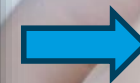


TRANSLATION OF RESEARCH INTO PRODUCT

The GENSPEED Journey





Max Sonnleitner

CEO at GENSPEED Biotech GmbH

Rainbach im Mühlkreis, Upper Austria, Austria

GENSPEED[®]
R2



CEO

GENSPEED Biotech GmbH · Full-time
Oct 2016 - Present · 6 yrs 7 mos
Austria



Lecturer

University of Applied Sciences Upper Austria
Mar 2019 - Present · 4 yrs 2 mos
Linz, Austria

Topics: Point of Care Testing, Microfluidics, Microarrays



Head of Rapid Testing Technologies/ Business Development

Greiner Bio-One Diagnostics / Lambda GmbH
Apr 2011 - Oct 2016 · 5 yrs 7 mos



Group Leader / Project Manager

Greiner Bio One / Lambda GmbH
Apr 2009 - Apr 2011 · 2 yrs 1 mo



CTO

BIOIDENT Technologies AG
Jul 2006 - Jan 2009 · 2 yrs 7 mos
Silicon Valley, California, United States



VP R&D Life Sciences

NANOIDENT AG
2006 - 2008 · 2 yrs



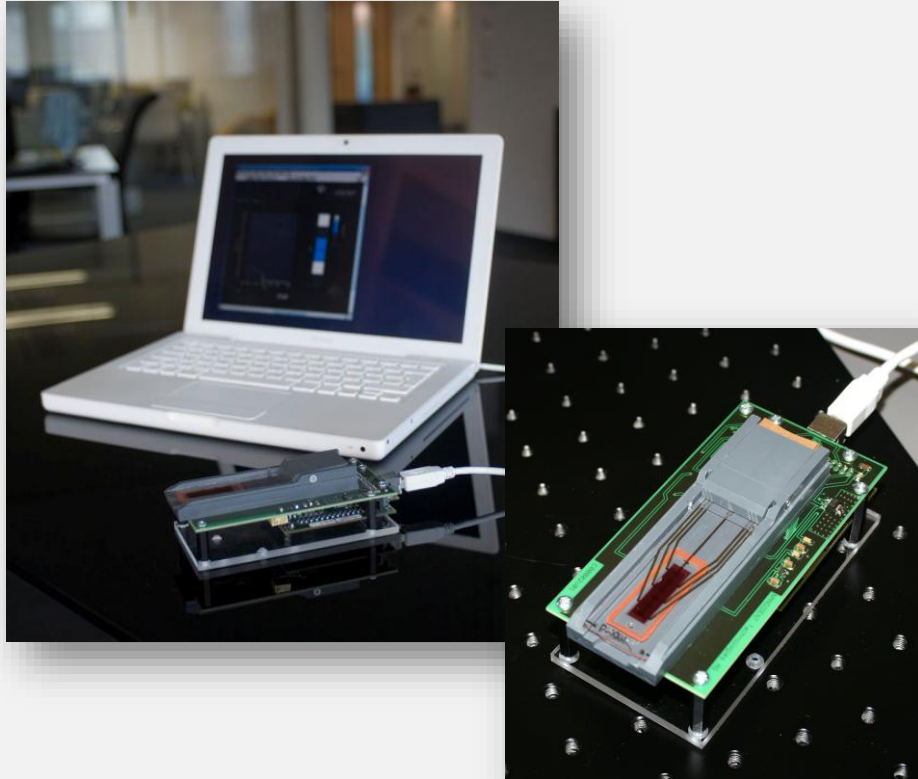
Head Device Development/Ultra-Sensitive Fluorescence Microscopy

Upper Austrian Research
2001 - Jan 2006 · 5 yrs 1 mo



2007 - WHEN IT ALL STARTED

@Nanoident/Bioident: printing Photodiodes onto microfluidics for reading out diagnostic tests



Quantitative detection via printed optoelectronic structures

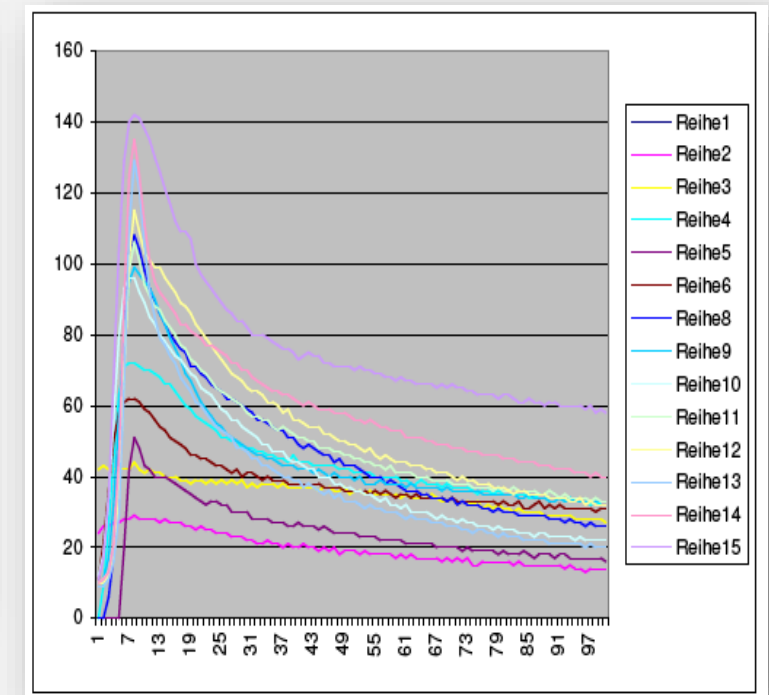
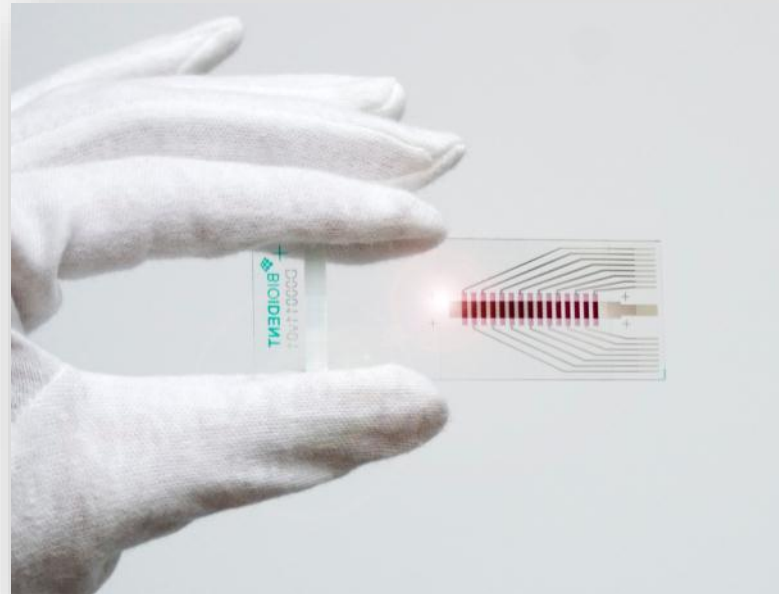
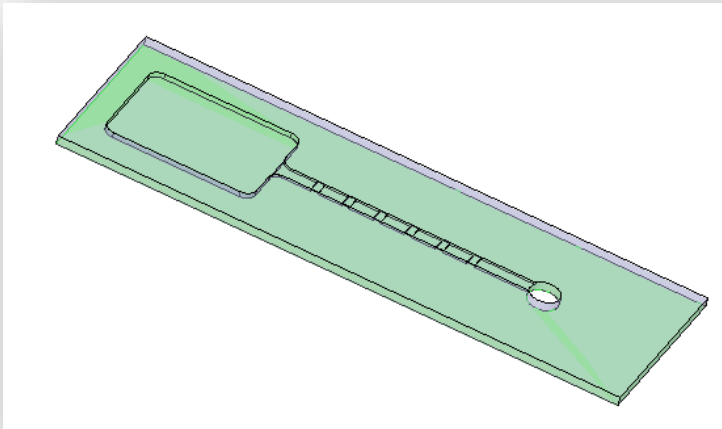
@Lambda/GBO: development of a Point of Care Test for detection of Periodontitis at the dentist's office



YES/NO answers
readout by eye using color reactions

COULD BE A GREAT COMBINATION?!

- ❑ Controller + Software + Sensors: first tests @LAMBDA/GB0 (Greiner Bio-One)
- ❑ Absorption/Chemilumineszenz
- ❑ Single Photodiode: Distance ~1mm
- ❑ Limit of Detection with Eye (Scanner): 0.13 nM
- ❑ Limit of Detection with printed Photodiodes: 0.01nM



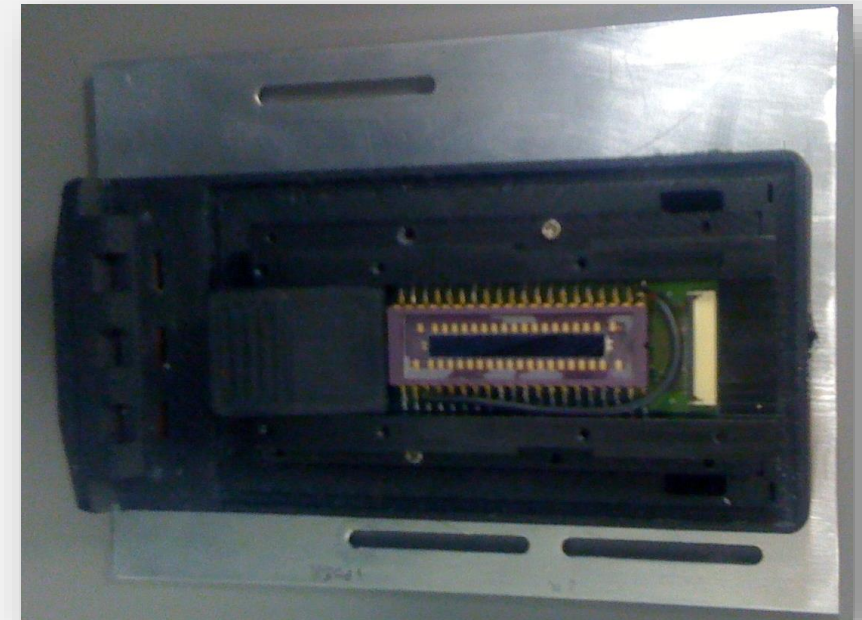
COOL DATA AT FIRST GLANCE – **BUT** LIMITED
REPRODUCABILITY OF PRINTED PHOTODIODES



LIMITED REPRODUCABILITY OF
PRINTED PHOTODIODES



Plan B: Silicon based Photodiode Array



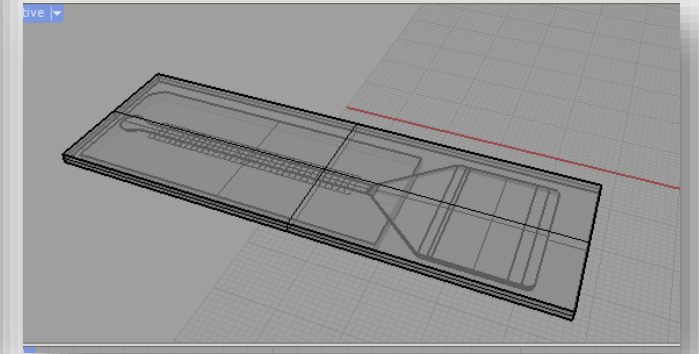
- ❑ Bankruptcy of Nanoident/Bioident – last chance: company sale to Greiner Bio-One - refused
- ❑ Start of team at Lambda/GBO with plan B (silicon photodiode array)
- ❑ Project Q4POC – quantification for Point of Care (using Chemiluminescence based readout)



Device redesign



First Hardware prototype



Redesign of microfluidic test chip

❑ Key patent

ABP
ANWÄLTE BURGER & PARTNER
Rechtsanwalt GmbH



Österreichische Patentanmeldung

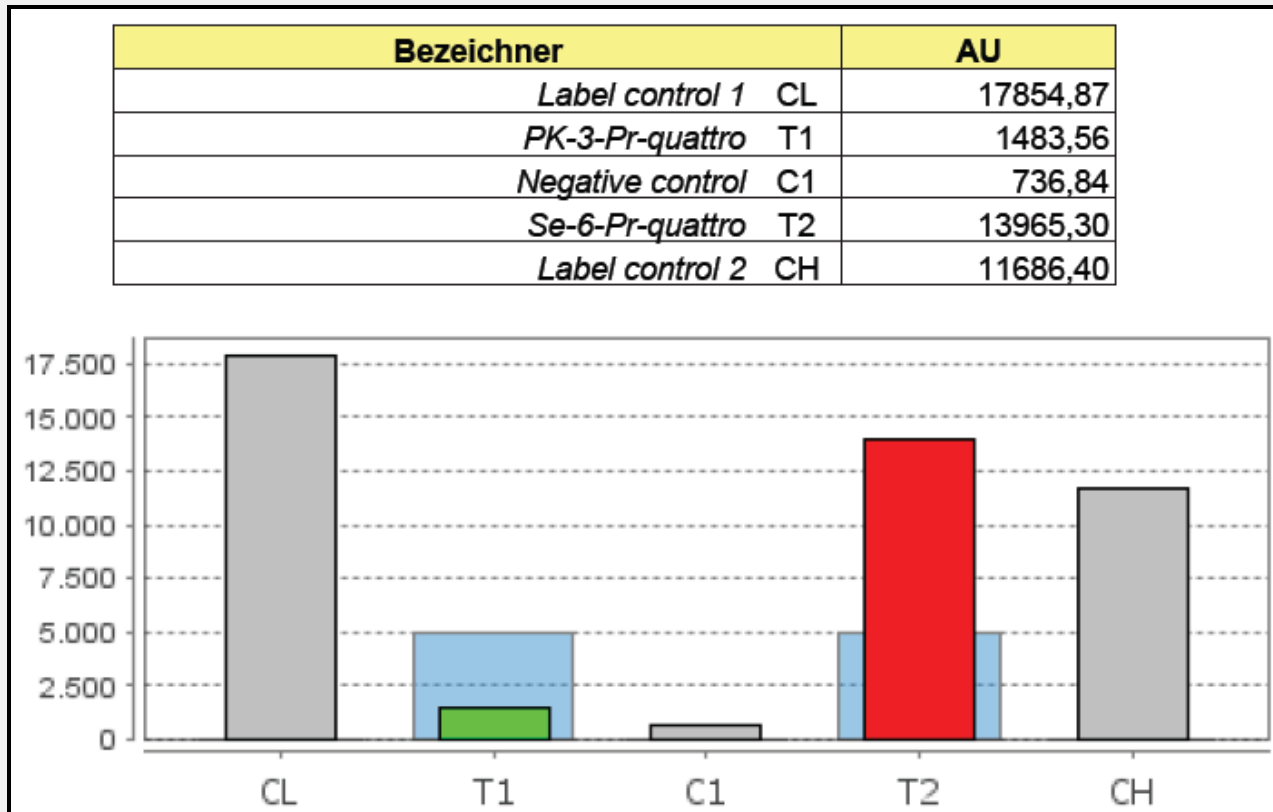
AT

„Messanordnung zur quantitativen optischen Auswertung einer chemischen Reaktion“



Unsere Referenz	A2010/02066
Schlagwort	POC-Testsystem
Anmeldenummer	A 2066/2010
Anmeldedatum	14. Dezember 2010
Anmelderin	Greiner Bio - One GmbH Maybachstraße 2 D 72636 Frickenhausen DEUTSCHLAND

- ❑ PerioPOC – originally initiated by GSK (lost interest)
- ❑ Cooperation with AMPLEX – PCR based detection of antibiotic resistant pathogens (MRSA – Methicilin Resistant Staph Aureus) → 1st product
- ❑ Name: **GENSPEED**



2012 - LAUNCH MRSA ON GENSPEED R1

☐ 1st order!



Amplex Biosystems GmbH
Kerkraeder Str. 11
35394 Gießen
Deutschland

Lieferschein Nr.: 2012-10-19-002

Bestellnummer: 21

Position: 1	Produkt: 453200, GenSpeed MRSA	Bestellmenge: 10
Position: 2	Produkt: 5401, Fixvolumen-Pipette	Bestellmenge: 10

Liefermenge	Charge/SerienNr.	Ablaufdatum
5	GSP1K124201	2013-02
5	GSP1K124202	2013-02
1*	GF769731	-
1*	GF769733	-
1*	GH777366	-
1*	GH777410	-
1*	GJ381137	-
1*	GJ381167	-
1*	GJ381232	-
1*	GJ381234	-

*Teillieferung: Fehlende Artikel werden nachgeliefert sobald verfügbar.

VERY COOL – BUT
LIMITED DISTRIBUTION
CHANNEL
AND
NOT AUTOMATED
AND
PCR BASED WITH
CONTAMINATION RISK

PUBLICATIONS

H. Kerschner, E.M. Harrison, R. Hartl, M.A. Holmes, and P. Apfalter:
»First report of mecC MRSA in human samples from Austria: molecular characteristics and clinical data«. New Microbes & New Infections, Vol. 3 (January 2015), No. C

Andreas Petersen, Alexandra Medina, Anders Rhod Larsen: »Ability of the GENSPEED MRSA test kit to detect the novel mecA homologue mecC in Staphylococcus aureus«,



Precise MRSA results in less than 100 min*



* Time can vary with validated PCR-cycler used.

- April 2016 – GBO refocussing → stop of Diagnostic developments → found EOSS Group (Graz) as investor
- October 2016 – Foundation of GENSPEED Biotech GmbH as spin-out of Greiner Bio-One (GBO)
- Basis: GENSPEED platform technology – **IVD CE / IVDR**
- **Focus change PCR → multiplex micro ELISA**
- Product-areas:
 - GENSPEED as enabling **OEM technology** for next generation point of care testing
 - GENSPEED branded **xPOC Tests** with Lab-Quality at Point of Care settings





GENSPEED R2 analyzer / tablet with Software und GENSPEED Testkit (25 tests)



Combination of

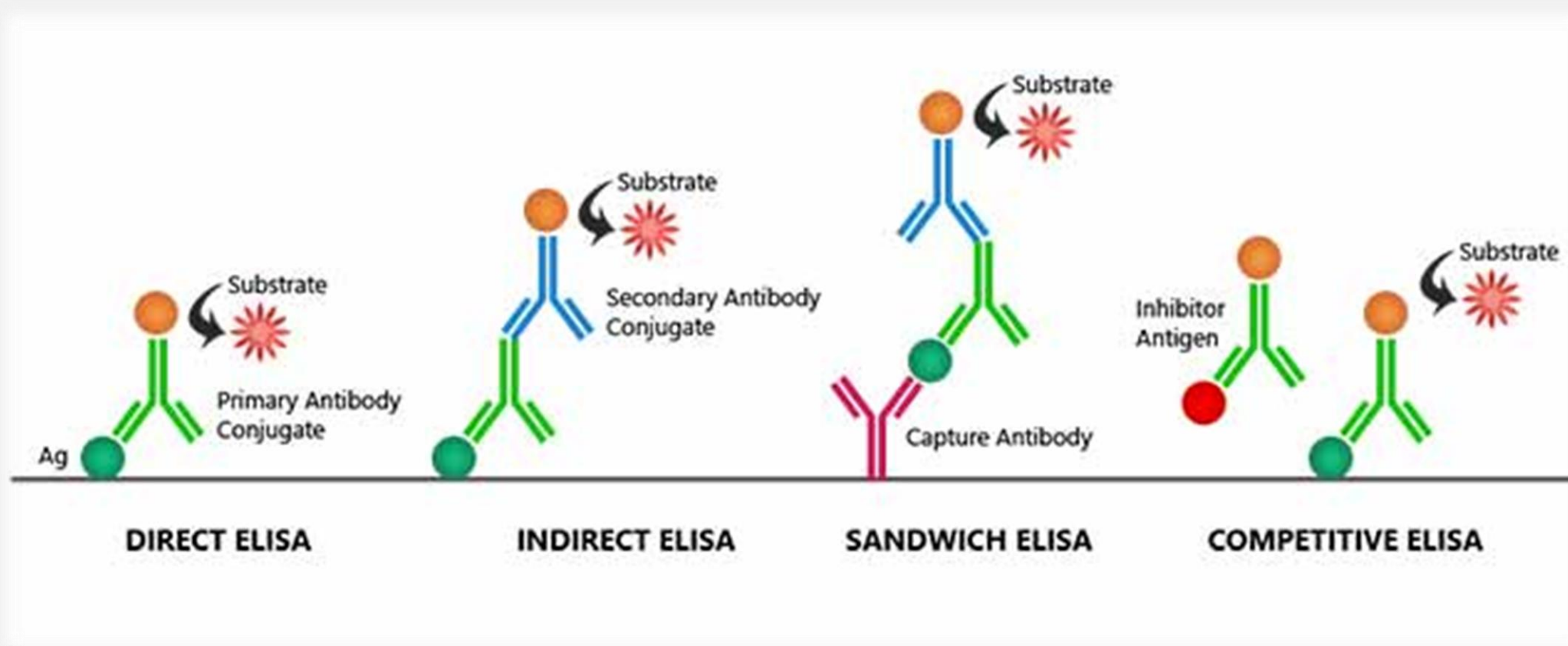
- Accelerated hybridization by novel microfluidics (capillary and shear force driven)
- Simple & highly sensitive readout (chemiluminescence based optical detection system)
- Automated dispensing of reagents (cartridge system)

→ MULTIPLEX MICRO ELISA TECHNOLOGY

- fully automated quantification of
- up to 8 (16) parameters in parallel
- in 15 minutes
- from various sample types

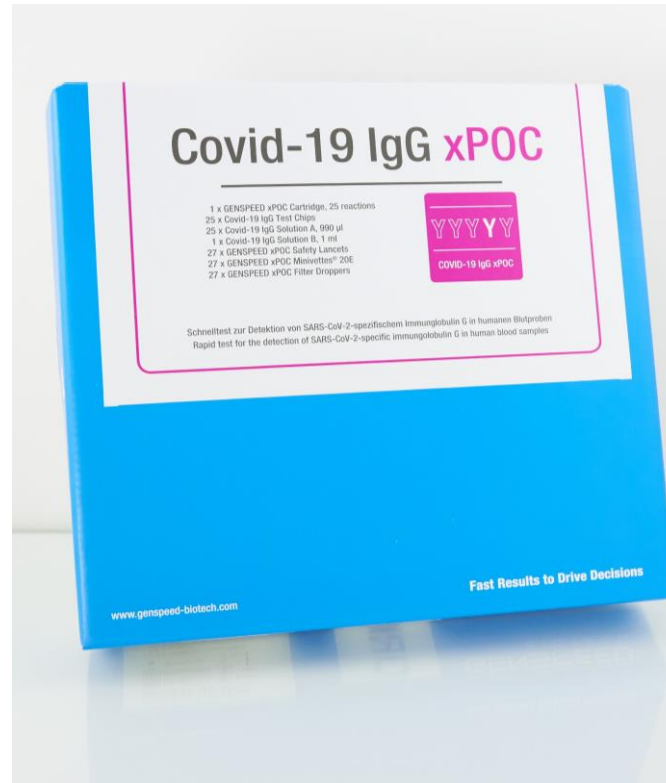
at the Point of Care

Different assay-format successfully tested in PBS, serum, saliva, capillary blood



Technology		Strip Tests	Lab ELISA	GENSPEED
Parameter				
QUALITY	Sensitivity	✗ Low	✓ High	✓ High (pg/ml)
	Specificity	✗ Low	✓ Good	✓ Good
	Quantification	✗ Semi-quantitative	✓ Possible	✓ Possible
	Multiplexing	✗ Problematic	✗ No	✓ YES, ≥ 8 parameters
USABILITY	Handling	✓ Quick & easy (1 step)	✗ Complex	✓ Quick & easy (1-2 steps)
	Test duration	✓ Short (10 min)	✗ Long (2-4h)	✓ Short (10 min)

2020 - COVID-19 IgG xPOC Antibody Test



COVID-19 IgG xPOC

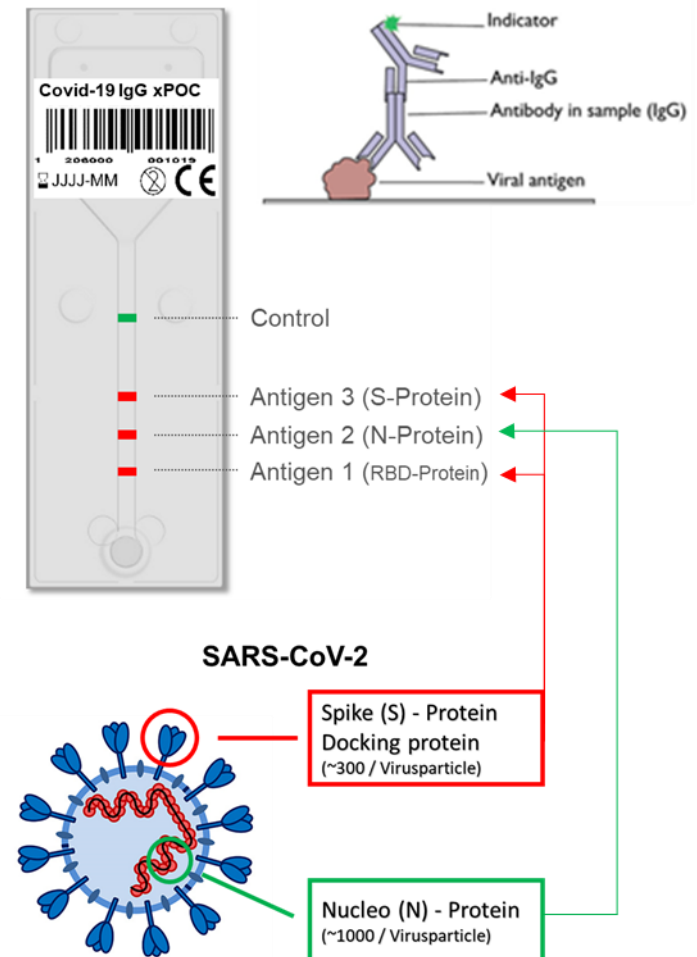
Features and benefits

- ❑ Measurement from a drop of blood (20 µl) from the fingertip
- ❑ Result in 15 minutes
- ❑ High sensitivity
 - ❑ 100% Sensitivity compared to Laboratory ELISA Test ¹
- ❑ High specificity
 - ❑ The GENSPEED test chip detects whether antibodies against three different antigens of SARS-CoV-2 are present in the blood ¹
- ❑ Information on the quantity and quality of antibodies
 - ❑ Semi-quantitative measurements enable progress control
 - ❑ Binding behaviour of the antibodies against special antigens (Receptor Binding Domain and Spike Protein) allows conclusions to be made about the quality of protection against new infection ^{2,3}

¹ C. Wechselberger et al., Performance evaluation of serological assays to determine the immunoglobulin status in SARS-CoV-2 infected patients, Journal of Clinical Virology 131, 2020

² F. Amanat, F. Krammer, SARS-CoV-2 Vaccines: Status Report. Immunity 52, 583-589 (2020).

³ Ni et al., 2020, Immunity 52, 971–977 June 16, 2020



2021 – Covid 19 IgG xPOC - How it works



2021 - COVID-19 IgG xPOC Antibodytest – Result

Results according to WHO Standard

3. Februar 2022 - 22:26

GENSPEED
BIOTECH

Dr. Max Mustermann

Dr. Max Mustermann

GENSPEED COVID-19 IgG

Patient: **Peter Sanderson** Patienten-ID: generated
Adresse: Musterstrasse 12 SV-Nr.: 1234290378
4010 Musterhausen
Austria
Geb.-Dat.: 29. März 1978 Geschlecht: männlich

Allgemeiner Laborbericht

Antikörper Typ	Ergebnis	Konzentration (BAU/mL)
COVID-19 Anti-Spike/RBD IgG	NACHGEWIESEN	603 BAU/mL
COVID-19 Anti-Nucleo IgG	NICHT NACHWEISBAR	-

Ergebnis: neutralisierende Antikörper gegen SARS-CoV-2 - NACHGEWIESEN

Resultat für Chip Nr.: 200902041204, verwendetes GENSPEED R2-Gerät: (SNr: 1028A1002)

Kommentar:

Autor: GENSPEED-Report v3.1.0.202202232250, 3. Februar 2022 - 22:26
Dr. Max Mustermann, 3. Februar 2022 - 22:26
Unterzeichnet: Dr. Max Mustermann, 3. Februar 2022 - 22:26

COVID-19 Anti-Spike/RBD IgG (Neutralisierende Antikörper)
Antikörper gegen das Spike/RBD (Receptor Binding Domain) Protein können das SARS-CoV-2 Virus neutralisieren. Die schützende Wirkung bzw. die Neutralisationsaktivität sowie die Dauer dieses Schutzes durch die Spike/RBD-spezifischen Antikörper ist derzeit noch nicht vollständig geklärt. Studien stellen aber einen Zusammenhang zwischen hohem Titer an neutralisierenden Antikörpern und hoher Impfwirksamkeit bzw. reduziertem Risiko einer symptomatischen Infektion her. Das Ergebnis wird in BAU/mL (standardisierte internationale Einheit Binding Antibody Units pro Milliliter) angegeben, entsprechend dem WHO International Standard Anti-SARS-CoV-2 Immunoglobulin (NIBSC 20/136). Cut-off/Schwellenwert = 10 BAU/mL.

Literatur:

Wajnberg et al., Science 370, 1227-1230 (2020)
Feng et al., Nature Medicine 27, 2032-2040 (2021)
Earle et al., Vaccine 39, 4423-4428 (2021)
Khouri et al., Nature Medicine 27, 1205-1211 (2021)

COVID-19 Anti-Nucleo IgG
Antikörper gegen das Nucleoprotein von SARS-CoV-2 haben nachweislich geringere Neutralisationskapazität als Antikörper gegen Spike/RBD. Nucleokapsid-spezifische Antikörper stehen in Verbindung mit einer vorausgegangenen Infektion oder werden bei Immunisierung mit inaktiviertem Impfstoff gebildet. Eine genaue Zuordnung des Antikörpertyps zur Neutralisationsaktivität ist wissenschaftlich nicht sinnvoll.

Literatur:

McAndrews et al., JCI Insight, 2020;5(18):e142386
Krutikov et al., Lancet Healthy Longev 2022;3:e13-21

GENSPEED COVID-19 IgG

Patient: **Peter Sanderson** Patienten-ID: generated
Adresse: Musterstrasse 12 SV-Nr.: 1234290378
4010 Musterhausen
Austria
Geb.-Dat.: 29. März 1978 Geschlecht: männlich

Allgemeiner Laborbericht

Antikörper Typ	Ergebnis	Konzentration (BAU/mL)
COVID-19 Anti-Spike/RBD IgG	NACHGEWIESEN	603 BAU/mL
COVID-19 Anti-Nucleo IgG	NICHT NACHWEISBAR	-

Ergebnis: neutralisierende Antikörper gegen SARS-CoV-2 - NACHGEWIESEN

Resultat für Chip Nr.: 200902041204, verwendetes GENSPEED R2-Gerät: (SNr: 1028A1002)

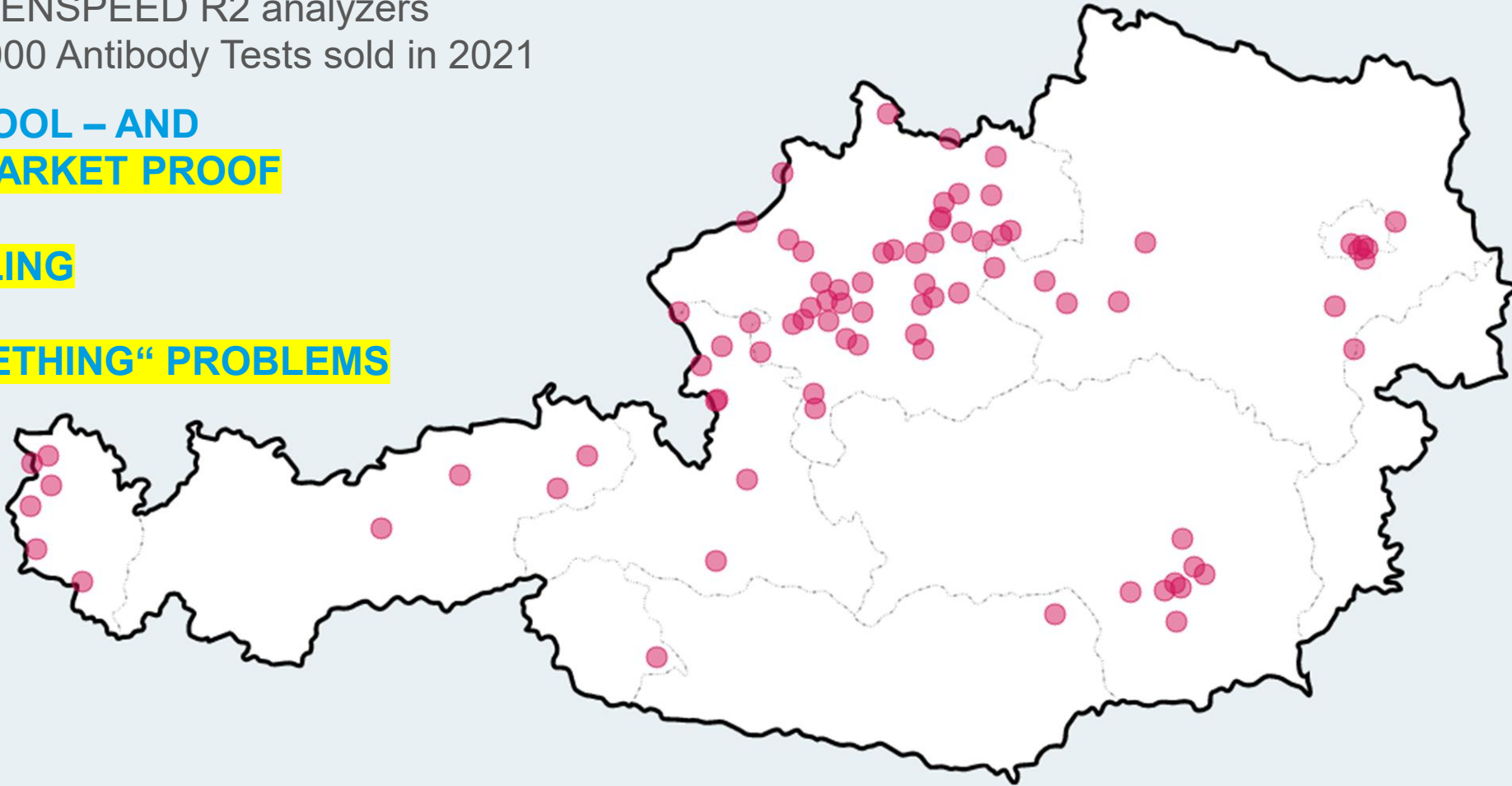
Kommentar:

- ❑ Protection level after vaccination/infection
- ❑ Differentiate vaccinated / recovered persons
- ❑ Result in Binding Antibody Units (BAU) / mL (WHO standard)
- ❑ CutOff ~ 10 BAU/mL (vgl. Abbott ~7 BAU / mL, Diasorin ~ 33 BAU / mL)

2021 - GENSPEED at Austrian Pharmacies

- 120 GENSPEED R2 analyzers
- > 70.000 Antibody Tests sold in 2021

VERY COOL – AND
REAL MARKET PROOF
AND
UPSCALING
AND
FIX „TEETHING“ PROBLEMS



www.antikoernachweis.at

PLZ

Suchen

Journal of Clinical Virology 131 (2020) 104589



Contents lists available at ScienceDirect

Journal of Clinical Virology

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



Performance evaluation of serological assays to determine the immunoglobulin status in SARS-CoV-2 infected patients

Christian Wechselberger^{a,*}, Susanne Süßner^b, Stefan Doppler^c, David Bernhard^a

^a Division of Pathophysiology, Institute of Physiology and Pathophysiology, Medical Faculty, Johannes Kepler University Linz, Linz, Austria

^b Austrian Red Cross, Blood Transfusion Service for Upper Austria, Linz, Austria

^c Department of Pathology and Microbiology, Institute of Pathology and Molecular Pathology, Kepler University Hospital, Linz, Austria

100% Sensitivity

C. Wechselberger et al.

Journal of Clinical Virology 131 (2020) 104589

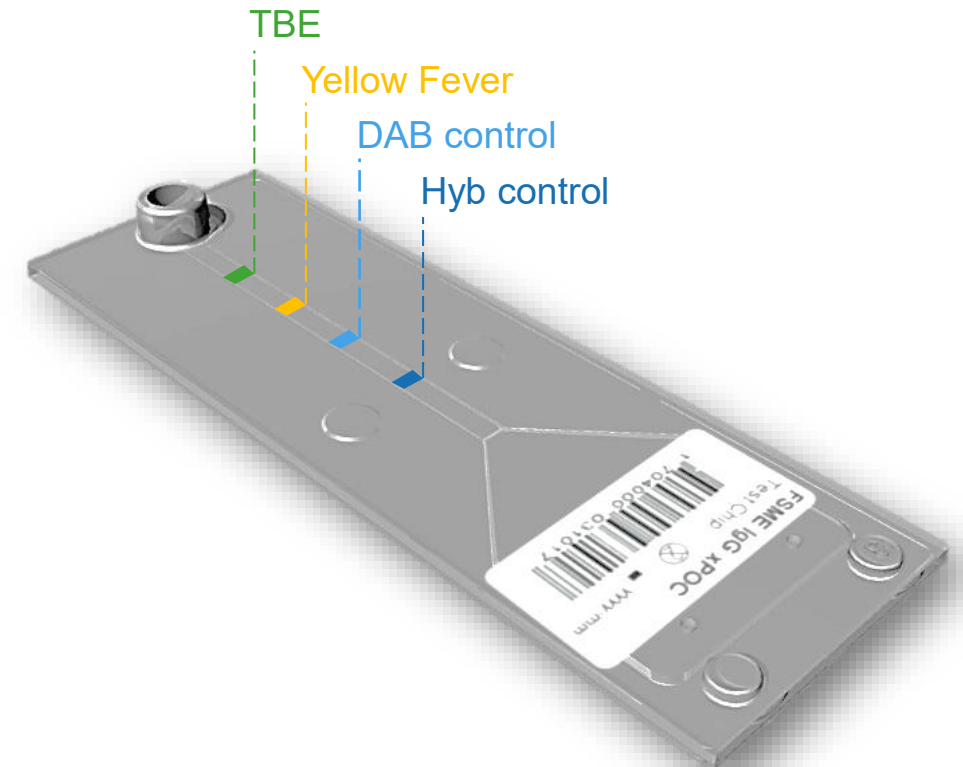
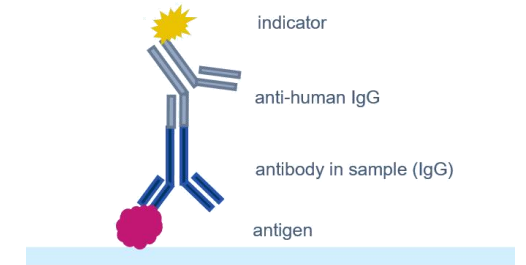
Table 2

Assay Manufacturer	True positive	False positive	True negative	False negative	Sensitivity	Specificity
Epitope diagnostics Inc.	50	13	46	1	0,98	0,78
Abbott Architect	48	0	59	3	0,94	1,00
Euroimmun AG	47	1	58	4	0,92	0,98
Vircell S.L.U.	50	10	49	1	0,98	0,83
Mikrogen GmbH	51	2	57	0	1,00	0,97
in-house ELISA	49	4	55	2	0,96	0,93
Genspeed Biotech	51	4	55	0	1,00	0,93

Sensitivity and specificity values for SARS-CoV-2 assays based on the detection of IgG.

Features and Benefits

- ❑ Measurement from a drop of blood (20µl) from the fingertip
- ❑ Electronic result in 20 minutes
- ❑ 99,3% Sensitivity ¹
- ❑ 100% Specificity ¹
 - In order to optimize the safety of the result, antibodies against yellow fever (due to vaccination/illness), which can cause incorrect results in the laboratory, are recorded with the special measuring method and, if necessary, taken into account in the evaluation.
 - No result impairment due to antibodies against other flaviviruses
- ❑ Information about individual protection
 - Semi-quantitative output with concentration ranges in the international standardized unit Vienna Units per milliliter (VIEU/mL)
 - Individual time course for vaccination protection



¹ Result of the comparative clinical study with laboratory ELISA EUROIMMUN Anti-TBE virus ELISA "Vienna" (IgG) - CE IVD

2022 - FSME IgG xPOC Antibody Test - Result

Output according to laboratory methods / including indication yellow fever

23. Mai 2022 - 08:57

Dr. Max Mustermann

Dr. Max Mustermann

GENSPEED FSME IgG

Patient: Sample Genspeed OD 20.05.22 15:00 - Patienten-ID:
Adresse: SV-Nr.: -
Geb.-Dat.: . Geschlecht:

Allgemeiner Laborbericht

Antikörper Typ	Konzentrationsbereich (VIEU/mL)	nicht nachweisbar	niedrig	hoch
FSME IgG	> 1000			

Ergebnis: neutralisierende Antikörper gegen FSME - NACHGEWIESEN

Resultat für Chip Nr.: 221100185216, verwendetes GENSPEED R2-Gerät: I (SNr: 2021-20B009)

Kommentar:

Spezifische Antikörper gegen Gelbfieber potenziell in der Probe vorhanden. Für zusätzliche diesbezügliche Abklärung bitte Speziallabor konsultieren

Autor: GENSPEED-Report v3.2.2.202205222143, 23. Mai 2022 - 08:57
Autor: Dr. Max Mustermann, 23. Mai 2022 - 08:57
Unterzeichnet: Dr. Max Mustermann, 23. Mai 2022 - 08:57

FSME IgG (Neutralisierende Antikörper)	Konzentrationsbereich (VIEU/mL)	Information/Empfehlung
nicht nachweisbar	< 165	Keine Immunität vorhanden. Auffrischungsimpfung oder Grundimmunisierung empfohlen
niedrig	165 - 1000	Immunität vorhanden. Titer Kontrolle oder Auffrischungsimpfung nach 1-2 Jahren entsprechend nationalem Impfplan
hoch	> 1000	Immunität vorhanden. Titer Kontrolle oder Auffrischungsimpfung nach 3-5 Jahren entsprechend nationalem Impfplan
Die angegebenen Werte gelten insbesondere, wenn keine Immunisierung gegen bzw. Erkrankung mit Flaviviren, z.B. Dengue, Japanische Enzephalitis stattgefunden hat. Die neue Messmethode erlaubt eine optimale Differenzierung von gegebenenfalls vorhandenen spezifischen Gelbfieberantikörpern. Etwaige diesbezügliche Auffälligkeiten werden im Kommentarfeld ausgegeben. Die Basis für diese Empfehlungen sind Durchschnittswerte und können individuellen Schwankungen unterliegen.		
Die Konzentrationsbereiche sind in standardisierten internationalen Vienna Units pro Milliliter (VIEU/mL) angegeben. Grenzwert/Schwellenwert = 165 VIEU/mL*		
*entsprechend Laborvergleichsmethode EURIOIMMUN Anti-FSME-Viren-ELISA "Vienna" (IgG) – CE IVD		

← semi-quantitative result in Vienna Units per milliliter (VIEU/ml)

← Comment with reference to pot. existing yellow fever antibodies

← specific information for each concentration range in the
Legend according to laboratory results

2024 - Vitamin D xPOC Test - Results

10. November 2022 - 14:06

Dr. Max Mustermann

Dr. Max Mustermann

Vitamin-D xPOC

Patient: Patienten-ID:

Adresse: SV-Nr.:

Geb.-Dat.: Geschlecht:

Allgemeiner Laborbericht

	Konzentration	Einheit	Versorgung
--	---------------	---------	------------

VERY COOL – BUT

Notified bodies like TUV need 12 to 18 months for checking technical documentation of products after clinical performance evaluation →

INNOVATION KILLER IVDR

AND

ONLY 12 NOTIFIED BODIES FOR 42000 IN VITRO DIAGNOSTIC TESTS IN EUROPE!?

Kommentar:

Resultat für Chip Nr.: 220600001203, verwendetes GENSPEED R2-Gerät: I (SNr: 1028A1002)

Autor: GENSPEED-Report v3.3.0.202211092215, 10. November 2022 - 14:06

Autor: Dr. Max Mustermann, 10. November 2022 - 14:06

Unterzeichner: Dr. Max Mustermann, 10. November 2022 - 14:06

Vitamin-D - 25(OH)D	Konzentration (ng/mL)	Interpretation/Empfehlungen
mangelhaft	< 12	Mangelhafte Versorgung mit einem erhöhten Risiko für Krankheiten wie Rachitis, Osteomalazie und Osteoporose.
unzureichend	12 - 20	Suboptimale Versorgung mit möglichen Folgen für die Knochengesundheit.
ausreichend	20 - 30	Ausreichende Versorgung in Bezug auf die Knochengesundheit.
optimal	30 - 50	Ausreichende Versorgung in Bezug auf die Knochengesundheit ohne weiteren Zusatznutzen für die Gesundheit.
überdosiert	50 -	Mögliche Überversorgung, die für den Körper negative gesundheitliche Folgen haben kann, zum Beispiel Hyperkalzämien, die zu Herzrhythmusstörungen oder Nierensteinen führen können.

Literaturquelle: RKI - Vitamin D - Antworten des Robert Koch-Instituts auf häufig gestellte Fragen zu Vitamin D.

0 5 10 15 20 25 30 35 40 45 50 100

ng/ml

← Ranges in the legend according to scientific status (Robert Koch Institute)

Meet the suPARnostic® POC+

The point-of-care solution for measuring suPAR

- Testing possible without laboratory involvement
- Ease of use
- Simple finger prick test
- Results available in 20 minutes

The suPARnostic® POC+ product is a point-of-care finger prick test which detects the level of suPAR in the blood.

The suPARnostic® POC+ has full CE-IVD accreditation for use in professional healthcare settings to identify inflammation and immune activation.

The suPARnostic® POC+ is based on the GENSPEED technology that allows quick and fully automated processing of finger prick blood samples. The test takes approximately 20 minutes.

The suPARnostic® POC+ is useful in acute care and in the pre-hospital settings.

A kit contains ready-to-use reagents sufficient to perform 25 tests.

Contact our experts about your needs and they will help you.

Contact us as sales@virogates.com

CSO at ViroGates Jesper Eugen-Olsen, PhD, says:
"With the POC+, we can finally measure the suPAR level in a drop of blood from the finger. This allows for easy determination of chronic inflammation, disease severity, and prognosis in settings without laboratories."

Read more about the
suPARnostic® POC+



suPARnostic® POC+ is quick and easy to use

The size and technology used in suPARnostic® POC+ ensure excellent accessibility and mobility of the device. The small footprint means that it fits into smaller spaces and can be carried between multiple departments.

Test benefits

- Empower the clinical staff
- 22% reduction in hospital admissions
- Reduce healthcare costs



1 Add a finger prick blood drop to the test cassette

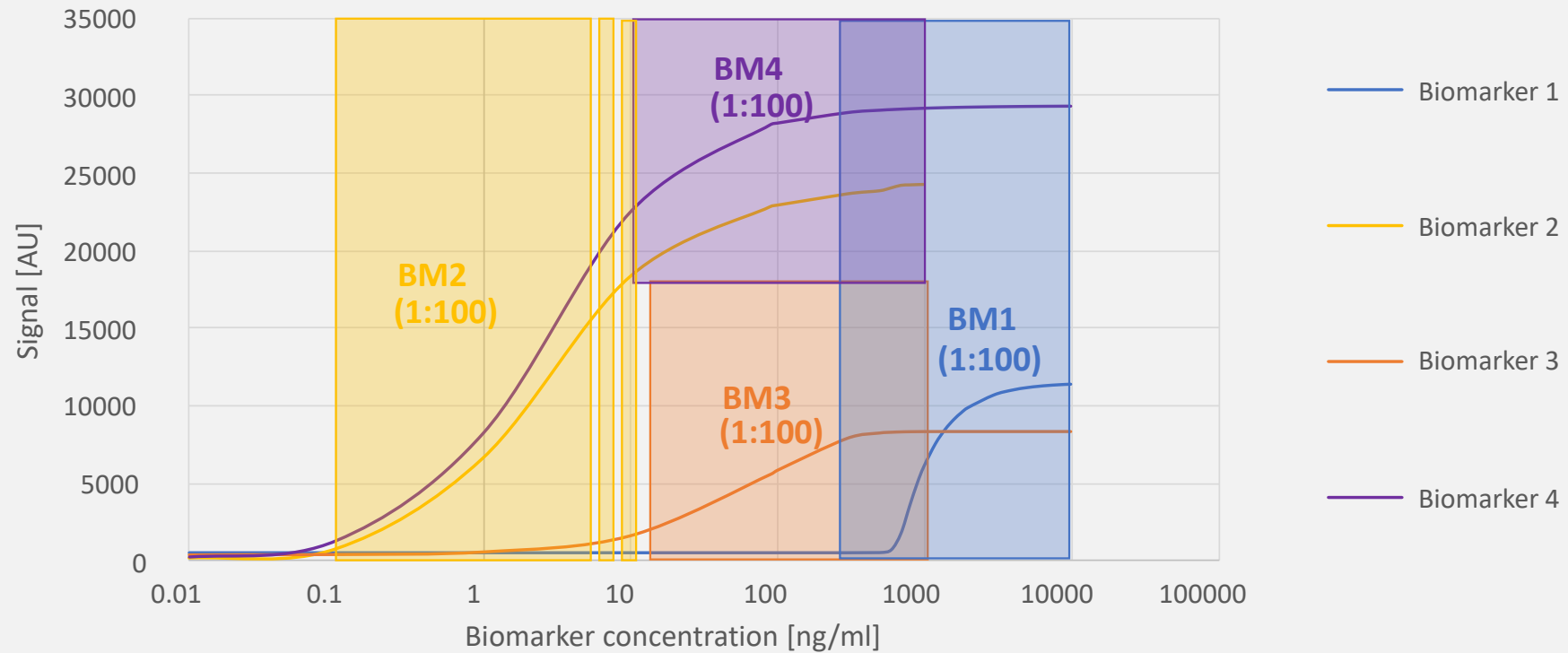
2 Place the sample in the POC+ device

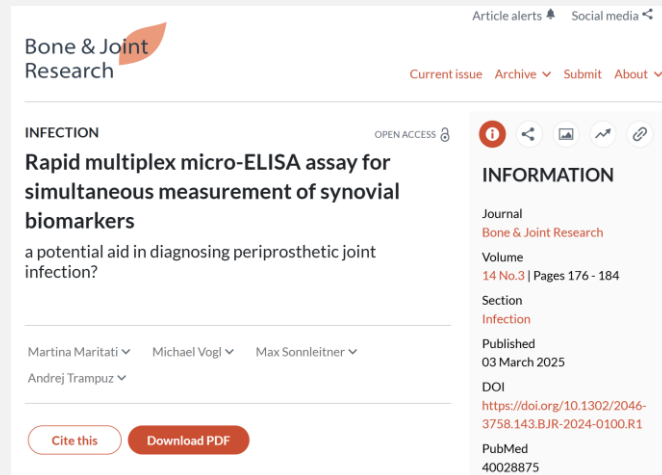
3 Wait 17 minutes

4 The result is available on the screen

5 Clinical decision making is supported

Combination of 4 Biomarkers - OEM Example





Abstract

Aim: The diagnosis of periprosthetic joint infection (PJI) remains a challenge as no single diagnostic test shows high diagnostic accuracy. Recently, the measurement of synovial biomarkers showed promising results. Aim of this study is to present a novel multiplex micro-ELISA method for the rapid and simultaneous measurement of alpha-defensin, IL-6 and calprotectin developed in a model buffer system and human spiked synovial fluid.

Methods: A microfluidics- and chemiluminescence-based multiplex micro-ELISA point-of-care testing system was employed for the rapid and simultaneous measurement of alpha-defensin, calprotectin and interleukin-6 (IL-6) developed in a model buffer system and spiked human synovial fluid. Cut-off values of 1.56 µg/ml for alpha-defensin, 50 µg/ml for calprotectin and 0.031 µg/ml for IL-6 were extracted from the literature as optimal cut-off values for the diagnosis of PJI and were used for comparison.

Results: The spiked synovial fluid assay determined limits of detection (LoD) of 0.08 µg/ml, 0.31 µg/ml, and 0.004 µg/ml for alpha-defensin, calprotectin, and IL-6, respectively.

Conclusion: These findings highlight the proposed platform's unique features, including simultaneous measurement of three key synovial biomarkers, minimal sample volume requirements (5-50 µl), lower LoDs compared to conventional tests, and a short processing turnaround time of 22 minutes. Further validation studies are necessary to confirm its clinical utility.

Keywords: peri-prosthetic joint infection; biomarkers; point of care test; micro-ELISA; multiple.



GENSPEED Team

Team

- 17 employees
- Multidisciplinary team of academics
- Biology, Chemistry, Physics
- Focus on development

Commercial success

- 5 CE IVD Products
- Launch GENSPEED Covid-19 IgG Test
- 150+ systems placed
- > 90,000 antibody tests in AT
- Global OEM Partnerships



Thank You! Questions?



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Gewerbepark 2
A-4261 Rainbach
Tel: +43 664 268 10 32
E-Mail: office@genspeed-biotech.com

www.genspeed-biotech.com