

## DIAGNOSTIC TECHNOLOGY FOR DETECTION OF *Chlamydia trachomatis*

Biotech Consortium India Limited (BCIL) is seeking companies interested in commercializing a diagnostic kit used for the detection of *Chlamydia trachomatis* in humans. Scientists at the Institute of Pathology (IOP), New Delhi have developed a novel antibody for reliable, accurate and relatively inexpensive diagnosis of *C. trachomatis* in humans. The method has been specifically designed for the population in the Indian subcontinent keeping in mind the inadequacy of trained staff at the healthcare facilities in the region.

### **Introduction**

*Chlamydia trachomatis* is an intracellular bacterial pathogen and causes a spectrum of clinically important diseases in humans. Acute infection with Chlamydia can cause Pelvic Inflammatory Disease (PID) and acute salpingitis. Long term effect of these conditions can result in chronic pain, ectopic pregnancy and infertility. A WHO study estimates that about 500 million people worldwide are at high risk of the infection with over 140 million people actually infected with the disease. Close to 5 million new cases of the infection are detected each year in the US alone. The annual worldwide cost of treating and caring for patients with PID is estimated to be US\$ 10 billion. Unavailability of a reliable and cost effective test for detection of the infection is a growing concern especially in developing countries.

### **Technology**

*C. trachomatis* is differentiated serologically in three serogroups with a total of 15 distinct serovars: the B serogroup (serovars B, Ba, D, E, L1 and L2), the intermediate serogroup (serovars F, G, K and L3) and C serogroup (serovars A, C, H, I and J). The antigen that confirms genus, serovar, species and serogroup specificities to *C. trachomatis* is the major outer membrane protein (MOMPs). Serovars A, B, Ba and C are etiologic agents of trachoma and serovars D to K are associated with sexually transmitted diseases. The method developed by scientists at IOP detects all serovars of *C. trachomatis* using a species specific MOMP Mab in Enzyme Immunoassays (EIA). Further, two other Mabs that are D serovar specific and serogroup specific have been developed and patented by the scientists.

### *Patents & Publications*

Indian patent filed for the Development of monoclonal antibody to *Chlamydia trachomatis* (Application No. 792/Del/2003).

Kumar A and Mittal A: Production and Characterization of monoclonal Antibodies to *Chlamydia trachomatis*. *Hybridoma* 2006; 25:293-299. (The research paper can be provided by the BCIL upon request)

### **The Need for New Technology**

Existing diagnostic modalities for the diagnosis of *C. trachomatis* include nucleic acid hybridization, EIA, Nucleic Acid Amplification Test (NAAT), culture and Direct Fluorescent Antibody (DFA) tests. Most of these tests are either low in specificity and sensitivity or are too expensive for the population in developing countries like India. Also many of these tests require highly trained staff for their operation which is unavailable in developing countries.

There is a high prevalence of genital chlamydial infections in women in India and there is a growing need for an indigenous, accurate and reliable diagnostic assay for the detection of the infection. There is no indigenous monoclonal antibody based EIA test currently available for diagnosis of *C. trachomatis* infections in India. The novel technology for diagnosis developed at IOP addresses this growing need.



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## Salient Features

- Most of the tests currently available in the market range from US\$ 250 to US\$ 1,800. The new product offers a much cheaper alternative to these tests in developing countries
- The test does not involve the laborious microscopic examination required in many other diagnostic kits available in the market, thus enabling its operation by relatively unskilled staff
- Provides an opportunity for expanding epidemiologic studies. Two Mabs developed by the scientists are D serovar specific and B serogroup specific and hence are suitable for epidemiological studies

## Marketplace India

It is estimated that genital chlamydial infection accounts for 50% of the cases of Sexually Transmitted Diseases (STDs) reported in India. Close to 20 million individuals are infected with *C. trachomatis* in the country. Considering the asymptomatic nature of the infection, the market for this test is formed by high risk individuals which are much greater in number than patients who are actually infected with the disease. The target patient pool is thus formed by high risk individuals and patients turning up at hospitals and clinics with symptoms of STDs. Moreover, the test also offers two Mabs that are suitable for epidemiological studies and can be used by companies conducting clinical trials in India.

A lot of companies are trying to enter this niche segment of diagnostic market in India. A Canada based company PAC Med Biotech is reviewing its licensing agreement for a test used for the detection of Chlamydia in India. The test has been developed by a US based diagnostics firm Diagnostics for the Real World (DRW). A number of diagnostic testing companies have already entered into agreement with distributors for the marketing of their product in India. Tests like RIDASCREEN® and IDEIA™ PCE are already available in the Indian market. Early entry into the market is likely to give an added advantage to companies trying to venture into the therapeutic area.

## About the Inventor

**Dr. Aruna Mittal** is presently Senior Deputy Director at Institute of Pathology, ICMR, New Delhi. Dr. Mittal was awarded the Title '*Chlamydia Farmer*' by Center for Disease Control (CDC), US in the year 1989. Later ICMR award was given to her in 2003 for her Chlamydia research. She has three patents under her name, has authored/co-authored 6 chapters in books on different subjects and has published more than 51 papers in peer reviewed journals of high impact. She has served as a visiting scientist in some of the top universities and institutes in the US. She received her PhD from V.P. Chest Institute, Delhi University in the year 1977 and Masters from Delhi University in the year 1971.

## About BCIL

BCIL was incorporated as public limited company in 1990 under the Indian Companies Act 1956. It is promoted by the Department of Biotechnology, Government of India and is financed by several all India financial institutions, venture capital funds and the corporate sector. BCIL has been actively involved in technology transfer, project consultancy, fund syndication, information dissemination, and manpower training & placement related to biotechnology over the last decade and half. BCIL has transferred more than 15 technologies in the last 5 years using its expertise in facilitating licensing agreements that allow healthy and productive cooperation between the inventor and the licensee.