



SOMAGEN™  
Inspired.



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SOMAGEN QUARTERLY WINTER 2007

# BNP Recommended by Canadian Cardiovascular Experts

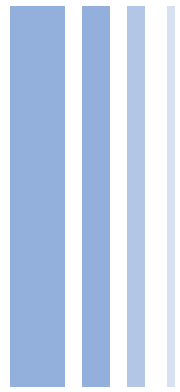
Heart Failure is a complex syndrome and an increasingly common diagnosis in Canada. It is associated with numerous hospitalizations and results in significant morbidity and mortality. In the past years Cardiology has seen major advances in the evolution of pharmaceuticals, implantable cardiac devices and new diagnostic tools. Guidelines for diagnosis and management are required to ensure these innovations are utilized properly and to the full extent by primary care physicians, specialists, nurses and pharmacists in order to standardize patient care and extend the quality of life in these patients.

The 59th Annual Scientific Meeting of the Canadian Cardiovascular Society recently held in Vancouver, where the 2006 Conference Recommendations of Heart Failure: Diagnosis and Management were presented. The guidelines are a result of a collaboration of Canadian experts in the diagnosis and treatment of heart failure. The committee states that the management of heart failure begins with an accurate diagnosis and is the cornerstone of heart failure care.<sup>1</sup> They recommend clinical history, physical examination and laboratory tests should be performed on all patients with suspected heart failure. Specifically, B-Type or Brain Natriuretic Peptide (BNP) should be measured in all suspect cases where diagnostic uncertainty exists. BNP is an excellent, objective marker of cardiovascular stress and has received a Level of Evidence A recommendation from the committee. Low concentrations (<100 pg/mL) are useful in the exclusion of heart failure and high concentrations (>500 pg/mL) can confirm heart failure in patients presenting with dyspnea.

BNP testing is a standard of care that all Canadian Hospitals should be offering. Dr. Tom Chan, Medical Director and Chief of Emergency and Urgent Care at The Scarborough Hospital in Ontario says, "a high BNP value is now included as part of our definition of heart failure" (personal communication, October 17, 2006). Since The Scarborough Hospital started BNP as part of their diagnostic workup of suspect CHF patients in June 2006, they have run 1-2 tests per day, resulting in a more accurate diagnosis, faster treatment decisions and an overall decrease of costly hospital admissions.

To discuss how BNP can impact patient care on your hospital, please contact Somagen Diagnostics.

- References:**
1. Arnold OA, Liu P, Demers, C, et.al. Canadian Cardiovascular Society consensus conference recommendations on heart failure 2006: Diagnosis and management. Can J Cardio 2006; 22;1:23-45



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# Complete Test System for Sickling Hemoglobins

Somagen is proud to announce that Streck, Inc. has purchased the *SICKLEDEX*® brand name from Ortho Clinical Diagnostics and will subsequently be renaming its Sickle-Chex® Solubility Kit *SICKLEDEX*.

Streck's Sickle-Chex Solubility Kits are conveniently packaged with two separate squeeze bottles, allowing for a combined 90-day dating, easy dispensing, and waste elimination. They are available in 100, 50 and 12-test formats.

The 12-test kit includes all necessary items required to perform a sickle cell screening test, including plastic components to help eliminate glass from the laboratory thus reducing the danger of breakage.

Sickle-Chex quality control material is also available from Streck, providing laboratories with a complete test system for Sickling Hemoglobins.

For more information regarding Streck's Sickle-Chex Solubility Kits, please call Somagen Diagnostics at 1-800-661-9993 and quote the following product numbers:

- 100 Test Solubility Kit  
2 x 100ml 217657
- 50 Test Solubility Kit  
2 x 50ml 217660
- 12 Test Solubility Kit  
2 x 12ml 217661



## Increase certainty in pregnancy monitoring

Premature rupture of membranes (PROM) represents one of the most important complications in obstetric practice today. The term is applied to leakage of amniotic fluid in the absence of labor irrespective of gestational age. Overall, about 10% of all pregnancies are complicated by PROM.<sup>1</sup> Ultimately, almost all women with PROM will deliver before term, and the majority of these women will deliver within one week of rupture despite their gestational age at the time of membrane rupture.<sup>1</sup> Consequences of PROM include substantial morbidity and mortality for the neonate associated with prematurity, labor and delivery complications that increase the risk for neonatal resuscitation and increased risk of infection for both mother and fetus.

Medix Biochemica manufactures the Actim™ PROM test, a rapid bedside dipstick test based on monoclonal antibodies detecting IGFBP-1 (insulin-like growth factor binding protein-1) from amniotic fluid. IGFBP-1 is not normally present in the vagina, but when fetal membranes rupture, amniotic fluid is released. The concentration of IGFBP-1 in amniotic fluid is 100 to 1000 times higher than in maternal serum. Since semen and urine contain insignificant quantities of IGFBP-1, the presence of IGFBP-1 in the vaginal sample is a reliable indication of membrane rupture.

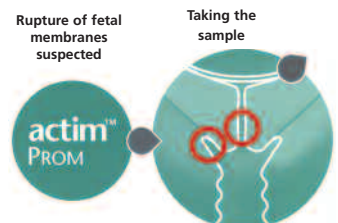
When compared to other methods commonly used for detecting PROM, neither the specificity nor the sensitivity of other markers compares to that of Actim PROM.

### Comparison of methods to detect PROM

Kubota & Takeuchi 1998

	Actim PROM	pH	Fern
Sensitivity	94.7	73.3	42.1
Specificity	93.1	72.4	75.9

The Actim™ PROM test can be performed quickly and simply by taking a vaginal secretion sample with a Dacron swab. If no liquid is visible, the sample can be taken from the cervix. The Dacron swab is then placed in the solution provided and the sample is rapidly extracted. The dipstick is then dipped in the solution and removed. A positive result can be read as soon as two blue lines, a control line and a positive result line, appear in the result area. If only the control line appears, a negative result can be ensured after five minutes.



Take a vaginal fluid sample from the posterior fornix of the vagina - or from the cervix if no fluid is visible - by leaving the polyester swab in the vagina for 10 to 15 seconds. This allows the swab to absorb a sufficient amount of specimen.

### References:

- 1Odunsi and Rinaudo. Premature Rupture of the Fetal Membranes Vol.2 No.4. Yale-New Haven Hospital
- 2Kubota and Takeuchi. Evaluation of Insulin-like Growth Factor binding Protein-1 as diagnostic tool for rupture of membranes. J Obstet Gynaecol Res (1998) 24: 411-417

The Actim™ PROM diagnostic test was developed to help physicians better monitor and more reliably ensure the health and well being of both mother and fetus. For more information on Actim™ PROM or other Medix Biochemica products please contact Somagen Diagnostics.

# Accurate quantitation of low levels of IgE using ImmunoCAP Total IgE Low Range 0-100 kU/l

E Persson, H Åkerström, A. Kober. Phadia AB, Uppsala, Sweden

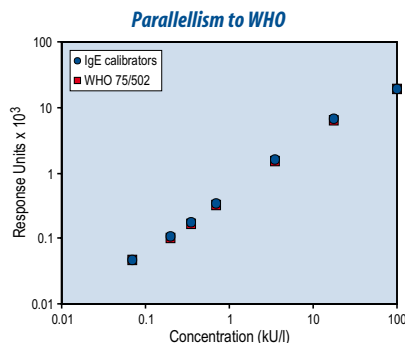
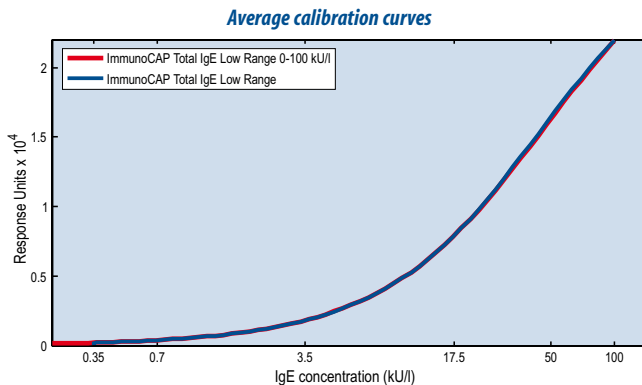
## Objective

The aim of this study was to show that IgE concentrations can be accurately measured down to very low levels using ImmunoCAP™ systems.

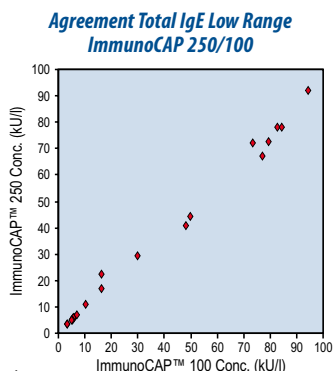
## Conclusion

The new ImmunoCAP Total IgE Low Range 0-100 kU/l makes it possible to accurately measure IgE concentrations on a continuous scale from 0.005 – 100 kU/l, with a very good precision.

**Figure 1.** The two superimposed calibration curves demonstrate that the change in calibration down to 0 kU/l does not affect the shape of the calibration curve, thereby maintaining the evaluated sample concentrations. Average calibration curves (n=18).



**Figure 2.** Parallellism between IgE Calibrators and WHO Reference preparation for IgE 75/502 shown by testing dilutions of WHO reference preparations.



**Figure 4.** Agreement between results for 20 samples tested with Total IgE Low Range in ImmunoCAP 100 and ImmunoCAP 250.

## Limit of Quantitation (LoQ)

ImmunoCAP	Instrument	Concentration low samples (kU/l)	LoB (kU/l)	LoD (kU/l)	Total CV% LoD*	LoQ (kU/l)
Total IgE	ImmunoCAP 100	0.018-0.065	0.002	0.002	13.8	0.005
Low	ImmunoCAP 250	0.023-0.097	0.001	0.001	12.8	0.005
Range	ImmunoCAP 1000	0.025-0.100	0.001	0.001	20.1	0.005

\*Total CV within sample, between runs and replicates.

Limit of Blank (LoB) and Limit of Detection (LoD) were estimated according to the NCCLS guideline EP17-A, approved October 2004. The LoB as well as the LoD for ImmunoCAP Total IgE Low Range were estimated to be 0.002 kU/l. High precision at LoD gives that Limit of Quantitation (LoQ) can be set as equal to LoD. The LoQ for ImmunoCAP Total IgE Low Range was set to 0.005 kU/l



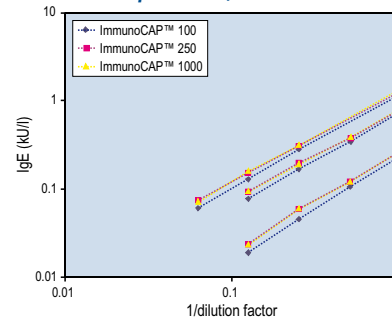
## Precision Total IgE Low Range 0-100 kU/l

System	Within (CV%)			Between (CV%)			Total (CV%)		
	A	B	C	A	B	C	A	B	C
Range, kU/l									
0 - 0.35	9.3	7.0	8.7	7.0	8.2	9.5	12.9	14.2	13.4
0.35 - 2.0	6.3	5.7	6.9	8.9	9.1	9.6	11.9	10.7	12.2
2.0 - 80	6.6	5.2	6.9	3.1	10.3	6.7	10.6	12.8	10.1
80 - 100		4.8	6.4		8.3	7.4		10.4	9.9

Systems: A: ImmunoCAP 100, B: ImmunoCAP 250, C: ImmunoCAP 1000

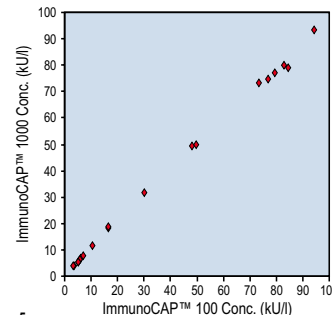
A precision study was performed using 3 ImmunoCAP 100, 2 ImmunoCAP 250 and 2 ImmunoCAP 1000 system. In total 19 samples were assayed in 2 replicates in 18 assay runs per system.

## Sample dilution, low levels



**Figure 3.** Dilutions, 1/2, 1/4, 1/8, and 1/16 of samples with very low concentrations of IgE. All dilutions together with undiluted samples were tested in three different instrument, ImmunoCAP 100, ImmunoCAP 250 and ImmunoCAP 1000. Linear dilutions down to very low concentrations (0.02 kU/l) were obtained in all systems.

## Agreement Total IgE Low Range ImmunoCAP 1000/100



**Figure 5.** Agreement between results for 20 samples tested with Total IgE Low Range in ImmunoCAP 100 and ImmunoCAP 1000.

## Background

In clinical practice, low levels of total IgE in cord blood has been used as a predictor of atopy. Numerous studies have also been performed in which the clinical performance of ImmunoCAP Total IgE in conjunction with ImmunoCAP Specific IgE in allergy diagnosis has been evaluated. The introduction of a zero (0 kU/l) calibrator gives an extended measuring range for ImmunoCAP Total IgE Low Range and may give further possibilities for clinical research. The technical performance of the new low range test was evaluated.

## Methods

The Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ) were determined as defined in NCCLS EP17-A. Limit of blank (LoB) is the highest measurement result that is likely to be observed with a stated probability for a

blank sample and Limit of detection (LoD) is the lowest amount of analyte in a sample that can be detected with a stated probability (95% in this work). Limit of Quantitation (LoQ) is the lowest amount of analyte in a sample that can be quantitatively determined with stated acceptable precision and trueness, under defined experimental conditions. LoB and LoD were determined using diluent and dilutions of samples containing IgE. Linearity in dilution was studied for 3 samples, 2 samples two-fold diluted to 1:8 and 1 sample two-fold diluted to 1:16 and all three from initial concentration levels of ~2 kU/l. The estimated coefficients of variation were plotted in a precision profile, used for defining the Limit of Quantitation (LoQ).

## Results

The LoB as well as the LoD for the ImmunoCAP Total IgE Low Range was 0.002 kU/l and the LoQ was set to 0.005 kU/l. The concentrations of all the diluted samples were accurately measured. The pooled total CV was 9.7% within the measuring range 0.06 - 1.2 kU/l.



# SEE YOU THERE!

Watch for Somagen at these upcoming conferences:

**AAAAI – American Academy of Allergy,  
Asthma and Immunology**

San Diego, CA  
February 23 - 27, 2007


**AMMI (Association of Medical Microbiology and  
Infectious Disease Canada) & CACMID (Canadian  
Association for Clinical Microbiology and  
Infectious Diseases) 2007 Annual Conference**

Halifax, NS  
March 14 - 18, 2007

## Exclusive Distributor of TREK Diagnostic Systems Products

Somagen Diagnostics is pleased to announce the addition of TREK Diagnostic Systems to its portfolio of products now available. Somagen Diagnostics is the exclusive distributor of TREK Diagnostic Systems products to the clinical market.

TREK Diagnostics is the manufacturer of the VersaTREK® Automated Microbial Detection System and the Sensititre® ARIS 2X System for Antimicrobial Susceptibility and Identification of bacteria.



TREK's VersaTREK system features a 4 in 1 testing platform, allowing for culture of blood, sterile body fluids, Mycobacteria detection, as well as Mycobacteria susceptibility testing, all on the same instrument. Its Any Bottle Anywhere Concept allows for maximum instrument utilization, and the modular design

of the instrument allows for easy expansion to any size laboratory. The VersaTREK data management system offers an easy to use Windows® format, providing comprehensive statistical reporting, quick patient information query capability and online HELP.

TREK's Sensititre ARIS 2X system provides the only fully customizable system (ARIS 2X, SWIN® Software, AutoReader, AutoInoculator, SensiTouch®) with a choice of completely automated, semi-automated, or manual equipment to cover all diagnostic testing needs in the clinical laboratory. The comprehensive Sensititre SWIN Software package allows technologists to generate fast, easy epidemiology reports, monitor resistance trends and customize expert rules.

More than 220 antimicrobials are available for susceptibility testing of bacteria and yeasts, including YeastOne® products, ensuring accurate first time results.

Somagen will be launching the product at our booth at the upcoming CACMID conference in Halifax. Please stop by for a detailed overview of the product or contact us for more information.



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