Q3 21 Presentation and projects update

October 21st, 2021

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Gentian’s value proposition

The growing diagnostic market puts increasing pressure on laboratories. Still, many of the existing, clinically relevant biomarkers are only available on slow and inefficient platforms.

By converting biomarkers to the most efficient automated, high-throughput analysers, Gentian contributes to saving costs and protecting life.

Introduction and highlights

Portfolio of high-impact tests provides solid growth opportunity

7* tests contributing to saving costs and protecting life

Revenue ambition of NOK 1bn in 5-7 years**

Industry leading team and knowhow

Delivered ~30% annual revenue growth 2017-20

* 5 launched, further 2 in development. **Dependent on timing of NT-proBNP launch

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7 diagnostic tests, including two potential blockbusters

ESTABLISHED PRODUCTS

Kidney disease

Cystatin C

2006

Inflammation & infection

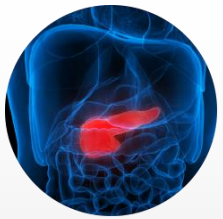
Canine CRP

2012

Inflammation

fCAL®

2015

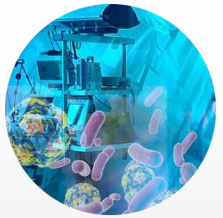


Pancreas

fPELA®

2020

IN MARKET DEVELOPMENT

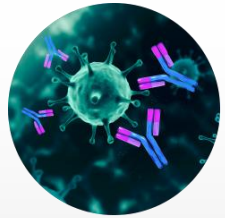


Inflammation & infection

GCAL®

2019

IN PRODUCT DEVELOPMENT



Inflammation

SARS-CoV-2

Q4 2021

Cardiac

NT-proBNP

TBD

Note: GCAL and NT-proBNP address high-value segments with serviceable markets of USD 300m and 800m, respectively.

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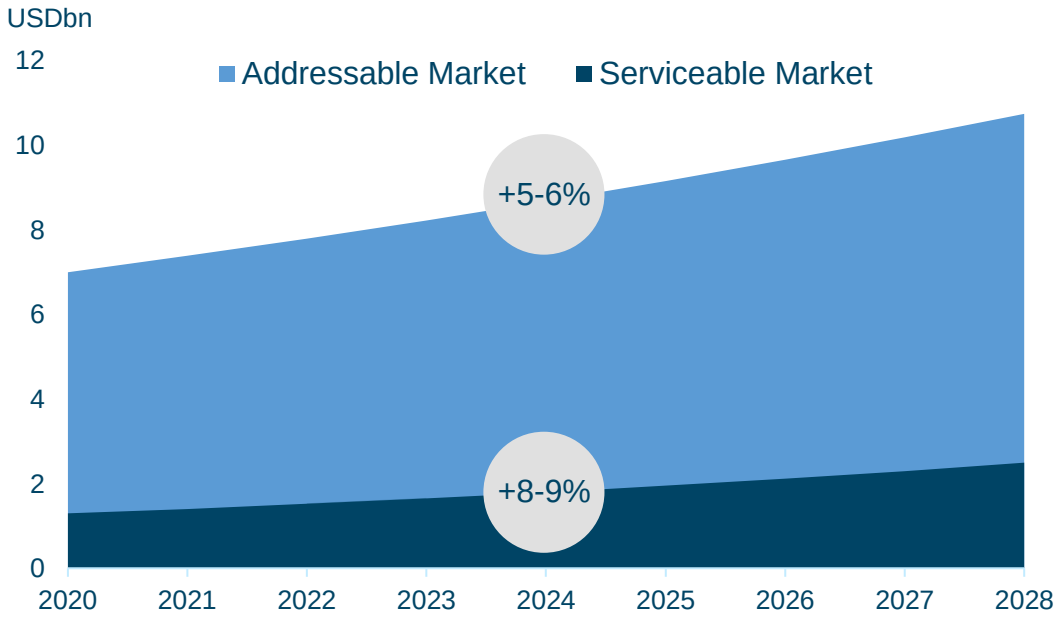
Ageing and growing population driving diagnostics demand

Market outlook



Key drivers

Addressable Market

- Increasing average age and population growth drives increase in chronic diseases and infectious diseases globally

Serviceable Market

- Gentian's selective approach, targeting attractive segments
- GCAL addressing severe infections and inflammations, providing exposure to one of the diagnostic industry's highest growing segments

Gentian market share

- High-value biomarkers offering clinical benefits
- Attractive solution to improve laboratory productivity

Addressable Market: Total demand within targeted markets 2020 (Kalorama 2020). Serviceable Market: The segment of the TAM targeted by Gentian's products (company estimates). Gentian's target market share is ~15-20%. Share of revenues net of partner take is 30-50% on average with product variations. Market growth rates = CAGR.

Ambitions for impact, high growth and value creation

Market opportunity and long-term ambitions

5-7 year revenue ambition*	NOK 1bn
Gross margin at volume production	60%+
Long-term EBITDA margins	40%

Strategic pillars

- Grow annual revenue from established products through additional commercial partners and regulatory approvals
- Prove clinical relevance of GCAL for sepsis and COVID-19
- Launch one new product per year; SARS-COV-2 Ab scheduled for Q4 2021
- Secure one new contract with a global commercial partner per year, building on established partnerships
- Grow gross margin through economies of scale
- Deliver healthy long-term EBITDA margins through operational leverage and cost discipline

* Dependent on NT-proBNP launch

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Q3 2021 highlights

Sales
NOK 17.2m
+30% vs Q3'20

EBITDA
NOK -4.2m
NOK 1.3m vs Q3'20

Cash
NOK 131.3m
NOK -21m vs Q3'20

SARS CoV-2
Ab on track
launch before end 2021

- Total operating revenue of NOK 19.4 million, up 20% from Q3 2020. EBITDA of NOK -4.2 million compared to NOK -5.5 in the corresponding quarter in 2020
- Sales revenue of NOK 17.2 million, up 30% compared to Q3 2020. Organic growth in Q3 2021 was 37%
- In final stage of negotiations with a leading global diagnostics provider for commercial rollout of GCAL®
- Achieved development of an independent reference method for NT-proBNP
- Development of the SARS CoV-2 assay is on track for launch towards the end of Q4 2021

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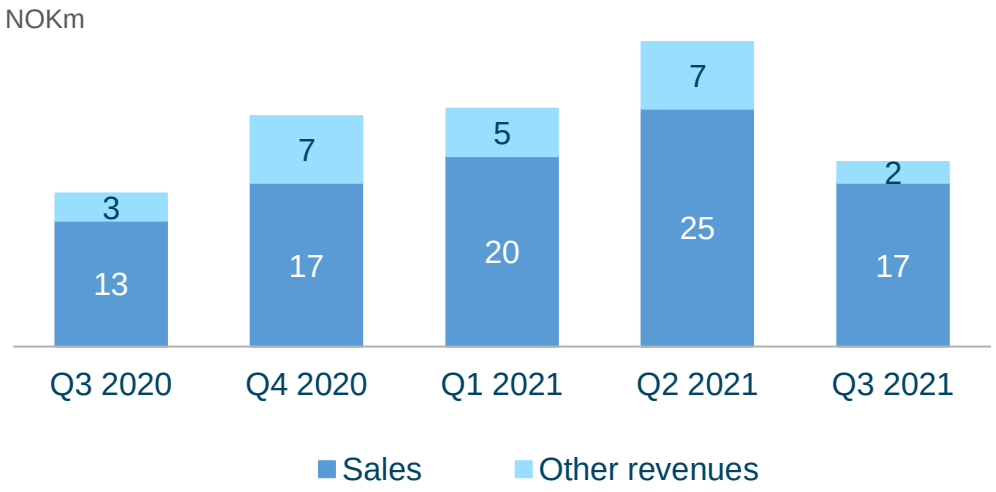
Financial review

Financial highlights

NOKm	Q3 2021	Q3 2020	YTD 2021	YTD 2020
Sales	17.2	13.2	61.4	46.1
Other revenues	2.2	2.8	13.7	8.9
Total revenues	**19.4**	**16.1**	**75.1**	**55.1**
COGS	10.8	7.3	32.6	32.6
Employee benefit expenses	8.9	9.7	27.3	28.1
D&A	2.4	1.5	6.3	4.7
Other OPEX	3.9	4.5	22.2	13.5
EBITDA	**-4.2**	**-5.4**	**-7.0**	**-10.1**
EBIT	**-6.7**	**-7.0**	**-13.3**	**-14.8**

Sales and other revenues

- Total revenue of NOK 19.4m in the quarter, up 20% vs Q3 20
- 37% growth in organic sales (30% reported)
  - Particularly driven by increased adoption of Cystatin C as a routine marker for chronic kidney disease and strong demand growth in China and South Korea
- Other revenues related to amounts received from associated research grants and tax incentives



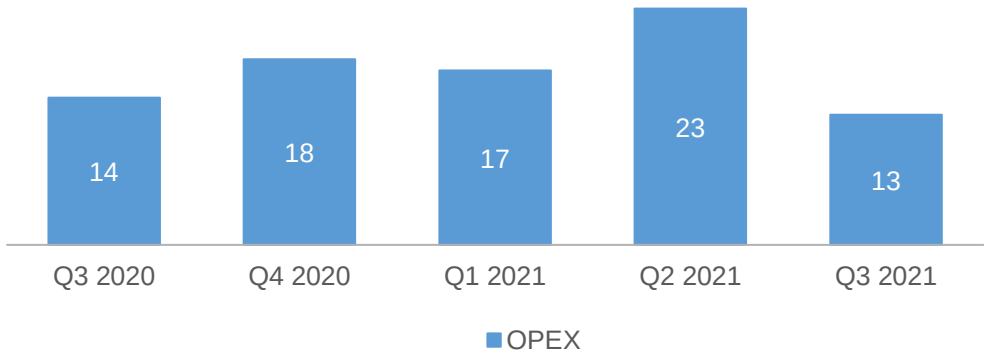
Sales - geographic split

NOKm	3Q21	3Q20	YTD21	YTD20
US	0.6	0.6	2.0	2.3
Europe	12.4	11.4	42.0	32.5
Asia	4.3	1.3	17.4	11.4
Total	**17.2**	**13.2**	**61.4**	**46.1**

Sales - product split

NOKm	3Q21	3Q20	YTD21	YTD20
Cystatin C	7.3	3.7	25.7	18.7
fCAL® turbo	5.4	5.6	22.2	14.8
Other	4.5	4.0	13.5	12.8
Total	**17.2**	**13.2**	**61.4**	**46.1**

Operating expenditures in the quarter



NOKm	Q3 21	Q3 20	YTD 21	YTD 20
Sales and marketing expenses	3.3	3.1	11.1	9.5
Administration expenses	5.1	4.7	19.5	15.7
Research and development expenses	4.4	6.4	18.9	16.4
Total	**12.8**	**14.2**	**49.4**	**41.6**

- Opex declined by NOK 1.7 million, driven by higher share of capitalisation of R&D expenses
  - Capitalisation of R&D expenses was NOK 3.9 million, up from NOK 0.3 million in Q3 2020

OPEX after capitalisation of R&D expenses

Strong cash position; fully financed business plan

NOKm	Q3 21	Q3 20	YTD 21	YTD 20
Operating activities	-2.1	-8.6	-13.9	-17.2
Investing activities	-4.1	-0.3	-10.3	-1.9
Financing activities	-1.1	-0.1	-2.3	-0.2
Changes in cash and cash equivalent	**-7.3**	**-8.9**	**-26.5**	**-19.3**
Cash and cash equivalent at the beginning of period	138.6	161.2	158.0	171.6
Cash and cash equivalent at the end of period	**131.3**	**152.3**	**131.3**	**152.3**

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Summary and outlook

Several de-risking milestones next ~18 months

	ESTABLISHED PRODUCTS	GCAL	SARS-COV-2 AB	NT-PROBNP
2021-2022 MILESTONES	Targeting additional large commercial partners Additional regulatory approvals, including IVDR*	Clinical studies confirming relevance for sepsis and COVID-19 – 6 ongoing Securing endorsements from key opinion leaders Securing global commercial partnerships and initiating EU rollout	Successful validation and launch, scheduled for Q4 2021 Entering commercial partnerships for the Nordics	Successful optimisation Publication on the reference method for standardisation Securing endorsements from key opinion leaders and global commercial partnerships

Further potential milestones in pipeline with 3 biomarkers currently in exploration and ‘proof of concept’

* IVDR: A new regulation coming into force 26 May 2022, requiring extensive documentation of the safety, performance and quality of each diagnostic test from manufacturers through several studies on both analytical and clinical performance.

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Projects update

Erling Sundrehagen, CSO
Gentian Diagnostics ASA

21st October 2021

NT-proBNP update

Agenda

- Introduction
- The science behind NT-proBNP
- Turbidimetric assay development
- Independent reference method development
- Outlook

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Introduction

Indicative advantages and commercial validity of Gentian's NT-proBNP assay

Clear value proposition

- Productivity gain and cost effectiveness vs. current products
  - Sample throughput of 2,000/h vs 700/h
- Enabling harmonisation and standardisation

Strong commercial interest

- Established biomarker, new technology
- Market sensing confirms the value proposition
- Market pull based on pre-launch information, organic strong interest from larger global IVD companies

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NT-proBNP detecting, monitoring and assessing congestive heart failure

- Well established biomarker, fully integrated in the clinical routines
- More than 60 million patients with heart failure per year
- A health challenge that is increasing rapidly due to an ageing population and increasing obesity
- Number of heart failure patients ~doubled since 1990

Source: Epidemiology of heart failure; Amy Groenewegen, Frans H. Rutten, Arend Mosterd, Arno W. Hoes; 2020

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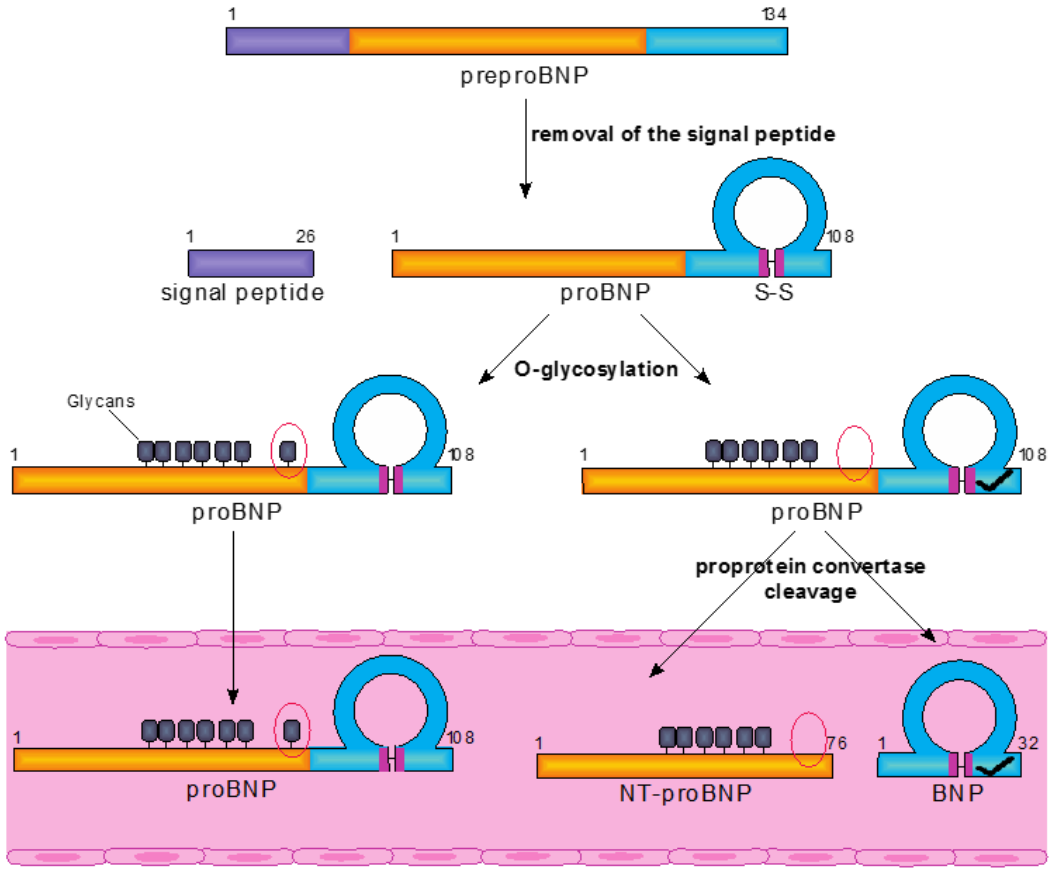
The science behind NT-proBNP

The market is moving towards NT-proBNP, which is more stable than BNP in the bloodstream



- BNP half life in blood stream: appr. 20 minutes
- NT-proBNP half life in blood stream: appr. 60-120 minutes

Source: Human proBNP, BNP and NT-proBNP, Technotes HyTest

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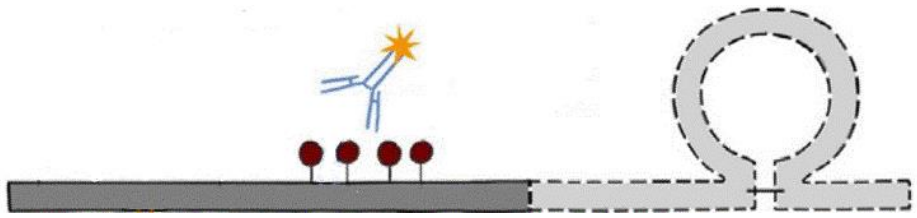
Existing assays underestimate the amount of NT-proBNP

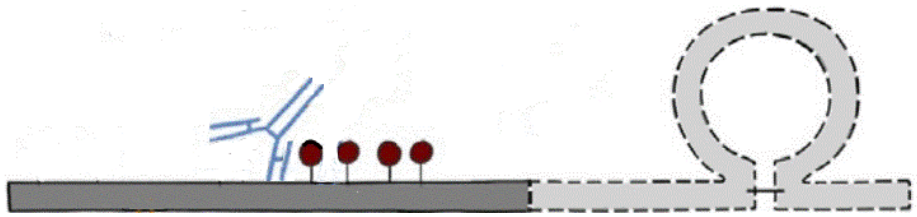
…due to NT-proBNP being heavily glycosylated in the middle molecule region

Existing assays do not recognise glycosylated NT-proBNP molecules



Existing NT-proBNP assays

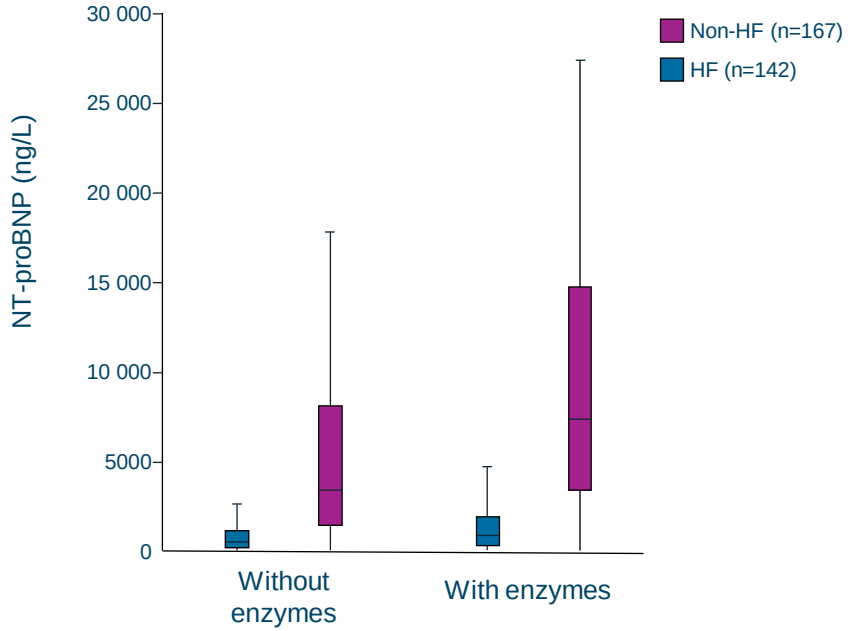
The Gentian assay binds in a non-glycosylated area of the NT-proBNP molecule



Gentian NT-proBNP assay

Existing publication supports Gentian developing a turbidimetric assay

Influence of enzymes on diagnostic and prognostic accuracy*



- 2015 publication confirmed underestimation in NT-proBNP assays, which validated Gentian's efforts to develop a turbidimetric assay
- Publication showed blood samples treated with enzymes measured higher NT-proBNP concentrations
- The hypothesis went from developing an assay which enabled higher throughput to also set a new market standard

*Influence of Glycosylation on Diagnostic and Prognostic Accuracy of N-Terminal Pro–B-Type Natriuretic Peptide in Acute Dyspnea: Data from the Akershus Cardiac Examination 2 Study
Helge Røsjø, Mai Britt Dahl, Marit Jørgensen, Ragnhild Røysland, Jon Brynildsen, Alessandro Cataliotti, Geir Christensen, Arne Didrik Høiseth, Tor-Arne Hagve, Torbjørn Omland
Clinical Chemistry, Volume 61, Issue 8, 1 August 2015, Pages 1087–1097

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Publication in 2015 highlights the the lack of transferability of the results obtained using different techniques to measure BNP and NT-proBNP levels clinical samples

Head-to-head comparison of 10 natriuretic peptide assays

Delphine Collin-Chavagnac * , Monique Dehoux , Fran ç ois Schellenberg , Bruno Cauliez , Fran ç oise Maupas-Schwalm and Guillaume Lefevre , on behalf of the Société Française de Biologie Clinique (SFBC) Cardiac Markers Working Group

Clin Chem Lab Med, Volume 53, Issue 11, October 2015, Pages 1825-37

“The multiplication of assays and antibody configurations clearly impacts the harmonisation of NT-proBNP results. Our findings on the inter-technique variability using fresh blood samples confirm the non-commutability of results between all BNP techniques and highlight the non-comparability between all NT-proBNP techniques.”

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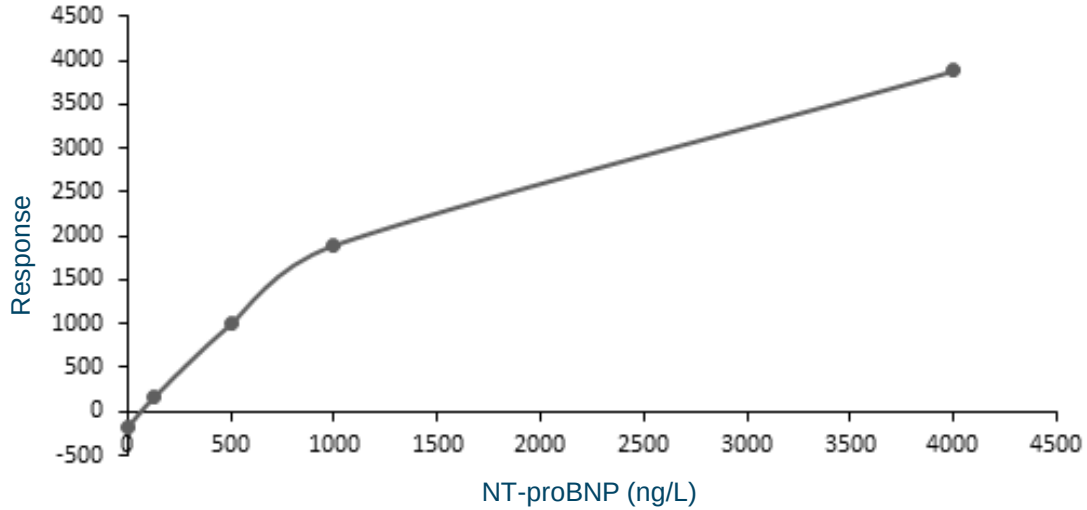
Turbidimetric assay development

Gentian has achieved turbidimetric assay calibration

NT-proBNP calibration curve – Peptide 1 calibrators

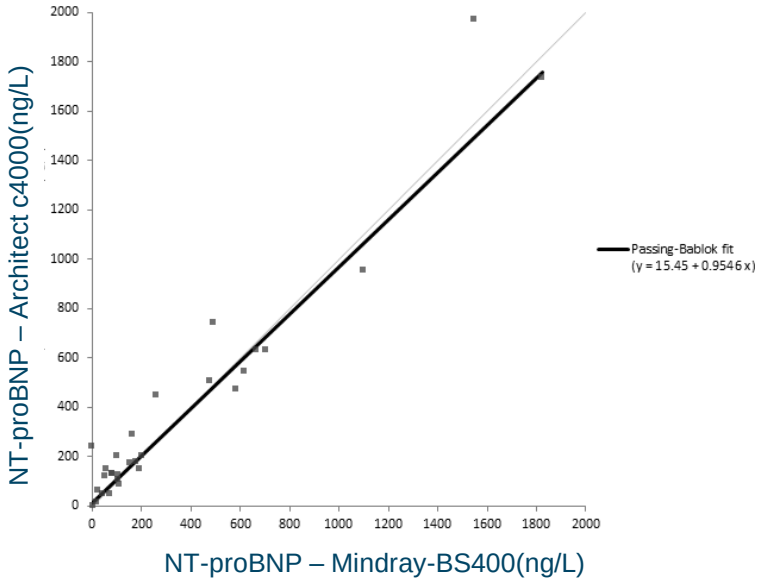


- In 2021, Gentian achieved turbidimetric assay calibration which was published in a patent application

Patent application: WO/2021/028520

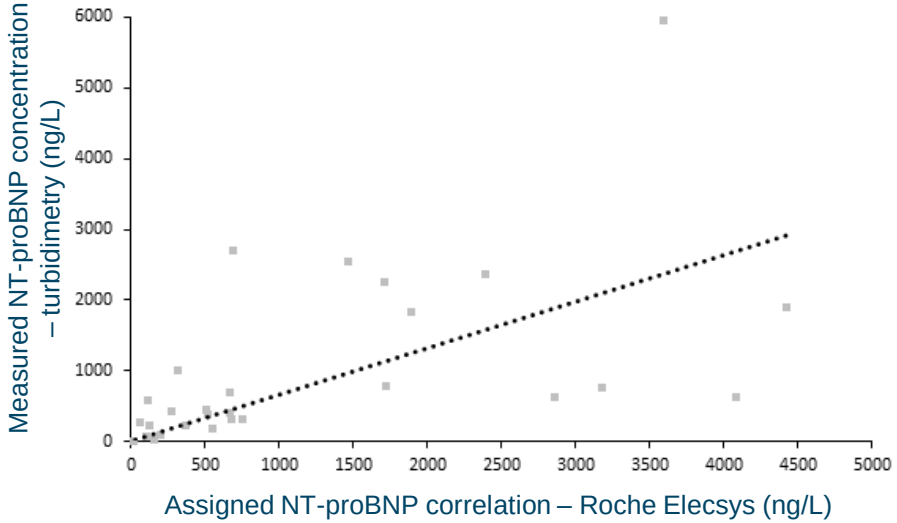
Gentian's assay indicates strong correlation between samples and methods, but the need for a reference method was identified

Measurement of correlation on Mindray and Architect c4000



- Early tests with few samples indicating highly encouraging results
- Gentian's assay under development indicated strong correlation between two different instruments

Turbidimetric NT-proBNP measurement vs Roche Elecsys



- Gentian's assay measured against the market leader, Roche Elecsys, shows lack of correlation
- Proves the need for Gentian to develop a reference method

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Gentian reference method development

Introduction

- Results from market confirm the lack of harmonisation and standardisation of NT-proBNP assays as a key concern among laboratory managers and clinicians
- Based on that, Gentian recently succeeded in developing an independent reference method based on established technology
- This reference method is not based on turbidimetry
- Offers the possibility to revise results from existing assays and to prepare and ensure the concentrations of the Gentian calibrators

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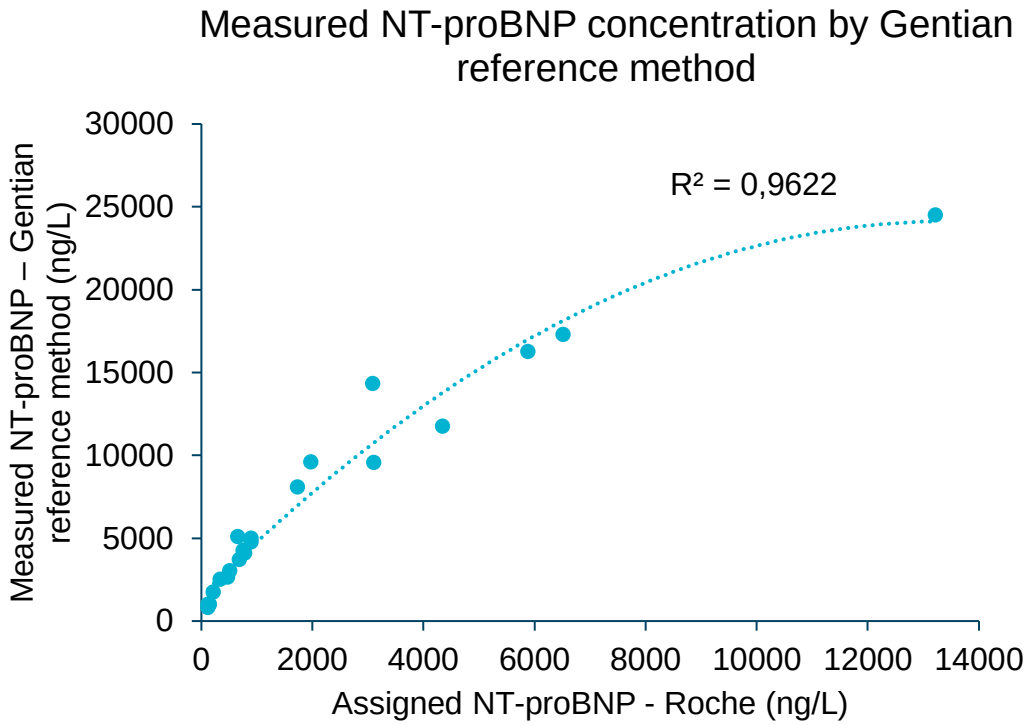
Gentian’s reference method shows increased NT-proBNP concentration compared to Roche



- Results of Gentian’s reference method show higher NT-proBNP concentrations than results from Roche method
- Based on these samples, there are positive indications that the development of a reference method will enable standardisation of results

Note: 20 plasma samples

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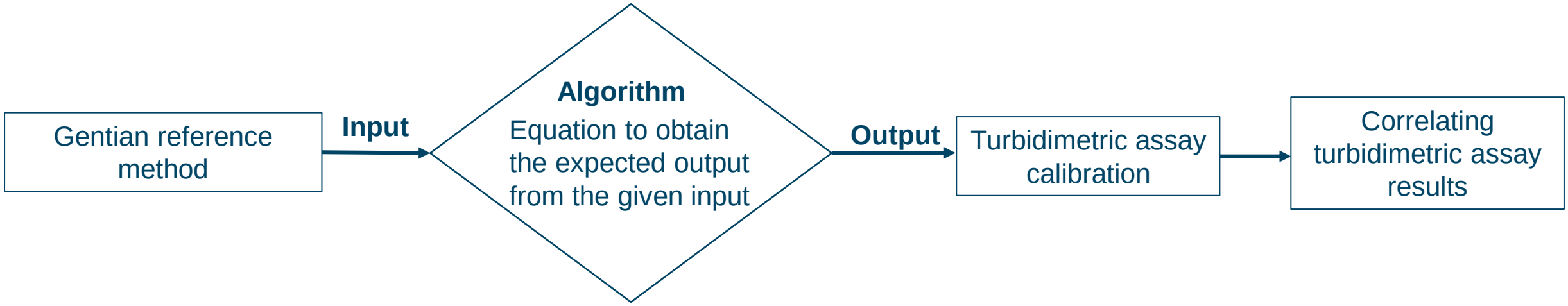
Gentian has succeeded in creating an algorithm that correlates the results



- To fully qualify the reference method, more tests are required, and the company has therefore initiated further trials to substantiate the method

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Outlook

Addressing NT-proBNP challenges and establishing a new timeline towards launch

«As communicated previously, we have encountered challenges in the optimization phase. Many of these are known challenges that we have successfully dealt with before, and as such, we will apply all the tools available to succeed with optimization and continue the development of NT-proBNP. It will take more time and cost more than we expected, but the additional investments are clearly justified by the significant commercial potential this assay holds. Currently, we work hard to address these challenges and to establish a new timeline towards launch.»

Erling Sundrehagen, CSO and co-founder, Gentian Diagnostics

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NT-proBNP challenges and how they are being addressed

Particle instability

- Known issue for turbidimetric assays
- Gentian has prior experience with solving these issues
- Several tried and tested solutions exist
- Good progress made in recent weeks

Measurement differences in plasma and serum samples

- Common issue for NT-proBNP assays on the market
- Currently focusing on plasma, which has good results
- Considering to delay development of an assay that can also measure serum samples

Consistency of results at low concentrations

- More work required to achieve consistently reproducible results at low concentrations to ensure competitive product
- Gentian has leading expertise in this field

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Aim to update revised timeline in connection with Q4 results

- While development risks remain, the Gentian team believes the challenges encountered in optimisation can be solved
- On the back of initial results from attempts to solve the current challenges, the company aims to revert to the market in connection with the Q4 results with an updated timeline towards launch
- The revised timeline will also take into account the effects from the new regulatory requirements in Europe, IVDR

Torsten Knüttel, VP R&D
Gentian Diagnostics ASA

21st October 2021

Development of a novel high-throughput SARS-CoV-2 antibody test

Agenda

- Introduction
- Pandemic Management
- Gentian SARS-CoV-2 Total Antibody Assay
- Assay application
- Assay quality and efficiency
- Documented Protection
- Summary & launch information

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Introduction

Introduction

- During the early days of COVID-19, Gentian has decided to contribute to the fight against this pandemic with the development of a quantitative antibody assay in case high volume testing will be required
- Due to the local partnership with Tromso university and our own commercial footprint the initial target market had always been the Nordics
- Early signs in the Nordics market confirm an increasing interest in a better understanding of the immune status of patients
- In terms of geographic expansion, we are realistic with the uncertainty of local healthcare guidance and policy relative to COVID serology testing outside the Nordics and we have so far not planned for additional market access efforts, for example an FDA (510)k application
- After a successful introduction into the Nordics markets, there is the opportunity to expand the commercialization through existing distributors and selected direct efforts in Central Europe, provided the guidance environment is positive to serology testing

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Pandemic Management

Pandemic Management

Provide tool for the long-term surveillance of immunity of the society

Guide educated decisions about herd immunity and vaccination strategy

‘Documented protection’ possibility for the population and for all Norwegian businesses including tourism/travel

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Gentian SARS-CoV-2 Total Antibody Assay

Gentian SARS-CoV-2 Total Antibody Assay

What	Quantitative detection of total antibodies to SARS-CoV-2 spike (S1) protein
Why	Intended to identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, or a successful response to vaccination
How	Total Antibody test targeting S1 on open channel high throughput clinical analysers

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Assay application

Assay application

- On already installed Clinical Chemistry Analysers
  - Large global install base, widely available
- No extra infrastructure needed
  - Standard blood test
- Fast High Throughput (up to 2.000 tests/hour)
  - Results after only 10 minutes analysis time
  - Immediate use after short application setup
- Cost efficient

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Assay quality and efficiency

Assay quality and efficiency

High sensitivity (98%) and specificity (98%)* * Preliminary results	Reliable assay with quantitative results
Measuring total antibody response targeting S1	Capturing the whole immune response and multiple virus variants
Aligned with WHO International Standard	Comparable results across laboratories and assays

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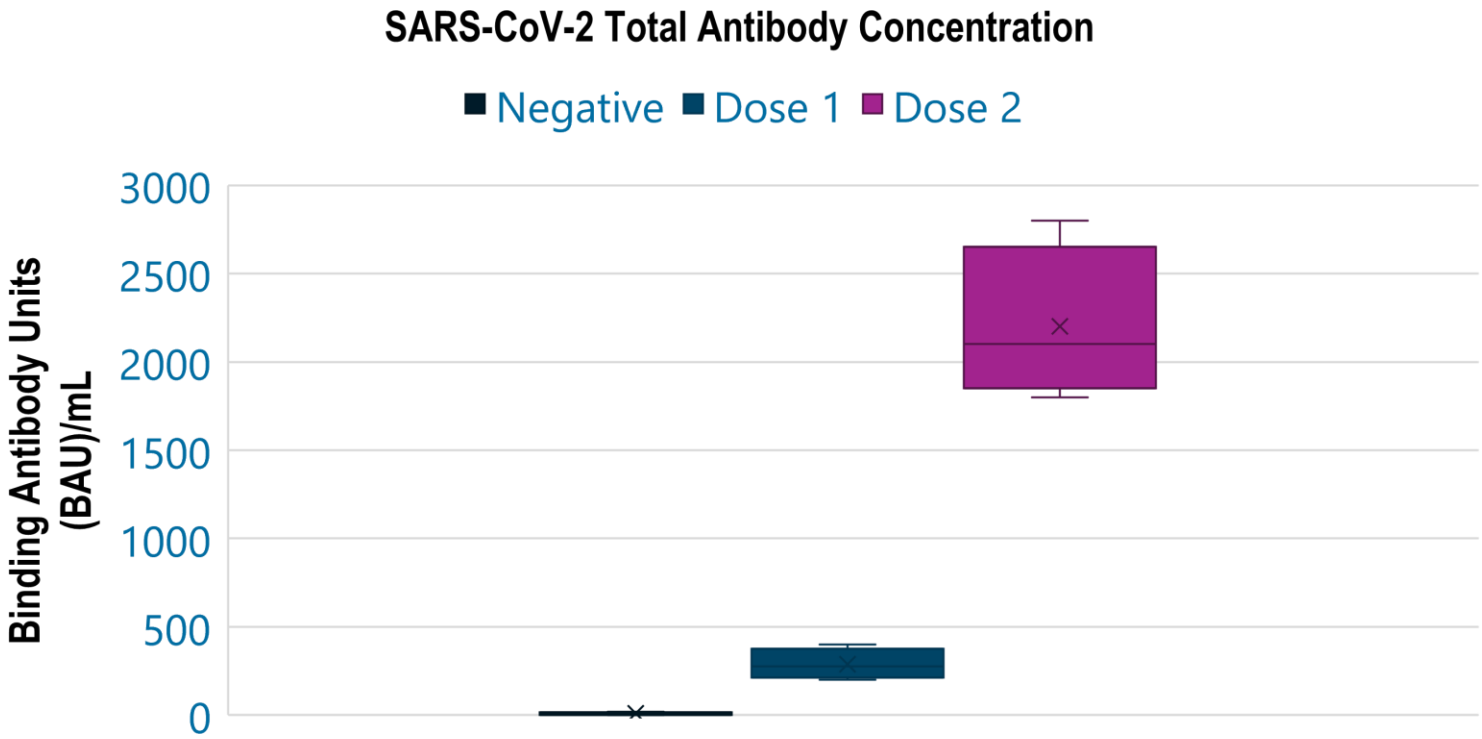
Documented Protection

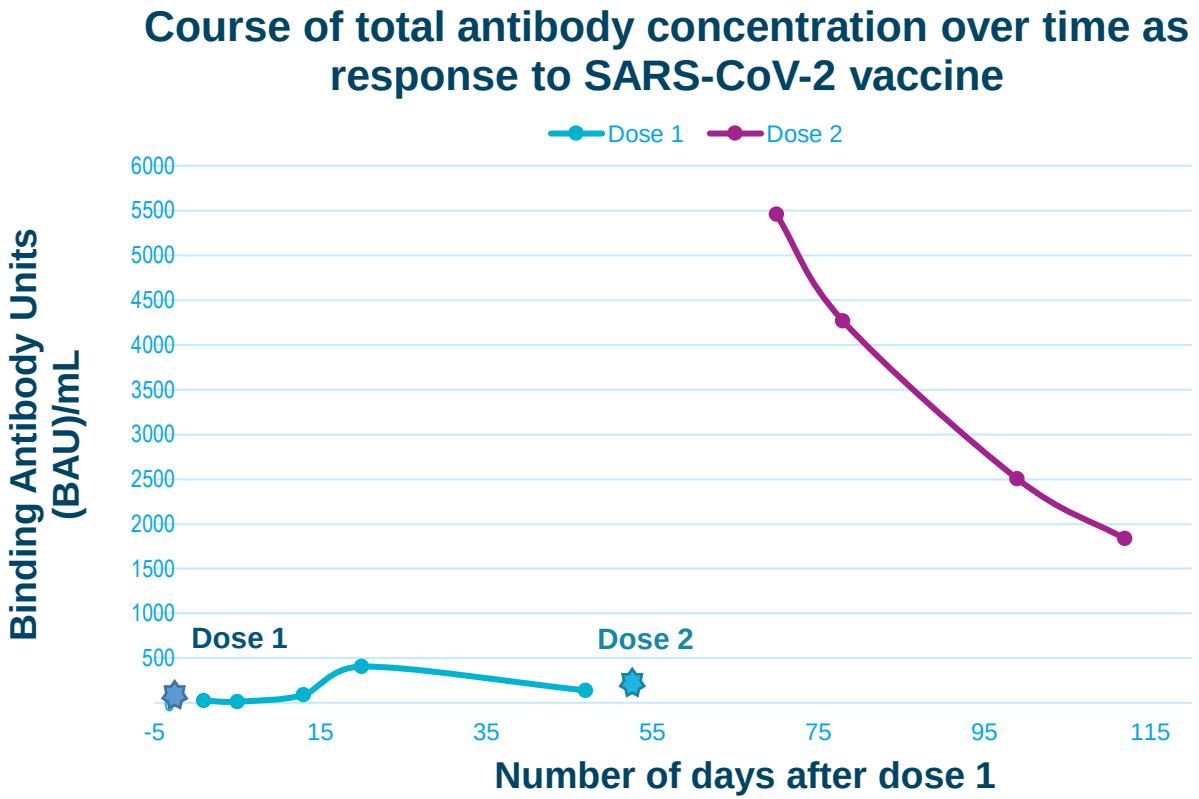
Documented Protection

Preliminary data from in-house blood samples show strong antibody response after vaccination, increasing from 1st to 2nd dose



Documented Protection – individual case

Preliminary data from in-house blood samples, following individual total antibody concentration from 1st dose vaccination to 2nd dose vaccination and thereafter



Summary

The Gentian antibody testing against SARS-CoV-2 can

Provide answers to individual and the population's immunity before and after vaccination and can be used as a tool for vaccine distribution

Indicate how long protection lasts after vaccination or infection

Assist with long-term monitoring, planning and management of the community under COVID-19

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Launch of the Gentian SARS-CoV-2 Total Antibody Assay

- The assay development is currently in the final validation phase
- Plan to launch the CE marked assay according to the IVD Directive within Q4 2021

“The test developed by Gentian can identify and quantitate the amount of immunoglobulins in the patients blood. This will verify the effect of the vaccine, and this information could be used to decide if the patient need another booster dose of the vaccine.

For patients with infections with different variants of the virus, currently and possibly future mutations and variants, the Gentian test will enable the physician to decide what vaccines to be used.”

Professor Ørjan Olsvik
Department of Medical Biology
UiT The Arctic University of Norway, Tromsø

Q&A