

Den store selskapskvelden – SMB i Oslo

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Gentian Diagnostics AS på Merkur Market: GENT-ME







Foto: Terje Bendiksby / NTB Scanpix

Established infrastructure funded by existing products





GENTIAN CYSTATIN C IMMUNDASSAY (CYSX)



GENTIAN CYSTATIN C IMMUNOASSAY (CYSX) FOR THE Unicel DxC SYNCHRON CLINICAL SYSTEMS

Cystatin C is a non-glycosylated basic protein produced at a constant rate in nearly every nucleated cell of the human body.¹ The cystatin C concentration has been shown to be independent of muscular mass, inflammatory diseases, sex, age or diet. It is freely filtered through the normal glomerular membrane and almost completely reabsorbed and catabolized by the proximal tubules.^{2,3} In studies cystatin C has been shown to be a sensitive early indicator of decreased renal function.^{2,3,4} These properties make it a superior marker of Glomerular Filtration Rate (GFR) compared to the traditional measurement of creatinine.^{2,3,4}

The Gentian* Cystatin C assay on the Beckman Coulter UniCel DxC Synchron systems is an *in vitro* diagnostic test for quantitative determination of cystatin C in human serum and plasma. The measurement of cystatin C is used in the diagnosis and treatment of renal diseases.

FEATURES OF THE GENTIAN CYSTATIN C ASSAY (CYSX) INCLUDE >

- > The Gentian Cystatin C reagent is all-liquid and ready-to-use
- Particle enhanced turbidimetric immunoassay (PETIA)
- Measuring range of 0.4 to 8.0 mg/L
- > Total imprecision < 7.0% CV









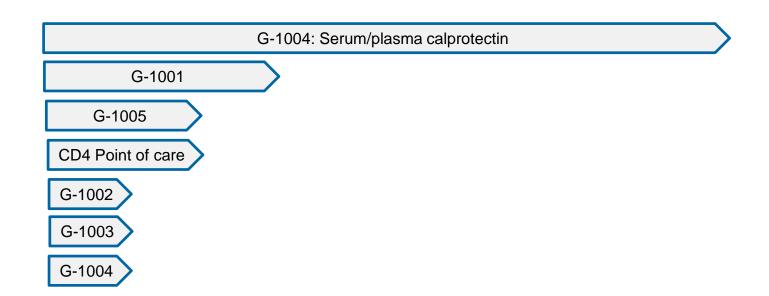
New generation screening test for cervical cancer





Product portfolio and pipeline

Proof of concept	Optimization	Verification	Validation	Launch
		Cystatin C		
		Fecal calprotectin		
		NGAL		
		Pretect SEE		
		cCRP		



Savings Example With Heart Pump Failure Marker

Cost savings per test

1

Reagent Cost Savings

Significant cost savings:

- Average market price =\$14/test
- Gentians discounted price =\$4/test

Reagent Cost Savings =\$ 10/test

2

Time Savings

A major customer testifies that time savings alone are \$2/ test

Significant implications



Implications for this lab

USD 1.5 million in annual savings¹ (10-15% EBITDA savings)



Implications for the healthcare sector

USD 1.8 billion in annual savings²



Implications for Gentian

USD 60 million in annual revenues³

Source: TriMark Publications, November 2011 Volume: TMRCMARK11-1101: Cardiac Marker Diagnostic Testing Markets

Providing Time and Cost Benefits by Moving Tests From Low to High Throughput

Low throughput





Gentian Technology



Current method for low concentration biomarker assays (separation based platforms):

Antibody and sample added

9 min particles added

9 min incubation

Exposed to magnet

to magnet

incubation

Detection using specialised to magnet

Vs. Gentian's method (homogenous platforms):

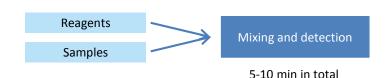
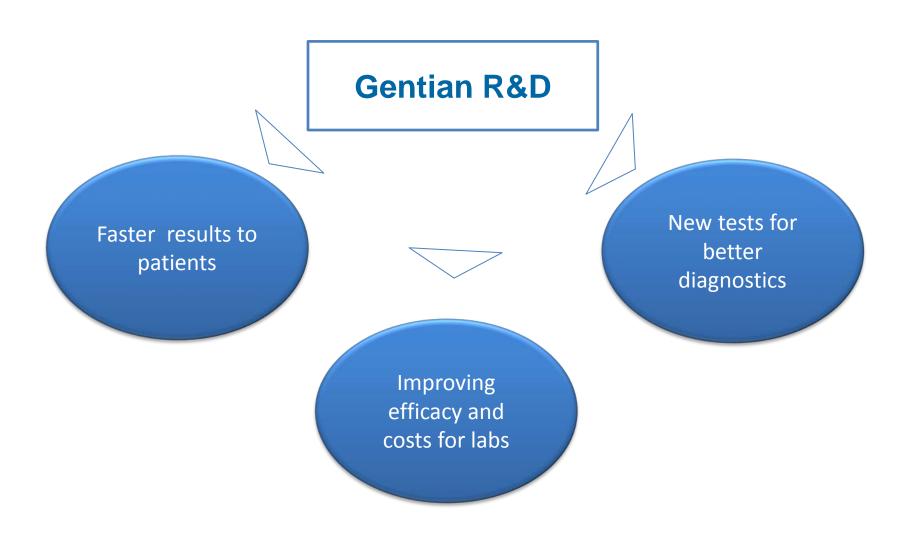


Illustration showing test principle of current technology, the electrochemiluminscent assay vs. the same test using Gentian's technology on a high throughput chemical analyzer. The new method utilizes current instruments, takes half the time and can process up to 10 times more samples per hour



Gentian addresses unmet needs in the market



Gentian Calprotectin Immunoassay

New serum and plasma assay for automated clinical chemistry analyzers

The Gentian seum and plasma Calprotectin Immunoassay is a new particleenhanced turbidimetric immunoassay (PETIA) that provides quantitative analysis of total Calprotectin in serum and plasma.



What is serum and plasma Calprotectin??

The new **Gentian gCAL assay** is a turbidimetric assay for calprotectin in serum and plasma samples. It allows very rapid and flexible random access use, as well as being the ideal solution for high throughput applications in the routine labo- ratory.

The assay can be applied on all automated plat- forms in clinical chemistry and allows short turn- around time from sample to reportable result.

Will be CE marked from June 2017

Plasma and serum is higher in patients with sepsis and in patients admitted for postoperative care after major surgery than in patients admitted due to intoxication, suggesting that calprotectin levels are markedly increased in systemic inflammatory response. Plasma Calprotectin accurately discriminates presence versus absence of systemic inflammation. Apart from the composite mortality prediction score, SAPS 3, plasma calprotectin performed better than any of the other inflammatory variables in predicting mortality at 30 days.

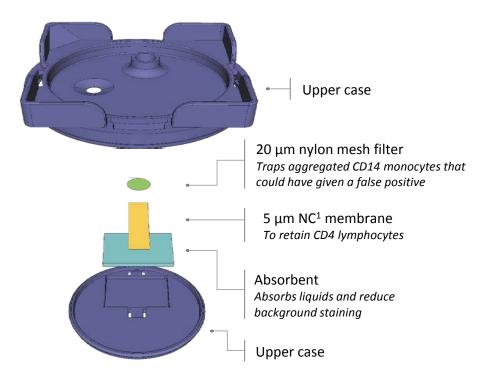


Pipeline projects: Whole-Blood Ferritin

- A new technology for testing blood donors on the spot
- Current market size: 100-200 million blood donations,
 10% subject for control
- Big saving opportunities in the donation centers
- Opportunities for pharmacy testing for drug dosage
- Novel technology being developed for whole-blood testing
- Estimated launch: 2018



Innovative vertical flow assays



Benefits

- Rapid turnaround time
 Results in <30 minutes
- Low cost
- High capacitySeveral tests can be run in parallel
- Clinically accurate
 Performance in pair with flow cytometry
- Low training need
 User friendly design

Financials: Solid base with substantial upside

Business Development

- M&A candidates:
 - Significant sales and/or profitability
 - Complimentary technology
 - Distribution

Improving Clinical Accuracy











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