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SOMAGEN QUARTERLY SPRING 2006

## CCP – A New Marker for an Old Disease

Most connective tissue diseases are rare disorders with less than three persons per 10,000 affected. The exception among the inflammatory rheumatic diseases is rheumatoid arthritis with a prevalence of about 1% in our population. If not properly controlled, the disease can have a major impact on patients' quality of life. It increasingly restricts the range of activities possible until even the ability to perform basic tasks is limited.


Rheumatoid arthritis has been known since ancient times. Paleo-pathological studies of specimens dating back 3000 to 5000 years have suggested evidence of rheumatoid arthritis in Native American tribes in North America. Evidence for rheumatoid arthritis in Europe first appeared in early 17th, possibly 15th, century. The disease was first defined by the English physician Alfred Baring Garrod in 1859. In the course of the disease, the clinical picture is usually very clear and, with the aid of the diagnostic criteria from the American College of Rheumatology (ACR), can be diagnosed with a high certainty.

However, in the early stage of the disease, diagnosis may be a challenge as symptoms at onset are often general and non-specific.

Early diagnosis of rheumatoid arthritis has become a high priority in recent years due to the availability of effective, disease-modifying anti-rheumatic drugs which not only improve patients' well-being but influence the eventual outcome in terms of joint destruction. For the physician, who must decide early whether to treat symptomatically or immediately begin with an aggressive treatment strategy, the development of the anti-cyclic citrullinated peptide (CCP) antibody assay as an aid in the early diagnosis of rheumatoid arthritis is of special significance. In 1996, the group of Professor Van Venrooij of the Radboud University in Nijmegen, Netherlands, introduced a new ELISA, which was coated with



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## CCP – A New Marker for an Old Disease **continued from page 1**

citrullinated filaggrin peptides and had a surprisingly high specificity for rheumatoid arthritis. Four years later, to increase the sensitivity, *cyclic variants of peptides* were used, in which the citrulline residue is optimally exposed for antibody binding. Since then, CCP antibodies have gained such interest and importance, that they have been implemented routinely in many laboratories.

Somagen Diagnostics is pleased to offer the Phadia ImmunoCAP 250 EliA™ CCP, the first

fully-automated testing system for CCP antibodies available to date. The test applies the so-called “second generation” CCP, in which the state-of-the-art antigen is used. The clinical performance of EliA™ CCP meets the expectations from literature findings for the second generation CCP format and supports the value of this new parameter. EliA™ CCP offers the advantages of the well-established, automated EliA™ product line, to include minimal hands-on-times, true walk-away for maximum convenience and standardized

conditions. Most importantly and as a general feature of EliA, this highly flexible system allows you to run just a single sample cost-effectively while still providing the option of higher throughput.

*Please contact Somagen Diagnostics for more information on the ImmunoCAP 250 EliA CCP and a copy of an excellent review article on the history and clinical utility of anti-CCP antibodies by Professor Van Venrooij et al, Copenhagen, Denmark.*

## Rapid Influenza A/B Testing

It is estimated that 4,000 – 8,000 Canadians die every year from pneumonia related to flu. Flu is a virus that is highly infectious, acute and generally self limiting. Common symptoms include headache, fever, dry cough, sore throat and muscle aches. Most people affected by the flu recover within 7 to 10 days however there are some, including the elderly, the immunocompromised, asthmatics and young children, that are at greater risk of more severe complications possibly leading to death.

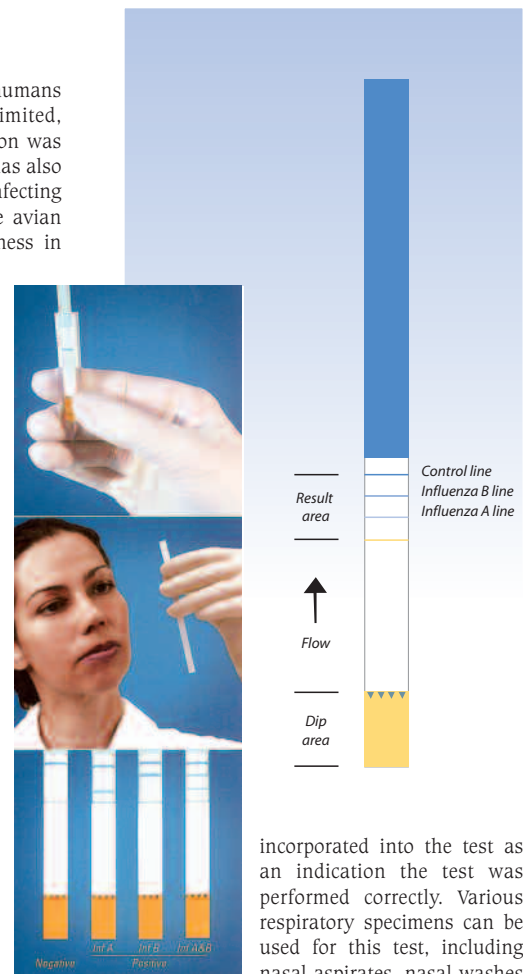
Gaining much attention and global concern as an emerging pandemic threat is the Influenza A avian subtypes. This particular type of influenza is a contagious viral infection that can affect all species of birds but can, although less commonly, infect mammals. There have been a few reported incidents of Avian Flu amongst birds across Canada including most recently the low pathogenic subtype H5N2 in Frazer Valley, British Columbia<sup>1</sup>. There have

been cases in South East Asia where humans have contracted avian flu and limited, inefficient human-to-human transmission was suspected in some instances. Avian flu has also been discovered in parts of Europe infecting many poultry populations. To date, the avian influenza strains that have caused illness in humans include the H5N1, H7N7, H7N3 and H9N2 subtypes, with H5N1 associated with the most serious illness<sup>1</sup>.

Once an individual contracts the influenza virus, antiviral drugs are available to treat them. Relenza (zanamivir) and Tamiflu (oseltamivir phosphate) are two recent drugs to hit the market. They are effective against Influenza A and B, which are the two types of influenza viruses that cause epidemic human disease. In addition to treating influenza, Tamiflu is also used in its prevention and is approved for pediatric use in children over the age of 12. These drugs however must be administered within 48 hours of symptom onset in order to be effective. With this limitation, a fast and effective diagnostic test must be available.

Somagen is proud to introduce Medix Biochemica, developer of actim™ Influenza A&B, an easy-to-use rapid detection test for influenza types A and B. It provides the patient with results in just 15-20 minutes including sample collection. This enables the right antiviral treatment to be prescribed avoiding unnecessary use of antibiotics, which can lead to antibiotic resistance.

This test uses the principle of immunochromatography in an easy dipstick procedure where a blue line in the result area indicates the presence of influenza virus in the sample. A black control line is



incorporated into the test as an indication the test was performed correctly. Various respiratory specimens can be used for this test, including nasal aspirates, nasal washes or swabs. As this is a discreet test for both Influenza types A and B, there is no need for a second test reducing wait time for complete results. Furthermore, the actim™ Influenza A&B tests for avian flu subtypes H5N3, H7N3, H9N2 and H5N1, giving it an advantage over other rapid detection tests.

*For more information on this Medix Biochemica product, please contact Somagen Diagnostics.*

<sup>1</sup> Public Health Agency of Canada, phac-aspc.gc.ca

<sup>2</sup> fda.gov





Figure 1

## Quality and Automation in Allergy and Autoimmune Testing

| ImmunoCAP 250 Menu                |                       |
|-----------------------------------|-----------------------|
| <b>Allergy</b>                    | EliA Sm               |
| Total Serum IgE                   | EliA Ro               |
| Specific Serum IgE                | EliA La               |
| Phadiatop                         | EliA CENP             |
| Tryptase                          | EliA Scl-70           |
|                                   | EliA Jo-1             |
| <b>Asthma</b>                     | EliA Symphony         |
| ECP (Eosinophil Cationic Protein) | EliA GBM              |
|                                   | EliA PR3              |
| <b>Autoimmunity</b>               | EliA MPO              |
| EliA dsDNA                        | EliA CCP              |
| EliA U1RNP                        | EliA Celikey IgA, IgG |
| EliA RNP70                        | EliA Gliadin IgA, IgG |

Diagnostic allergy and autoimmune disease testing is growing as Canadians become educated to new and more targeted therapies as well as increasingly aware of the dire outcomes of undiagnosed anaphylactic reactions. Pressure on the clinical diagnostic laboratory to do more with less is a reality in our current health care environment. Fortunately solutions are available with the development of the automated **Phadia ImmunoCAP™ 250** (Fig. 1) immunochemistry platform that provides the economics and testing efficiencies necessary for today's laboratory without compromising the sensitivity of the results so critical to proper allergy and autoimmune disease diagnosis.

### Thirty years of market leadership

Phadia developed in vitro allergy testing in the early 1970's pioneering allergy test development and creating the allergen code standard. Today's ImmunoCAP™ systems are the result of thirty years of technology, chemistry and instrument development and are the most frequently used technologies in routine testing and in clinical studies worldwide – the reference systems in allergy testing.

### ImmunoCAP 250

The new generation ImmunoCAP 250 platform was engineered to increase laboratory efficiencies and provide consolidation of allergy and autoimmune testing without compromising quality, accuracy, reproducibility or consistency of results. Comparison studies between the ImmunoCAP 100 and 250 platforms show excellent equivalence with CV's between 4-8%.

The ImmunoCAP 250 is a continuous random access instrument running 60 tests per hour. Time to first result is 90 minutes followed by results every 60 seconds - batching samples is no longer required. (Fig 2)

Three barcode scanners provide positive identification and traceability as well as extended stock management. On board refrigeration allows for less set up time and larger package sizing results in minimal hands on time and more efficient use of reagents.

Instrument calibration is performed once every 28 days. A curve control is run once at the beginning of each day resulting in more efficient testing of samples and less reagent usage. Automatic start up, shutdown and daily rinse also contribute to less operator interaction and more proficient time management in the lab.

Extended stock management and inventory of on board reagents permits specific sample target values to be set and order values to be designated for effective management of order and load lists. Because the instrument has bi-directional mainframe capability, reagent orders can be sent automatically and electronically to purchasing, new test requests can be sent direct to the lab and results can be downloaded to the mainframe as determined.

Automatic sample dilutions are performed as required and reflex testing can now be set to automatically run following panels or individual allergens. This is achievable with

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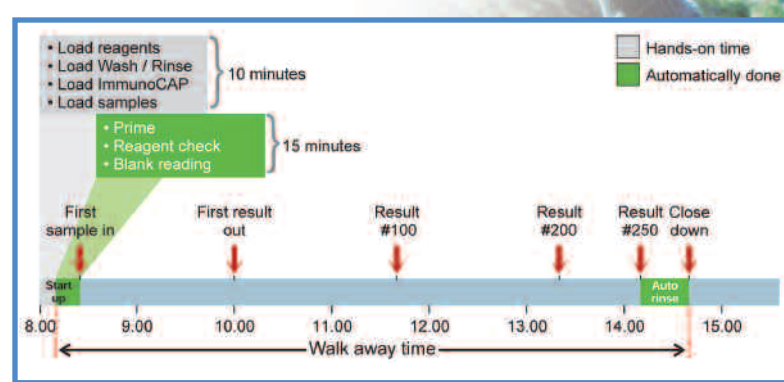


Figure 2





# SEE YOU THERE!

## Watch for Somagen at these upcoming tradeshows:

**AAAAI – American Academy of Allergy, Asthma and Immunology**  
Miami Beach, Florida  
March 3 – 7, 2006

**CACMID – Canadian Association for Clinical Microbiology and Infectious Disease**  
Victoria, British Columbia  
March 16 – 19, 2006

**NSH – National Society for Histotechnology Region IX Education Day**  
Montréal, Québec  
May 6, 2006



## Quality and Automation in Allergy and Autoimmune Testing continued from page 3

the stand alone IDM software which can be customized for each unique laboratory environment.

The ImmunoCAP 250 has the ability to run 6 different methods of both allergy and autoimmunity and can manage multiple tests in one run. In addition to the streamlined capability of providing the most referenced results worldwide, the potential to capture both allergy and autoimmune testing makes the ImmunoCAP 250 the best solution for the laboratory wishing to provide a complete

menu of diagnostics services to their Allergy/Autoimmune Specialists.

*For more details on the Phadia ImmunoCAP 250 instrument or further information on allergy and autoimmune diagnostics please call Somagen.*

**Johansson SGO; Yman L. In vitro Assays for Immunoglobulin E. Clinical Reviews in Allergy; 1988; 6: 93 - 139.**

**Axén R; Drevin H; Kober A; Yman L. A new laboratory diagnostic system applied to allergy testing. New England and Regional Allergy Proceedings; 1988; 9(4):503.**

## Phadia

**ImmunoCAP™**  
**Phadia**

## Pharmacia Name Change

Pharmacia Diagnostics AB has changed their company name to Phadia AB effective January 15, 2006.

This conversion was implemented to more clearly express their identity as an independent dedicated diagnostics company.

Products in the Phadia AB portfolio include ImmunoCAP™ Allergy, ImmunoCAP™ Autoimmune and Elia™.

Only the company name is changing. Ownership, organization and staff remain the same as does their commitment to supplying allergy and autoimmunity test solutions that provide value for doctors, patients and laboratories.

Somagen Diagnostics Inc. continues to provide distribution, service, education and support for the ImmunoCAP™ and Elia™ products in Canada. Please do not hesitate to call us if you have any questions regarding this change of name or for further information on the Phadia AB portfolio of Allergy and Immunology products.

Past issues of the Somagen Quarterly are available on our website.

Visit our website at [www.somagen.com](http://www.somagen.com)



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