Diagnostic Kit for the Identification of Human Infection with Urogenital Mycoplasmas (Mor)

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Background

Mycoplasmas are a group of bacteria characterized by unique features - they are the smallest replicating, free-living bacteria. Comprising a minimal genome and lacking a cell wall, properties making difficulties in research and diagnosis.

Mycoplasmas are very common inhabitants of the respiratory and genitourinary systems. Only several species are pathogenic in humans, and only some carriers, colonized with the bacteria, develop an infectious disease.

Urogenital Mycoplasmas were shown, to be involved in a variety of diseases, and can cause silent and chronic infections or post-infection pathologies. Recently, scientists have also been exploring an association between mycoplasma and cancer, further arise the need to confront the bacteria. Aside from various infectious diseases and infertility problems caused by Mycoplasmas, Ureaplasmas are the most prevalent of all infectious agents in intra-uterine infections, causing pregnancies to result in recurrent abortions, preterm deliveries and other complications including fetal death. Premature neonates can be severally affected from these bacteria causing life threatening infectious diseases. Mycoplasmas are also involved in human inflammatory autoimmune disorders, such as reactive arthritis and rheumatoid arthritis.

In spite of an increasing amount of evidence accumulated in the literature regarding mycoplasmal pathogenic mechanisms, unique characteristics of the bacteria, made it hard to diagnose its presence or produce an efficient and reliable diagnostic test to identify human infection with urogenital mycoplasmas.

Current tests are reluctant in diagnosing Urogenital Mycoplasma infectious diseases, since they do not enable to distinguish between colonization (i.e. presence of the bacteria, in a certain location) and disease caused by the bacteria (i.e aberration of the host cells' functions leading to the symptoms and morbidity). Such methods include:

1) Culture - Isolation of live Mycoplasma, from a specimen.

2) PCR - Identification of mycoplasmal DNA, in a specimen.

In contrast, serological methods, measuring the level of anti-mycoplasma antibodies in the serum or other body fluids, are indicative of an immune response of the host to the infecting bacteria and thus differentiate between carriers (only colonized) and those who developed a certain pathology. The current serological tests reported in the literature for urogenital Mycoplasmas, are unsatisfactory, mainly due to the antigens used in these assays. Firstly, the antigens are usually prepared from strains that do not constitute an adequate scope of antigenic variety. Secondly, the preparation of those antigens involves procedures that are detrimental to the bacterial proteins. Thus, the tests

reported are not adequate, regarding both specificity and sensitivity.

In order to discriminate between subjects who are only colonized (i.e. carriers) and those who are at risk, or already developed an active disease, a new diagnostic technique has been developed.

Our Innovation

A new technique has been developed by Prof Horowitz:

Attributes and advantages:
1. Highly sensitive test, detecting a high percentage of people who developed an immune response to the urogenital Mycoplasma
2. Highly specifictest, which distinguishes between colonization and active infectious disease. A titer above a pre-determined cut-off value is indicative of an acute and/or chronic mycoplasmal infection.

The Opportunity
Regarding pathologies associated with urogenital Mycoplasma a large scope of situations might benefit from detecting mycoplasmal infection, using the innovative serological test. Up until now these following markets were lack of an appropriate detection assay:

Obstetrics and Gynecology (High Risk Pregnancies)
Neonatology (intensive care and others)

Urology (urinary tract infections in men and women)

Infertility (male factor) and IVF clinics.

Rheumatology (reactive arthritis, rheumatoid arthritis, etc)

Internal Medicine (neurology, cardiology, dermatology)
High risk populations (AIDS, STD, drug addicts, etc.

Status

The innovative serological test is routinely used in the National Center for Mycoplasma of Clalit Health Services, located in the Soroka University Medical Center.

A Feasibility Study was conducted and with the "New" test both the sensitivity and the specificity were higher than those in the "Old" benchmark serologic test using commercial (ATCC) strains-derived antigens. Moreover, the problem of borderline, intermediate or questionable results, occurring in the formerly "Old" test was resolved, using the "New" preparation.

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