
Preface

Sexually transmitted infections (STI) continue to be a major cause of morbidity and mortality in the twenty-first century, both in developed industrial countries and in the developing world. The WHO estimates that there are 448 million new curable infections per year, many of which will result in infertility, perinatal morbidity, and death (<http://who.int>). Human immunodeficiency virus infections and the ensuing opportunistic infections are a major drain on the human and financial resources of many countries in the developing world, and even with the availability of effective treatment the epidemic is not yet contained. Many STI are inapparent or asymptomatic, which makes their control very difficult and places the emphasis on screening for infections among this group. In wealthy industrialized countries most people have ready and regular access to health services, such as during school, at the work place, or during pregnancy, and therefore screening for asymptomatic STI poses no major problem other than in the disadvantaged. The vast majority of the population in the developing world has no regular access to health care, and services are often days away from the home. Screening in this group is difficult and there is a need for simple reliable cheap diagnostic methods that can be performed at the point of care, on the same day and by staff with limited training. To add to the already considerable burden of STI, an increase in the resistance of many of the treatable organisms causing infection has been observed recently, and thus a need for rapid detection of resistance is desirable.

A number of organisms can cause STI, the most common of which are *Treponema pallidum*, *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Haemophilus ducreyi*, *Mycoplasma genitalium* and *M. hominis*, *Ureaplasma urealyticum*, *U. parvum*, *Klebsiella granulomatis*, *Candida*, viruses such as HIV, HSV, HBV, HCV, CMV, HPV, parasites such as *Trichomonas vaginalis*, scabies. Testing for this wide range of pathogens has not been useful due to technological limitations in regions where STI prevalence is highest, and therefore a syndromic approach has been propagated by the WHO (<http://who.int>). This syndromic approach to therapy classifies STI into seven syndrome complexes; urethral discharge, genital ulcer disease, inguinal swelling, scrotal swelling, vaginal discharge, lower abdominal pain, and neonatal eye infections. Application of this approach has probably led to an overtreatment as many patients with symptoms do not have an STI. Therefore newer better applicable diagnostic tools are urgently required and the term “ASSURED” tests was introduced to describe the ideal test: Affordable, Sensitive, Specific, User-friendly, Rapid and robust, Equipment-free, Delivered.

Molecular biological methods are very attractive for the diagnosis of STI since a well-defined range of pathogens is responsible for the infection. In particular, the screening of asymptomatic patients requires an affordable and reliable (sensitive and specific) test. In addition new advances in molecular biology methods and techniques will undoubtedly lead to simple robust and affordable tests. We only have to look at the advances in PCR technology to see how far we have come in a decade. Tests developed and applied in developing countries will more than likely lead to ASSURED tests in developing countries.

This book strives to cover the full range of molecular testing for STI. Special attention was given to including a range of methods from the simple and inexpensive to complex

sophisticated methods, thus hoping to provide scientists in many different situations with the information they seek. Aspects of DNA extraction from small-volume samples or difficult tissues, simple, nested, or multiplex PCR, use of duplex primers or other modifications of primers and PCR conditions, sequence analysis for genotyping, denaturing gel analysis, microarrays using liquid beads or microspheres, and silicon nanoparticle-enhanced microcantilever detection of DNA are dealt with in individual chapters. Due to the increasing concern for antibiotic resistance in modern medicine and the appearance of resistant neisseria, the rapid and simple testing for resistance genes is an important factor for molecular testing, and chapters addressing this and the expression of virulence and host factors have also been included. Due to the high prevalence of STI and the asymptomatic nature of many diseases, self-collection of specimens has become more common, and the issue concerning self-collected specimens is dealt with in Chapter 27. Where appropriate, the authors have provided a set of guidelines to aid the reader in the process of establishing a method from scratch. We have also included chapters on the ethical issues of sexual abuse and molecular testing as well as those issues pertaining to STI-testing and close the book with a review about the “transparent patient.”

Laboratory diagnostic tests must meet strict standards in order to be approved for use in the diagnosis of disease in patients. In many instances the application determines the standards to be met; for example, a test in a low-prevalence region requires a higher specificity than would be required in a high-prevalence population. Redesigning molecular tests to suit point-of-care testing will be a challenge for the future; however, the market is huge and the need for inexpensive tests in middle-income regions such as China, India, South Africa, and South America is urgent considering the expanding burden of HIV and related diseases in these regions. Molecular testing will undergo the same evolution as other methods; the greater the usage the better the evaluation resulting in the truly robust methods becoming established and refined and the less useful tests falling by the wayside. We hope this book will be a useful adjunct to the literature in order to help this process.

The twenty-first century will certainly witness an exciting expansion in the use of molecular methodologies for the diagnosis of a wide range of human (and animal) diseases, and this will be particularly relevant for the diagnosis of STI. We are confident that the current volume in the series of “Molecular Methods” will be a valuable addition to the reference literature for the scientist looking to establish this kind of test in their own lab.

Düsseldorf, Germany

*Colin R. MacKenzie
Birgit Henrich*



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