perinatal complications as well as susceptibility to HIV and HSV acquisition and transmission. FDA-cleared NAATs allow testing from the same screening specimens used for CT and NG testing and/or from specimens collected for vaginitis with significantly improved sensitivity over wet mount or hybridization tests [361, 367].

There are currently 2 FDA-cleared CLIA-waved tests, the Binx Health io® CT/NG Assay (Boston, Massachusetts) for use with female vaginal specimens (aged 16 and above) and male urine (aged 17 and above), and the Visby Medical™ Sexual Health Click for CT/NG/TV (San Jose, California) (approved for ages ≥14 years old), for use with female vaginal specimens. Both tests are cleared for screening or diagnostic testing, as well as clinician or self-collected specimens. Assays can be performed at any site operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation, with results in about 30 minutes. Clinical performance estimates with testing performed by non-laboratory trained personnel for Visby, has shown 97%–99% sensitivity and 97%–99% specificity for CT, NG, and TV, respectively, compared to standard laboratory NAATs and infected patient status [384, 385]. Similarly, performance for Binx IO has shown sensitivity and specificity for CT of 96% and 99% and 92% and 99% for women and men, respectively, and sensitivity and specificity for NG of 100% and 99% and 97.3% and 100% for women and men, respectively [386, 387]. Visby allows instrument-free testing and screening of the highest risk group, that is, females, with optimal specimen type, a vaginal swab. The limitation to date has been inability to use other specimen types and a high initial indeterminate rate of >7%. Binx IO requires a small instrument, and although it uses vaginal swabs for females and urine for males, it is not FDA-cleared for TV and extragenital sites, especially for MSM. For both systems, PPV in low prevalence settings will have to be assessed. However, these kinds of tests performed at the point-of-care, specimens sent from home or in smaller healthcare settings are important for STI detection and screening, as the trend in healthcare has shown a 6-fold increase in the reliance of urgent care visits within the United States involving a diagnosis of unspecified STIs. Directed treatment in these settings is vital as these are often patients lost to follow-up [388].

M. genitalium is a recognized pathogen causing nongonococcal urethritis (NGU) and non-chlamydial NGU in males and likewise cervicitis and PID in females. In sum, 15%–25% of infections may be due to this organism and resistance to first line agents, macrolide (ie, azithromycin) or quinolone (ie, moxifloxacin), is significant, especially in HIV positive males [389]. NAATs are the best option for detection of *M. genitalium*, due to lack of culture availability secondary to specialize growth needs and cross-reactivity with serologic tests with *Mycoplasma pneumoniae*. Currently, 2 NAATs for *M. genitalium* are FDA cleared (Hologic Aptima® M.Gen Assay, and Abbott's Alinity™ STI assay) for use with urine and urethral, penile meatal, endocervical, and vaginal swab samples [380]. Routine screening is not recommended in asymptomatic men or women. Testing should be considered in persistent NGU or PID. Molecular tests for resistance markers to macrolides and fluoroquinolones are not commercially available in the United States, but detection of mutations associated with these drugs are under evaluation. Culture or NAATs for *Ureaplasma* are not recommended because of the high prevalence of colonization in asymptomatic, sexually active people [390].

Much like HIV, pooling for testing is an emerging practice to reduce total testing and reduce costs for STI screening. Evaluations have included combining multiple recommended specimen sources, such as urine or urethral, rectal, and oropharyngeal from a single patient (eg, MSM) and combining multiple different patient specimens for CT/NG testing. Both practices have shown valid sensitivity and specificity as well as cost savings [391, 392].

Infections of the Female Pelvis

Pelvic inflammatory disease (PID) refers to acute and subclinical infection of the upper genital tract in females, involving any or all of the uterus, fallopian tubes, and ovaries and includes any single or combination of endometritis, tubo-ovarian abscess, and salpingitis. PID has the highest incidence in ages 15–25 years, can lead to ectopic pregnancy and chronic pelvic pain, and is the leading cause of infertility in women. PID can be sexually transmitted (85% of cases) or naturally occurring (15%) with organisms from vaginal microbiota, enteric organisms (eg, *Escherichia coli, Bacteroides fragilis*, Group B streptococci, and *Campylobacter* spp.) or respiratory pathogens that have colonized the lower genital tract. Clinical diagnosis remains the most important practical approach but can be clinically difficult to identify when patients present with mild or non-specific symptoms. Difficulty in diagnosis, low NPV of tests, and significant potential sequelae should make the threshold for therapy low. Finding symptoms on physical exam (cervical motion tenderness) as well as other criteria (elevated temperature or mucopurulent discharge) increases the positive predictive value of laboratory tests. Testing for CT/NG and consideration for syphilis and HIV are recommended in patients with PID as is a pregnancy test to rule out ectopic pregnancy in those with pelvic pain. Bacterial culture tests performed on specimens collected in a non-sterile manner (endocervical or dilatation and curettage [D and C]) have limited utility in diagnosing PID [393].

Actinomyces spp. Is part of normal oropharynx, gastrointestinal, and urogenital tract microbiota and can often be seen on Pap smears. Approximately 7% of women using an IUD may have a finding of *Actinomyces*-like organisms on a Pap smear. In the absence of symptoms, women do not need IUD removed or antimicrobial treatment. Infection occurs most commonly