

***gentian***

# Meet Gentian at AACCC 2022

## Visit us at booth #4421

Open channel clinical chemistry immunoassays for a  
wide range of clinical indications



**WE INNOVATE DIAGNOSTIC EFFICIENCY**

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# GENTIAN DIAGNOSTICS

Gentian is a Norwegian IVD company that specializes in the manufacturing of turbidimetric assays that empower clinical lab professionals to achieve greater operational efficiency. The current portfolio and pipeline of diagnostic reagents span areas of kidney disease, cardiac disease, inflammation, infection and veterinary medicine.

## Global market reach

We manufacture reagents for both laboratories and industry partners. R&D, production, marketing and distribution are performed at our headquarters in Norway. Global operations are supported by subsidiaries in Sweden and the US, and through a representative office in China.

- OEM partnerships
- Distribution opportunities
- Direct sales channel

## Innovating diagnostic efficiency

By leveraging both its expertise in Particle-Enhanced Turbidimetric Immunoassays (PETIA) and proprietary nanoparticle technology, Gentian develops immunoassays that enable users to transition from traditional low volume immunology platforms to fully automated clinical chemistry instruments. The typical Gentian customer enjoys shorter turnaround times, streamlined workflows and improved cost efficiency.

## Immunoassays

- GCAL® - Plasma and serum calprotectin
- Cystatin C
- Canine CRP
- SARS-CoV-2 Total Antibody



## CONTACT OUR MANAGEMENT



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### OEM & Partnerships

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# BIOMARKERS IN GROWING DEMAND

## CYSTATIN C

- A superior kidney marker<sup>1</sup>



Equations that include cystatin C estimate GFR more accurately than serum creatinine in children<sup>\*2</sup>, adults<sup>3</sup> and older adults<sup>4</sup>. Accurate assessment of kidney function is crucial to ensuring efficacy and safety of drugs that are renally eliminated<sup>5</sup>.

- ➔ Combining cystatin C and creatinine based eGFR helped double the portion of patients reaching goal trough concentrations of Vancomycin compared with usual care<sup>6</sup>
- ➔ Cystatin C offers the opportunity to avoid the race coefficient that is required for any current creatinine-based eGFR equation<sup>5</sup>
- ➔ Superior to creatinine-based equations in predicting end-stage renal disease, cardiovascular manifestations, hospitalization and death<sup>5</sup>



Cystatin C Global Product Manager

Gaute Tangen

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## CALPROTECTIN IN PLASMA AND SERUM

- Early detection and assessment of inflammation

Calprotectin has shown potential applications for early and sensitive detection of infections, particularly for conditions where timely access to results is critically important. Earlier detection guides treatment decisions and risk stratification of severe infections, including sepsis and COVID-19<sup>7-9</sup>. In addition, calprotectin is a sensitive biomarker in non-infectious inflammatory conditions, like rheumatoid arthritis (RA), where it correlates with both disease activity and severity<sup>10</sup>.

- ➔ Fast kinetics in response to infection<sup>11</sup>
- ➔ Differentiates between bacterial and viral infections<sup>12</sup>
- ➔ Disease assessment even at low inflammation activity<sup>10</sup>



GCAL<sup>®</sup> Global Product Manager

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\*Not validated for children <14 years in the US

## SARS-CoV-2 TOTAL ANTIBODY IMMUNOASSAY

Long-term monitoring and community management of COVID-19

The Gentian SARS-CoV-2 total antibody test will provide a powerful high-throughput tool for the long-term monitoring and community management of COVID-19. Gentian will bring SARS-CoV-2 serology testing to clinical chemistry platforms, increasing both testing capacity and laboratory efficiency.

The assay will detect total antibodies ensuring high sensitivity<sup>13,14</sup> and by targeting spike protein of the virus it will provide high specificity<sup>15</sup>, correlation to neutralizing antibodies<sup>16</sup>, and cover targets of vaccine programs<sup>17,18</sup>. The Gentian SARS-CoV-2 total antibody test aims to join the effort for future effective and reliable monitoring of the virus behavior in communities and possible assessment of population immunity and vaccination responses.



SARS-CoV-2 Product Manager

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## UNDER DEVELOPMENT: NT-proBNP ON CLINICAL CHEMISTRY ANALYZERS

Same accurate diagnostic results as available chemiluminescence immunoassay analyzers

The Gentian NT-proBNP assay is an in vitro diagnostic assay for the quantitative measurement of N-terminal pro-brain natriuretic peptide (NT-proBNP). Gentian's proprietary antibody and nanoparticle based technology allows for biotin interference-free measurement of low concentrations of NT-proBNP on high volume clinical chemistry analyzers. This test fulfils the need for accurate and rapid diagnosis of congestive heart failure (CHF), which will enable better patient outcomes and increased laboratory productivity.

- ➔ Ability to standardization across platforms and laboratories
- ➔ Low-concentration cardiac biomarker on high-volume clinical analyzers
- ➔ No biotin interference



NT-proBNP Global Product Manager

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# PARTNERSHIPS AND OEM SOLUTIONS

## Partner with Gentian to benefit from our OEM solutions and unique capabilities

Gentian offers products and biomarkers as part of an OEM solution for use within partners' applicable market segments. Any formulations or solutions (kitting, bulk supply, packaging and private label) of our products or biomarkers already introduced to the market or in development are available.

- ➔ Partner with us for high quality, security of supply, customization and expertise
- ➔ Benefit from product expertise and clinical knowledge to position products through your own market channels
- ➔ Leverage the Gentian robust manufacturing capabilities to speed your way to market

### OEM & Partnerships

Jack Andreassen, VP Business Development

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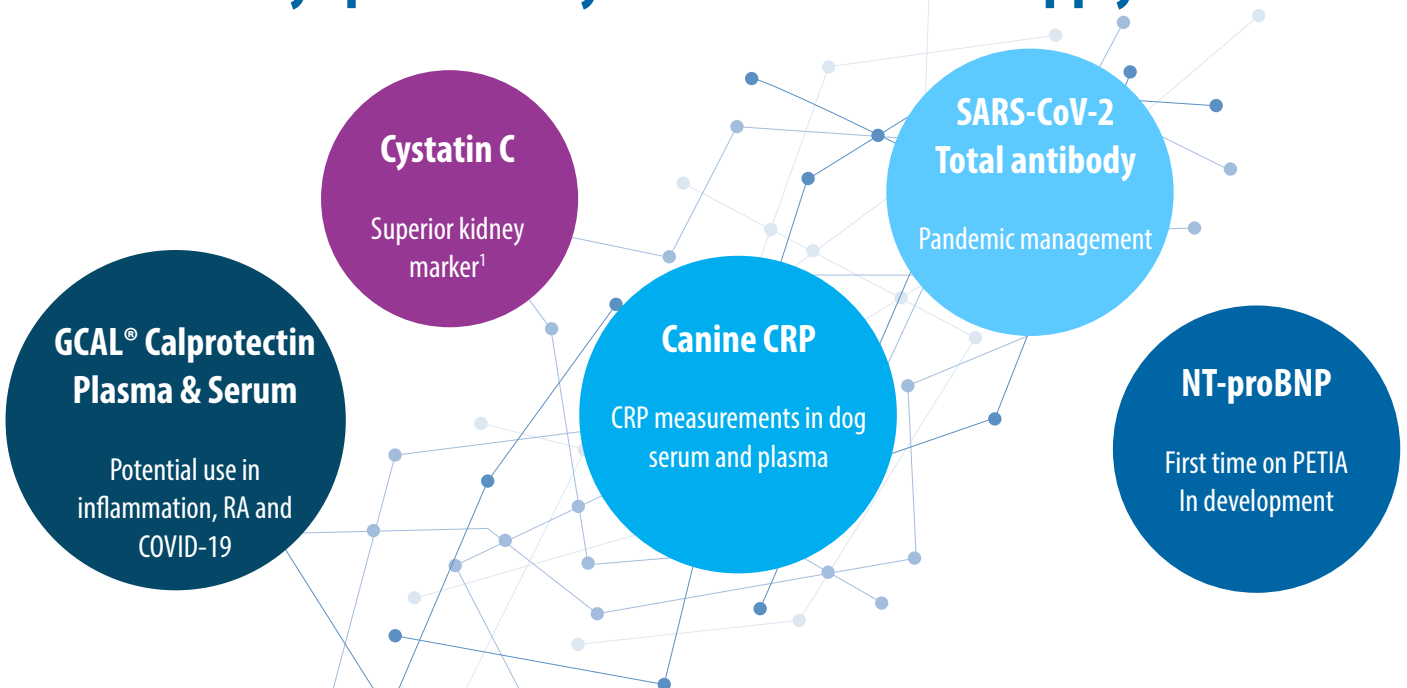
### Business Development

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## Gentian assays particularly relevant for OEM supply:



# CYSTATIN C: OPEN CHANNEL TURBIDIMETRIC ASSAY

## Recommended for assessment of Glomerular Filtration Rate (GFR) and kidney function<sup>5</sup>

Analyzing cystatin C and creatinine together can give the physician more accurate information on the patient's eGFR than creatinine alone. A joint task force assembled by the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) recently recommended the increased use of cystatin C in combination with creatinine, as a confirmatory assessment of GFR or kidney function.

### Removing the race factor from creatinine equations

The NKF-ASN task force recommends implementation of the CKD-EPI Creatinine equation refit without the race variable<sup>23</sup>. Simply removing the race factor introduces systematic misclassification that cannot be eliminated even when numerous non-GFR determinants of serum creatinine levels are accounted for. Cystatin C based eGFR equations do not have a race coefficient and cystatin C can be used alone or in combination with creatinine to calculate eGFR. The combination of both markers has been shown to be the most accurate<sup>24</sup>.

### Calibrator standardization

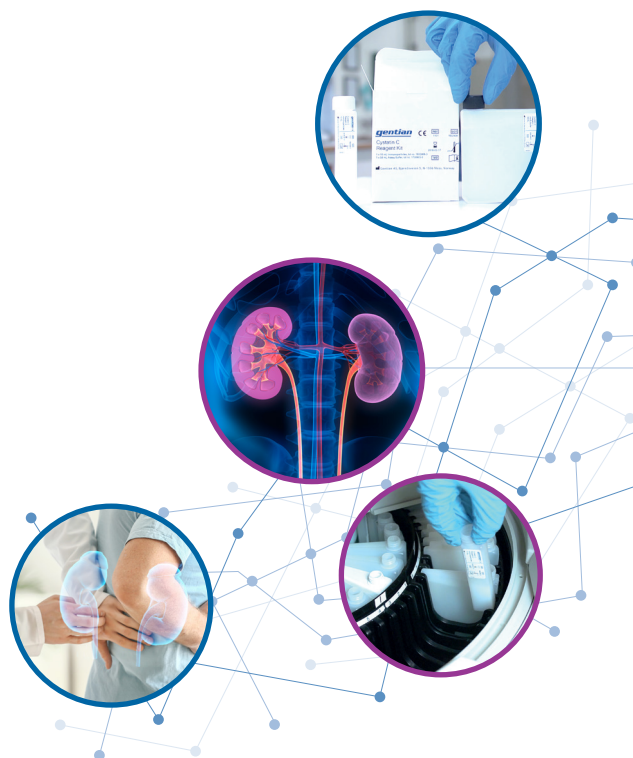
The calibrator for the Gentian Cystatin C Immunoassay is available in two versions, one-level calibrator for auto-dilution or a 6-point pre-diluted calibrator kit. Both types of calibrators are standardized against the international calibrator standard ERM-DA471/IFCC.

### Cystatin C on instruments already in your lab

- Abbott Laboratories
- Beckman Coulter
- Mindray
- Ortho Clinical Diagnostics
- Roche
- Siemens Healthcare

### Gentian Cystatin C Immunoassay advantages

- ERM-DA471/IFCC standardized
- FDA510 (k) cleared and CE-marked
- Available for a wide range of clinical chemistry analyzers with documented high inter-instrument accuracy
- Avian antibodies - Avoids interference from rheumatoid factor



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# PRODUCT PORTFOLIO

## INFLAMMATION



### **GCAL<sup>®</sup> - plasma and serum calprotectin**

#### **Detection and assessment of inflammation and inflammatory response to infections**

Calprotectin is a promising biomarker for neutrophil activation and inflammation in multiple infections and non-infections inflammatory conditions. Its fast increase in inflammation enables an early and sensitive detection of inflammation and risk stratification<sup>7-9,11</sup>.

GCAL<sup>®</sup>, the Gentian Calprotectin Immunoassay, is the first turbidimetric assay for the quantitative measurement of calprotectin in plasma and serum intended as an aid in the detection and assessment of inflammation.

- ➔ Can be applied on a wide range of automated clinical chemistry analyzers
- ➔ Avian antibodies – less interference
- ➔ CE-marked

#### **ORDERING AND INFORMATION:**

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## RENAL



### **Cystatin C**

#### **Preventing severe kidney failure**

The Gentian Cystatin C Immunoassay (CE marked and FDA-510(k) cleared) is an IVD test for quantitative determination of cystatin C in human serum and plasma, supporting an early detection of reduced kidney function.

- ➔ Independent of race, protein intake, gender, age and muscle mass avoiding the creatinine blind area<sup>19-22</sup>
- ➔ Ignoring the potential additional information gained by cystatin C testing leads to systematic over-estimation of kidney function with adverse impacts on patient care<sup>5</sup>
- ➔ Improved accuracy when selecting the dose of important drugs<sup>5</sup>

#### **ORDERING AND INFORMATION:**

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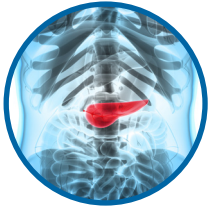


## fCAL<sup>®</sup> turbo

### Automated analysis of fecal calprotectin, reducing the need of colonoscopy

The BÜHLMANN fCAL<sup>®</sup> turbo is an immunoassay for quantification of fecal calprotectin on clinical chemistry instruments, providing fast results to clinicians. Calprotectin is a highly sensitive biomarker, that supports diagnosis of inflammatory bowel disease (IBD), such as Crohn's disease (CD) and ulcerative colitis (UC), and aids in the differentiation of IBD from irritable bowel syndrome (IBS).

- ➔ The product is sold exclusively through Gentian's partner BÜHLMANN
- ➔ CE marked and FDA-510(k) cleared
- ➔ Compatible with the stool extraction device CALEX<sup>®</sup> Cap which allows for safe and convenient stool extraction



## fPELA<sup>®</sup> turbo

### Aid in determination of Pancreatic Exocrine Insufficiency (PEI)

The BÜHLMANN fPELA<sup>®</sup> turbo is an immunoassay for quantification of fecal pancreatic elastase on clinical chemistry instruments. The product is an aid in determining pancreatic exocrine insufficiency (PEI), which can be caused by many underlying disorders and often has similar symptoms as inflammatory bowel disease (IBD).

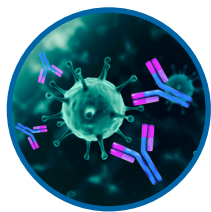
- ➔ The product is sold exclusively through Gentian's partner BÜHLMANN
- ➔ CE marked and FDA Exempt
- ➔ Compatible with the stool extraction device CALEX<sup>®</sup> Cap which allows for analysis of fecal pancreatic elastase and fecal calprotectin in the same sample (in combination with BÜHLMANN fCAL<sup>®</sup> turbo)

## PARTNERSHIP OPPORTUNITIES:

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## SARS-CoV-2 TOTAL ANTIBODY IMMUNOASSAY

### SARS-CoV-2 serology test on clinical chemistry analyzers

The Gentian SARS-CoV-2 total antibody test will provide a powerful high-throughput tool for the long-term monitoring and community management of COVID-19. Gentian has taken the SARS-CoV-2 serology testing to clinical chemistry platforms increasing the testing capacity and improving the laboratory efficiency.

- High-throughput testing for SARS-CoV-2 total antibodies
- Detecting antibodies to the spike protein targeted by many vaccines
- Reliable tool for future community and immunity monitoring

#### ORDERING AND INFORMATION:

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## VETERINARY



## Canine CRP

### Sensitive inflammation biomarker for systemic inflammation

The Gentian Canine CRP Immunoassay is an IVD test for the quantitative determination of canine C-reactive Protein (CRP) in dog serum and plasma. The assay uses canine-specific antibodies to ensure consistent specificity to the canine CRP antigen. The Gentian Canine CRP Immunoassay is an easy, reliable and cost-efficient test, which is essential for an efficient and uncomplicated inclusion of this inflammation marker into the veterinary routine test panel.

- Quantitative measurement of canine CRP
- Canine-specific antibodies
- Reliable and efficient assay for routine testing

#### ORDERING AND INFORMATION:

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#### References:

1. Dharnidharka VR et al. *Am J Kidney Dis.* 2002;40(2):221-6. 2. Bjork J et al *Pediatr Nephrol.* 2019;34(6):1087-1098. 3. Inker LA et al. *N Engl J Med.* 2012;367(1):20-29. 4. Schaeffner ES et al. *Ann Intern Med.* 2012;157(7):471-481. 5. Ebert N et al. *Curr Opin Nephrol Hypertens.* 2020;29(6):591-598. 6. Frazee E et al. *Am J Kidney Dis.* 2017;69(5):658-666. 7. Havelka A et al. *Sci Rep.* 2020;10(1):4208. 8. Bartakova E et al. *Diagn Microbiol Infect Dis.* 2019;93(3):219-226. 9. Jonsson N et al. *Crit Care Resusc.* 2017;19(3):205-213. 10. Parke et al. Meeting abstracts, *Critical Care* 2020, 24(Suppl 1):87. 11. Shi et al. *J Leukoc Biol.* 2020 Sep 1. 12. Silvin et al. *Cell.* 2020 Sep 17;182(6):1401-1418.e18. 13. Zhao J et al. *J Clin Infect Dis.* 2020;ciaa344. Epub ahead of print. 14. Ma H et al. *Cell Mol Immunol.* 2020;17(7):773-775. 15. Cui J et al. *Nat Rev Microbiol.* 2019;17(3):181-192. 16. Luchsinger LL et al. *J Clin Microbiol.* 2020;JCM.02005-20. 17. Chen WH et al. *Curr Trop Med Rep.* 2020;1-4. 18. Krammer F *Nature.* 2020;586(7830):516-527. 19. Tangri N et al. *Kidney Int.* 2011;79(4):471-7. 20. KDIGO Guidelines 2012 published in *Kidney International Supplements Vol3 Issue 1, Jan 2013.* 21. NCIC Clinical guideline (CG182) updated Jan 2014 section2 <https://www.nice.org.uk/guidance/cg182/chapter/2-Implementation-getting-started> 22. Grubb A et al. *eJIFCC* 2017;28(4):268-276. 23. Miller, WG et al. National Kidney Foundation Laboratory Engagement Working Group Recommendations for Implementing the CKD-EPI 2021 Race-Free Equations for Estimated Glomerular Filtration Rate: Practical Guidance for Clinical Laboratories. *Clinical Chemistry*, 2021. 24. Delgado, C et al. *Am J Kidney Dis*, 2021



## NT-proBNP

### Pushing the boundaries of PETIA with a low-concentration cardiac biomarker

Gentian's NT-proBNP immunoassay will provide the same accurate diagnostic results as separation-based tests on immunochemistry analyzers. This new product offers for the first time, a low-concentration cardiac biomarker on fast, cost-effective and high-volume clinical analyzers.

- ➔ Same accurate diagnostic results as available tests based on chemiluminescent technology
- ➔ No biotin interference
- ➔ OEM solutions for access to the NT-proBNP product in any formulations

#### INFORMATION AND OEM OPPORTUNITIES:

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## QUESTION ABOUT OUR PRODUCTS? GET IN TOUCH TODAY



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# GENTIAN AT A GLANCE



## Particle-Enhanced Turbidimetric Immunoassays

By leveraging both our expertise in Particle-Enhanced Turbidimetric Immunoassays (PETIA) and our proprietary nanoparticle technology, Gentian develops immunoassays that enable users to transition from traditional low volume immunology platforms to fully automated clinical chemistry instruments. The typical Gentian customer enjoys shorter turnaround times, streamlined workflows and improved cost efficiency.

## Avian antibodies for improved sensitivity

Gentian's assays incorporate immunoparticles that have been manufactured with avian antibodies. Phylogenetic differences between chickens and humans ensure minimal cross-reactivity of antibodies against rheumatoid factor and proteins of the complement system. As a result, Gentian's immuno-particles provide both increased sensitivity and decreased background signal when used in turbidimetric assays.



## Building strong partnerships

Gentian is open to collaborating with OEMs and end-users in all stages of research, development, manufacturing and distribution of immunoassays. By collaborating with Gentian, our partners are afforded the ability to expand their test menus without additional investments in R&D infrastructure. Research, development and manufacturing operations are performed in-house at the Gentian HQ in Norway.

## On instruments already in your laboratory

Through our customer-centric approach to assay development, we aim to have our products available for use on all major clinical chemistry platforms currently on the market. This means that Gentian's immunoassays can be added to your laboratory test menu without additional investment in instrumentation.



# WE INNOVATE DIAGNOSTIC EFFICIENCY

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