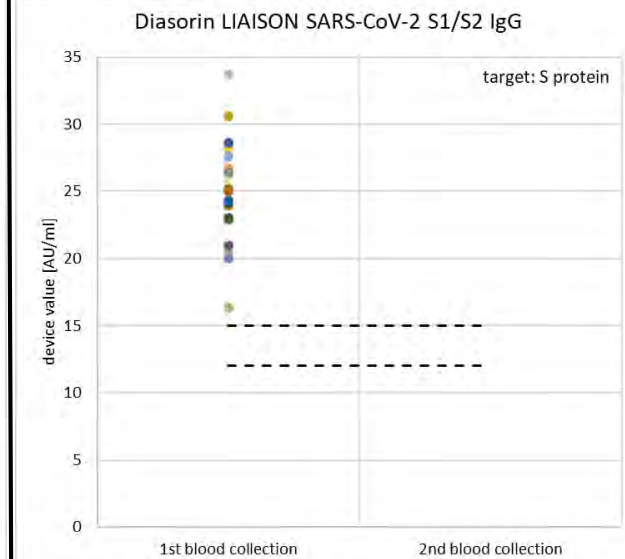
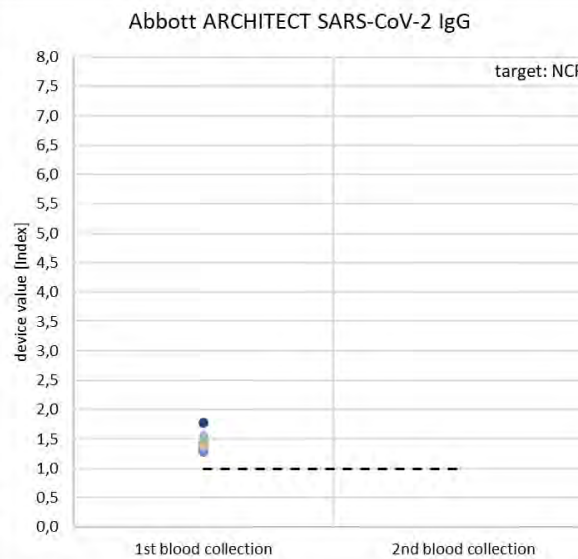
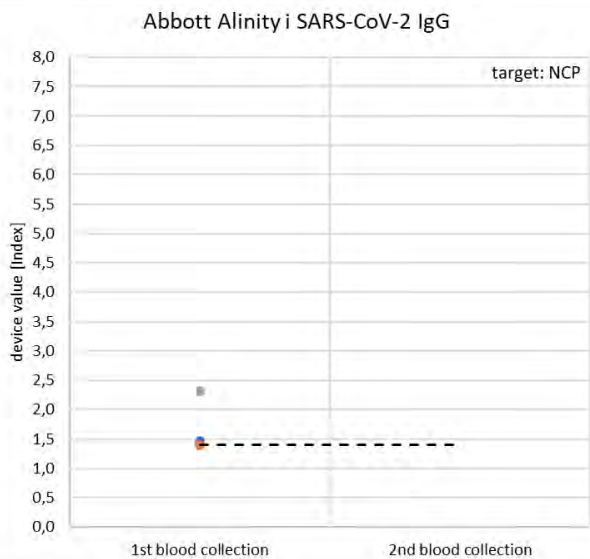
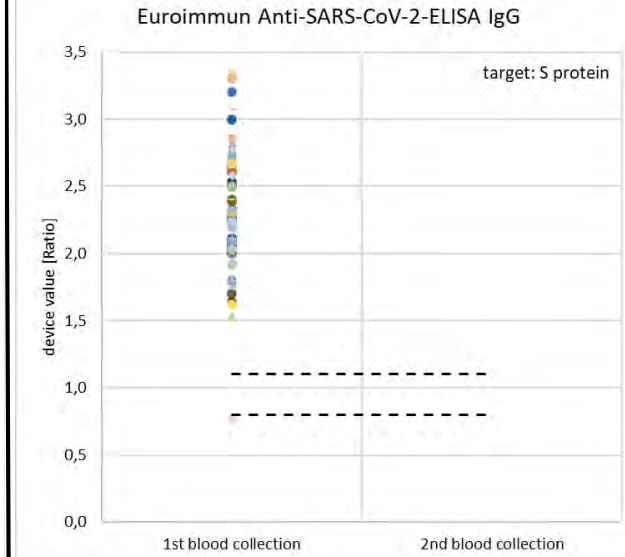
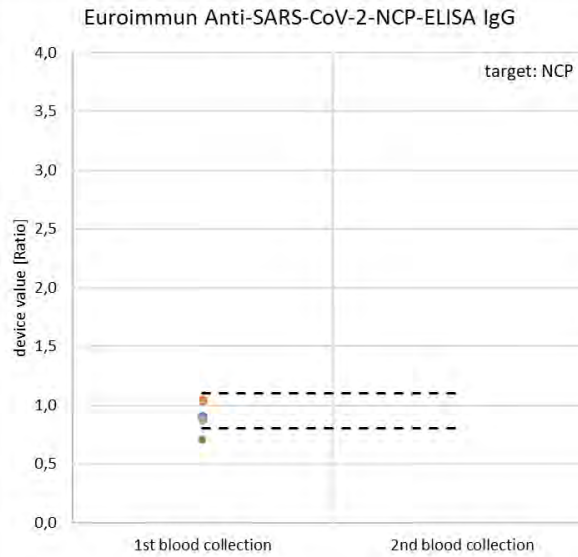
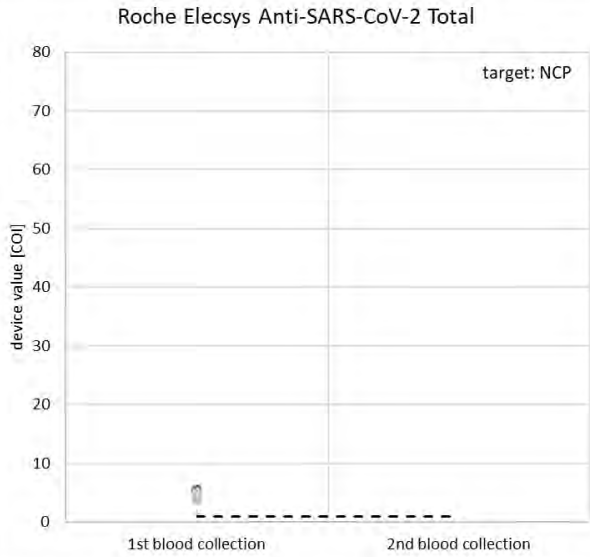






# INSTAND EQA Scheme (416) Anti-SARS-CoV-2 - Sep 2020

## individual immune response – example patient 10 (S > N)

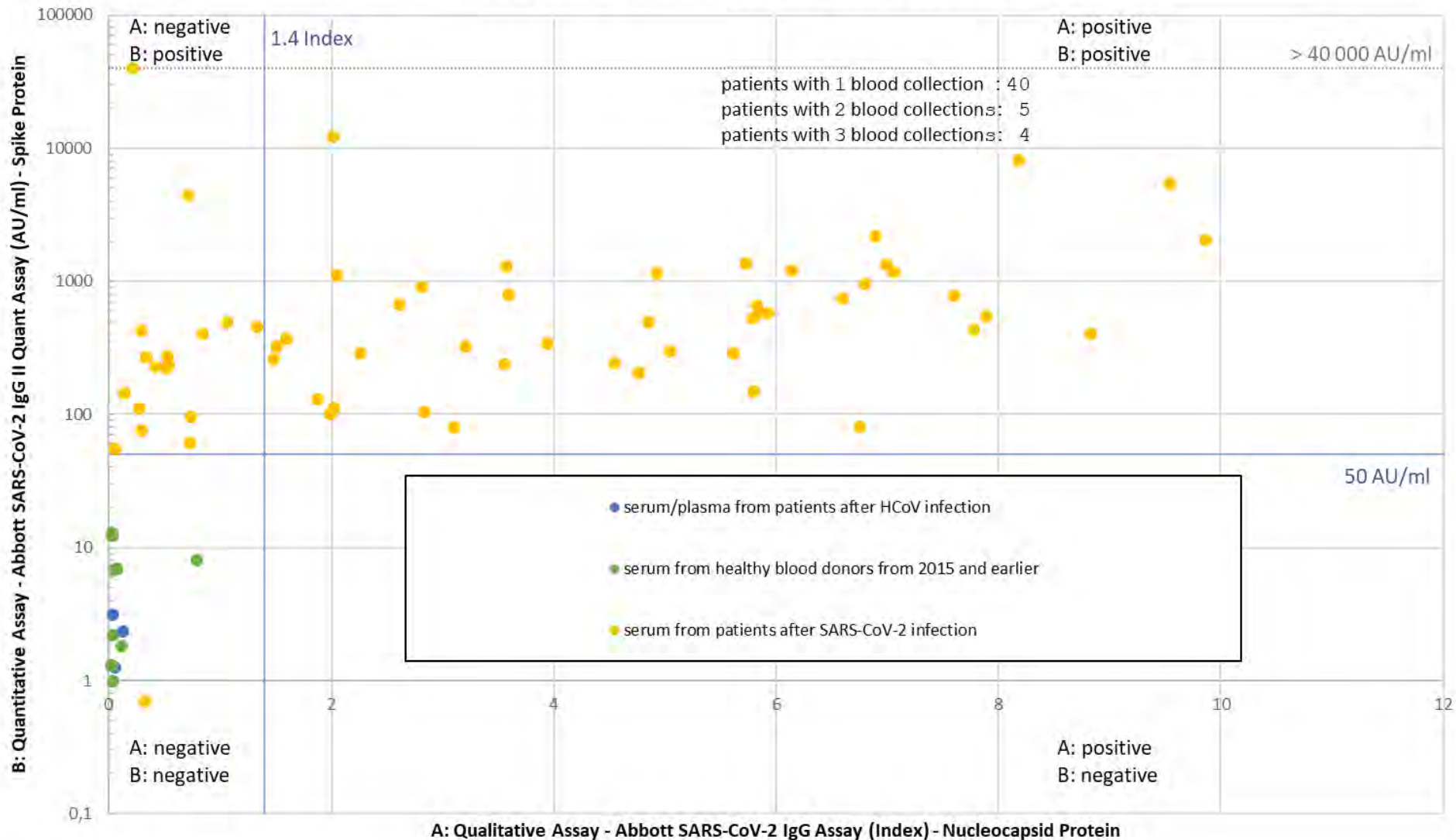


# Outlook

- INSTAND External Quality Assessment (EQA) Schemes
  - pre-study
    - automated immunoassays
- EQAS for SARS-CoV-2 antibody detection
  - qualitative results - performance of laboratories with different tests
  - follow-up sera of the same patient with individual immune response
    - tests for IgG
    - antibodies against S and/or N antigen
    - tests for total ab
    - tests for IgA and/or IgM
- Pre-characterization of convalescent sera and sera of vaccinees
  - comparative results of qualitative and quantitative tests

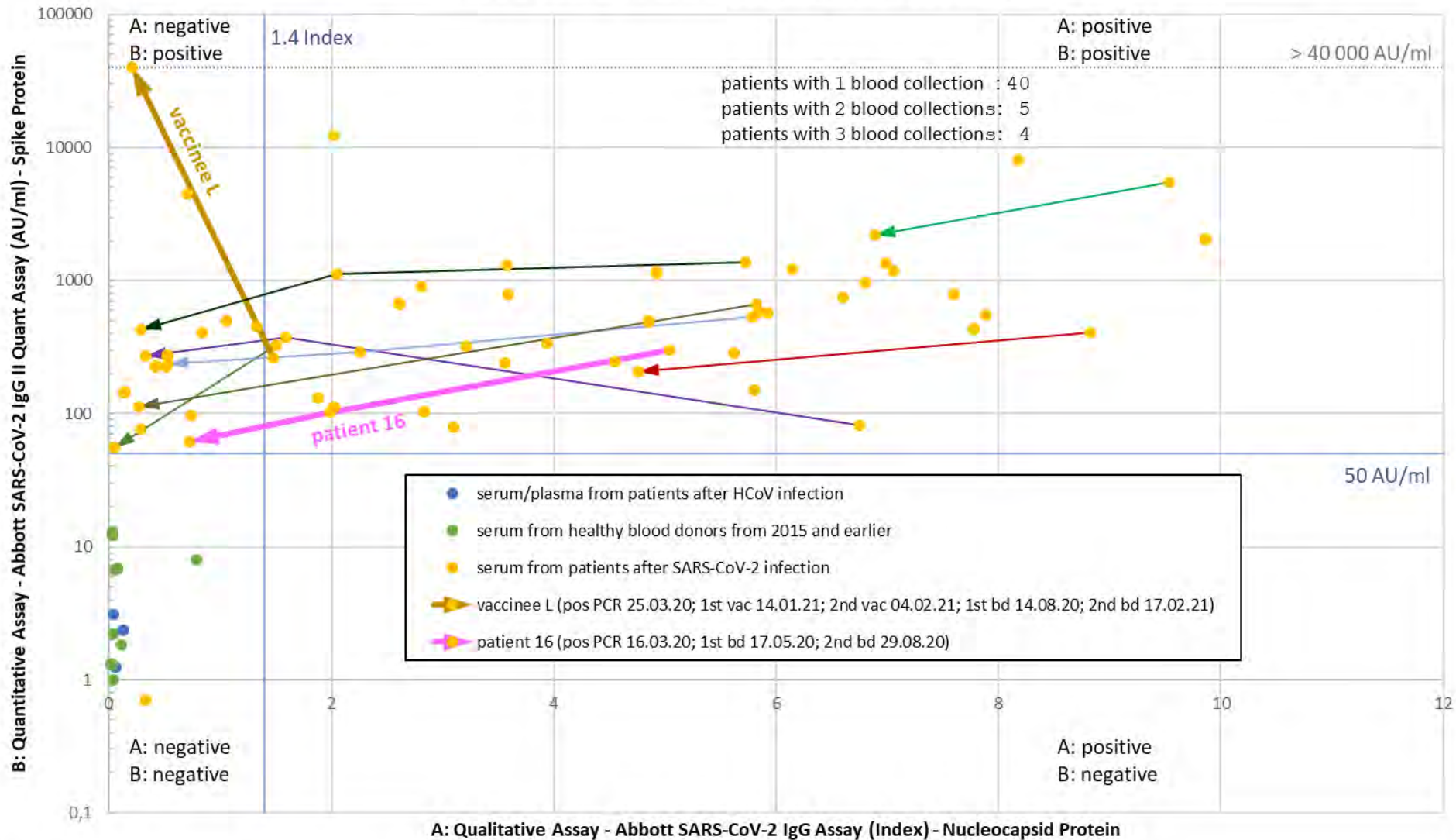
# Pre-Characterization of Anti-SARS-CoV-2 sera (GBD)

Anti-SARS-CoV-2 - Abbott Qualitative Assay (Nucleocapsid Protein)  
versus Abbott Quantitative Assay (Spike Protein)



# Pre-Characterization of Anti-SARS-CoV-2 sera (GBD)

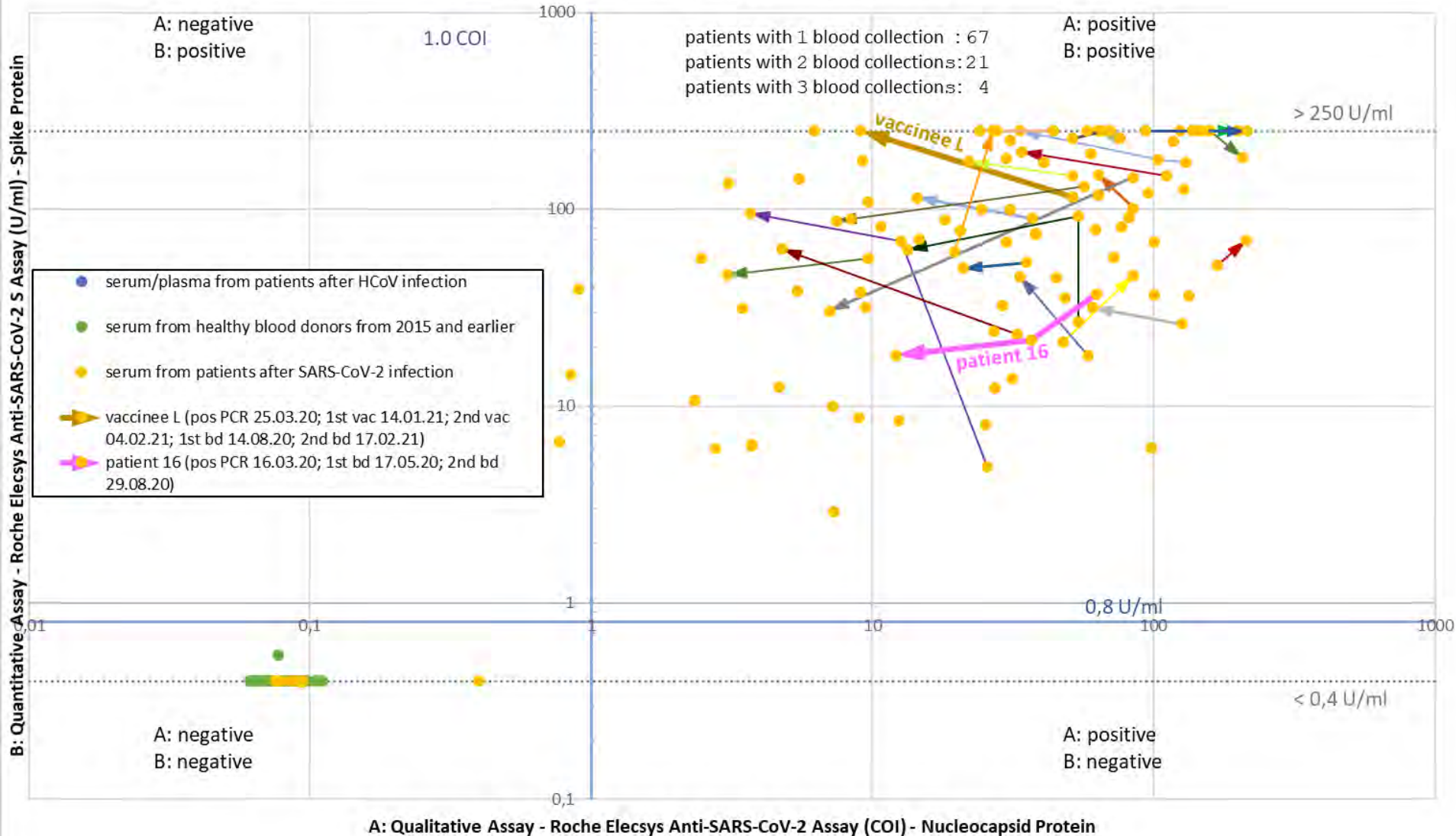
Anti-SARS-CoV-2 - Abbott Qualitative Assay (Nucleocapsid Protein) versus Abbott Quantitative Assay (Spike Protein)





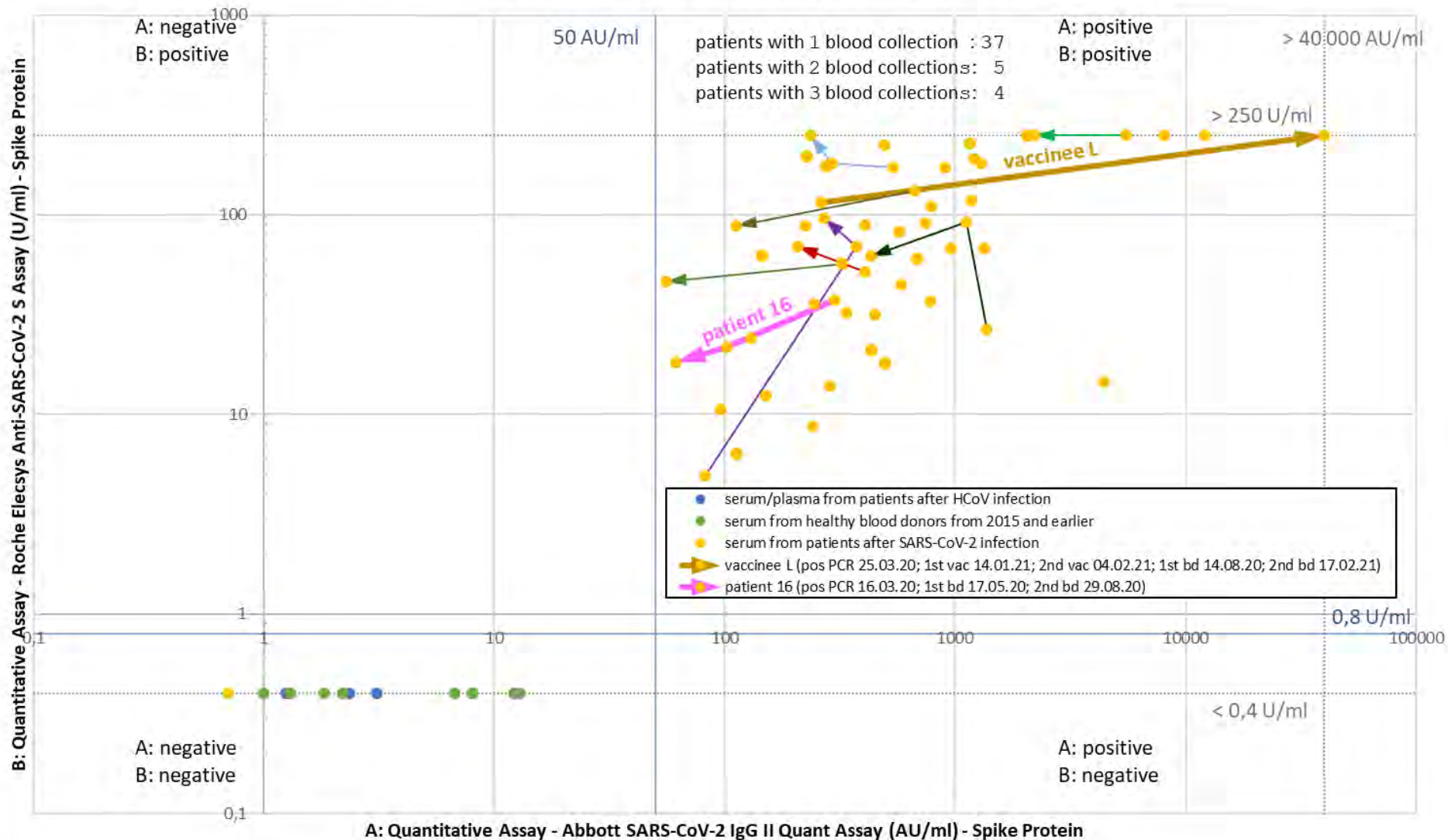
# Pre-Characterization of Anti-SARS-CoV-2 sera (GBD)

Anti-SARS-CoV-2 - Roche Qualitative Assay (Nucleocapsid Protein) versus Roche Quantitative Assay (Spike Protein)



# Pre-Characterization of Anti-SARS-CoV-2 sera (GBD)

Anti-SARS-CoV-2 - Roche Quantitative Assay (Spike Protein)  
versus Abbott Quantitative Assay (Spike Protein)





# Thank you very much!

Univ.-Prof. i.R. Dr. Heinz Zeichhardt  
Charité-Universitätsmedizin Berlin

## Correspondence address

Prof. Dr. Heinz Zeichhardt and Dr. Martin Kammel  
IQVD GmbH

Institut für Qualitätssicherung in der Virusdiagnostik  
Potsdamer Chaussee 80  
14129 Berlin, Germany

Tel.: +49-30-81054300

Fax: +49-30-81054303

Email: [Heinz.Zeichhardt@iqvd.de](mailto:Heinz.Zeichhardt@iqvd.de)  
[M.Kammel@iqvd.de](mailto:M.Kammel@iqvd.de)

INSTAND EQA schemes in virus diagnostics

Web: [www.instandev.de](http://www.instandev.de)