P1748
Poster Session VI
Molecular diagnosis of sexually-transmitted pathogens

A NOVEL MOLECULAR-BASED DIAGNOSTIC SCREENING TEST UTILIZING THE NANOCHIP® MICROARRAY TECHNOLOGY FOR SIMULTANEOUS DETECTION OF MAJOR SEXUALLY TRANSMITTED INFECTIONS

Z. Greenberg[1], M. Fridlender[1], R. Sabban-Amin[1], Y. Mali[1], J. Kopelowitz[1]

[1]Research & Development, Savyon Diagnostics Ltd., Ashdod, Israel

Objectives. Sexually transmitted infections (STI)are widely abundant all over the world, presenting constantly a yearly growingtrend and consequently increased annual health costs. STIs may cause acutesymptoms, chronic infections, infertility, ectopic pregnancy,blindness, cervical cancer, susceptibility to HIV infection anddeath. Most cases are treatable, however no or late treatment may lead tosevere health complications. This is further emphasized in view of the commoncarriage of STIs in asymptomatic state. Therefore, there is a need for detectionof early stages of STIs is in order to control andprevent these diseases. Savyon Diagnostics has recently been engaged withdevelopment of a novel molecular-based screening test for simultaneousdetection of the most abundant STIs utilizing its proprietary NanoCHIP®XLmolecular electronic microarray system. The panel of pathogens is composed of *Chlamydiatrachomatis*, *Neisseria gonorrhea*, *Trichomonas vaginalis*, *Ureaplasmaurealyticum/parvum, Mycoplasmagenitalium* and *Mycoplasma hominis*. The *Ureaplasmaurealyticum/parvum* results are reported in a semi-quantitative manner, inorder to better differentiate between colonization and acute states, and bythat avoiding unnecessary antibiotic treatment. The aim of this work is todemonstrate the utility of the newly developed test for screening purposes ofSTIs especially in high-risk populations, demonstrating a highly performing,time-saving and cost-effective test.

Methods. DNA was extracted from characterized urethral samplesor urine swab specimens using a variety of readily available manual andautomatic methods. Specific bacterial and parasitic genes were amplifiedthrough multiplex PCR and subjected to the NanoCHIP® detectionand analysis system. The generated amplicons were electronically addressed todiscrete loci on the NanoCHIP® cartridge, pre-activated withspecific capture oligonucleotides. Detection was achieved through specificfluorescent reporter oligonucleotides. The molecular method used in the testinglaboratory, and STD6 ACE Detection kit of Seegene were used as referencemethods.

Results. The NanoCHIP® results were inaccordance with the characterizations of the tested samples in terms ofclinical sensitivity and specificity. The Nanochip® multiplexanalysis provided clear results about the identity of the pathogen, eitherbacterium or parasite, within a working day time frame.

Conclusions. The NanoCHIP® based test has provento be a useful system for medium-high throughput screening of urine and swabsamples for reliably detection of STIs. The NanoCHIP®technology presents significant advantages, mainly in terms of minimal hands-ontime, improved laboratory workflow and turnaround time, enabling flexibilityand saving costs.