

Gentian Diagnostics at ADLM 2024

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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, nutrition & lifestyle associated diseases 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

- Cystatin C
- Canine CRP
- GCAL® - Plasma and serum calprotectin*
- Retinol-Binding Protein (RBP)

GET IN TOUCH TODAY



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THE CYSTATIN C COMPANY SINCE 2006

- Open channel turbidimetric assay

Cystatin C is recommended by KDIGO¹ and The NKF-ASN task force^{2,3} for assessment of Glomerular Filtration Rate (GFR) and kidney function

Analyzing both cystatin C and creatinine together provides physicians with a more accurate estimation of a patient's eGFR compared to using creatinine alone. The 2024 KDIGO guidelines for the management of CKD and the joint task force assembled by the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) recommend the increased use of cystatin C in conjunction with creatinine for this purpose.

Why measure cystatin C?

Cystatin C is a superior GFR marker for the diagnosis and therapeutic control of renal function and Chronic Kidney Disease (CKD). The biomarker's key advantage lies in its resilience against factors affecting muscle mass, like diet, sex, race, and physical activity.⁴⁻⁶ Certain vulnerable groups, including children, amputees, and the elderly, therefore benefit from more accurate eGFR measurements using cystatin C.

- ➔ Cystatin C equations are superior to creatinine-based equations in predicting end-stage renal disease, cardiovascular manifestations, hospitalization and death^{7,8}
- ➔ Cystatin C in combination with creatinine based dosing of pharmaceuticals such as Digoxin, Carboplatin and Vancomycin can lead to better patient outcomes, decreased length of hospitalization stay and lower treatment cost⁹

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.

Gentian's cystatin C assay on instruments already in your lab

Gentian is one of the largest suppliers of cystatin C assays and the open channel assay is available on most instruments: Abbott Laboratories (CLIA for Alinity c), Beckman Coulter (CLIA for AU480, AU 5800, AU 680, Immage 800, DxC 700AU), Mindray, Roche and Siemens Healthineers.

- ➔ ERM-DA471/IFCC standardized
- ➔ FDA 510(k) cleared since 2007
- ➔ CE-marked and IVDR certified



Cystatin C Global Product Manager

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CYSTATIN C

- One of the largest suppliers of cystatin C



Equations that include cystatin C estimate GFR more accurately than serum creatinine in children, adults⁷ and older adults.⁷ Accurate assessment of kidney function is crucial to ensure efficacy and safety of drugs that are renally eliminated.¹⁰

- ➔ Combining cystatin C and creatinine based eGFR helped double the portion of patients reaching goal trough concentrations of Vancomycin compared with usual care⁹
- ➔ Cystatin C offers the opportunity to avoid the race coefficient that is required for any current creatinine-based eGFR equation
- ➔ Superior to creatinine-based equations in predicting end-stage renal disease, cardiovascular manifestations, hospitalization and death⁷⁻⁸



Global Product Manager

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CALPROTECTIN (S100A8/A9) IN BLOOD

- Novel biomarker for 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.¹⁻⁴ 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.⁵

- ➔ Fast kinetics in response to infection⁶
- ➔ Differentiates between bacterial and viral infections¹
- ➔ Disease assessment even at low inflammation activity⁵



Global Product Manager

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CANINE CRP

- Continuously available since 2013

C-reactive protein (CRP) is an inflammation marker in canine serum and plasma, important in diagnosis of infections and inflammatory conditions such as gastrointestinal diseases, surgical trauma, autoimmune diseases and neoplasia.¹ As a major acute phase protein, CRP levels can quickly rise to more than 100 times its original concentration, with significant changes detectable after just 4-6 h.^{2,3} Due to its short half-life, CRP can also be analyzed to monitor disease development and treatment efficacy.⁴



- ➔ Early assessment of inflammatory diseases and disorders¹
- ➔ Reflects the degree of inflammation^{2,3}
- ➔ Monitors disease development and treatment efficacy⁴



Product Manager

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RETINOL-BINDING PROTEIN (RBP)

- Nutrition & lifestyle associated diseases



Retinol-Binding Protein (RBP) is a carrier protein for vitamin A (retinol) in blood. RBP is synthesized and stored in the liver until it binds to retinol and enters circulation. It is cleared by renal filtration after retinol release, where it is almost completely re-absorbed by the proximal renal tubule.^{1,2}

The concentration of RBP in circulation remains semi-constant in healthy individuals, though the levels can be altered in many conditions and disorders such as;

- ➔ Vitamin A deficiency
- ➔ Undernutrition
- ➔ Diabetes
- ➔ Renal dysfunction

Product Manager

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Avian antibodies immunoassays

Gentian is developing immunoassays using avian antibodies. Our long expertise in avian antibody production allows us to create highly scalable antibody solutions with very low interference for our assays. We have used avian antibodies since 2003, when antibodies purified from chicken egg yolk were validated.

Increased interest for IgY

Today mammalian immunoglobulin G (IgG) antibodies are the most widely used antibodies in immunoassays, but the interest for avian immunoglobulin Y (IgY) antibodies increases. Benefits range from cost-effectiveness in purifying large amounts of antibodies directly from egg yolk to robust and stable assays with less interference.

IgY is the major antibody type in birds, which is the avian equivalent to mammalian IgG. Both mammalian IgG and avian IgY consist of two heavy chains and two light chains. Despite similar biological roles there are differences in immunological and physical-chemical characteristics between IgY and IgG.¹ These differences are to the advantage of antibody product since human proteins will amplify a greater reaction in the phylogenetical different chicken antibody.²

➔ Less interference

IgY based immunoassays are expected to evoke less interference from human samples as the human complement system is not activated by the chicken.

➔ Less false positive

There is no reaction between the avian antibodies and human anti animal antibodies (HAAA), for instance anti mouse antibodies (HAMA) or rheumatoid factor (RF).^{2,3} HAAA and RF are considered a major problem in immunoassays as they are a well-known cause of erroneous test results in tests based on mammalian antibodies.

➔ More colloiddally stable

IgY coated polystyrene particles appear to be more colloidal stable when compared with their IgG counterpart.⁴

➔ Animal welfare

The IgY is transferred from the serum of the mother hen into the egg yolk with even higher concentration than in serum.² Therefore, only the eggs need to be collected for antibody purification.



Scientific Product Manager

Paula Lindner, PhD

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GLOBAL PRODUCT PORTFOLIO

RENAL



Cystatin C

Preventing severe kidney failure

Gentian is one of the largest suppliers of cystatin C assays, and the Gentian Cystatin C Immunoassay (FDA 510(k) cleared since 2007) is an IVD test for quantitative determination of cystatin C in human serum and plasma, supporting an early detection of reduced kidney function.

- ➔ Over a decade of experience and FDA 510(k) cleared since 2007
- ➔ ERM-DA471/IFCC standardized
- ➔ Less interference due to avian antibodies



ORDERING AND INFORMATION:

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VETERINARY



Canine CRP

Serving veterinary laboratories since 2013

The Gentian Canine CRP Immunoassay is an IVD test for the quantitative determination of C-reactive protein (CRP) in plasma and serum from dogs. Utilizing canine-specific antibodies ensures consistent specificity to the canine CRP antigen, thus limiting batch to batch variation. The assay is easy, reliable and cost-effective, all essential for an efficient and uncomplicated inclusion of the inflammation marker into the veterinary routine test panel.

- ➔ Produced with canine-specific antibodies and antigen of canine origin
- ➔ Wide measuring range up to 300 mg/L
- ➔ Instrument-independent and validated on a wide range of clinical analyzers

ORDERING AND INFORMATION:

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GCAL® - plasma and serum calprotectin

First available (since 2019) turbidimetric assay for circulating calprotectin

Calprotectin (S100A8/A9 or MRP8/14) 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.¹⁻⁶

GCAL®, 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 and inflammatory response to infections.

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

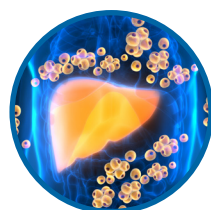
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NUTRITION & LIFESTYLE ASSOCIATED DISEASES



RETINOL-BINDING PROTEIN IMMUNOASSAY

Retinol-Binding Protein (RBP) on clinical chemistry analyzers

The Gentian Retinol-Binding Protein Immunoassay is a quantitative immunoassay for detection of retinol-binding protein (RBP or RBP4) in human serum and plasma. The assay is instrument-independent and our validation team can assist with establishing applications on clinical chemistry instruments of interest.

- ➔ Instrument independent
- ➔ CE-marked, UKCA-marked
- ➔ FDA Exempt

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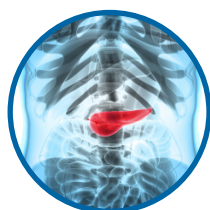


fCAL® turbo

Automated analysis of fecal calprotectin, reducing the need of colonoscopy

The BÜHLMANN fCAL® turbo is an immunoassay used 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
- ➔ FDA 510(k) cleared, CE-marked and IVDR certified
- ➔ Compatible with the stool extraction device CALEX® Cap which allows for safe and convenient stool extraction



fPELA® turbo

Aid in determination of Pancreatic Exocrine Insufficiency (PEI)

The BÜHLMANN fPELA® turbo is an immunoassay used 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
- ➔ FDA Exempt, CE -marked and IVDR certified
- ➔ Compatible with the stool extraction device CALEX® Cap which allows for analysis of fecal pancreatic elastase and fecal calprotectin in the same sample (in combination with BÜHLMANN fCAL® turbo)

CARDIAC - IN DEVELOPMENT



NT-proBNP

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

Gentian's NT-proBNP immunoassay will transform cardiac biomarker testing by accurately measuring NT-proBNP on cost-effective and high-throughput clinical chemistry analyzers. This groundbreaking assay will ensure reliable results by uniquely targeting glycosylation-independent detection sites, eliminating common inaccuracies due to variability in glycosylation pattern of NT-proBNP.

- ➔ Same accurate diagnostic results as available tests based on chemiluminescent technology
- ➔ Avoiding underestimation of NT-proBNP levels due to glycosylation
- ➔ No biotin interference

INFORMATION AND OEM OPPORTUNITIES:

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PARTNERSHIPS AND OEM SOLUTIONS

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

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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.



QUESTION ABOUT OUR PRODUCTS? GET IN TOUCH TODAY



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Cystatin C

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