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At-Home Diagnostics Solutions for Chlamydia and Gonorrhea

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STIs, particularly chlamydia and gonorrhea, continue to be major public health concerns in the United States. In 2022, reported rates were 495.0 and 194.4 per 100,000 people, respectively (https://www.cdc.gov/std/statistics/2022/overview.htm). Traditional testing methods have limitations due to accessibility and stigma. This is reflected in persistently low screening rates, e.g., in reproductive age women or in rural or under-resourced areas. Moreover, the COVID-19 pandemic further impacted access to care, as demonstrated by decreased chlamydia case reports which have not yet returned to pre-pandemic levels. Existing barriers necessitate innovative solutions to detect, treat and prevent STI spread, noting that STI diagnostic options remain far fewer than for COVID-19.

FDA recently granted the first marketing authorization of a diagnostic test system "Simple 2" that accepts mailed-in specimens self-collected with the included kit[1]. A person can order the over-the-counter (OTC) test online, collect urine or a vaginal swab at home and send it to LetsGetChecked®'s designated laboratory. Results are provided in 2–5 days with a follow-up from a clinician for positive or invalid tests. The person can request a virtual consultation for an additional fee. If the chlamydia test was positive, oral treatment can be sent home. A positive gonorrhea test requires a healthcare visit elsewhere, likely for an intramuscular ceftriaxone injection, the CDC-recommended treatment for uncomplicated cases[2].

This authorization is an important milestone for increased STI testing access. This article should not be interpreted as endorsing one product, rather, randomized controlled trials have demonstrated that the approach can increase the number of people tested, with care linkage comparable to in-clinic testing (e.g.,[3] and references in[4]). Without vaccines in hand, the approach is essential for progress. That is, if it is made accessible to the millions of people in need of testing per US screening recommendations[2].

STI self-testing in the privacy of one's home has immediately apparent advantages due to persisting barriers. This is reflected in scientific literature on high acceptability, user experiences, increased uptake and acceptable performance, summarized in WHO recommendations supporting HIV and STI self-testing[4]. The term "at-home" is used for easy understanding to indicate autonomy in nonclinical settings without direct medical supervision. It is not meant to exclude the homeless, incarcerated or others not at home.

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Such testing can reach people who may not otherwise test like people who distrust or avoid health care systems due to STI stigma, embarrassment or questions about sexual behaviors. It is convenient, i.e., if delivered to a home, requires no transportation or clinic appointment, key factors for young, sexually active people with busy lives and limited resources. STI self-testing allows self-control and empowers individuals to take measures to protect themselves and their loved ones through temporary behavior change and by seeking treatment, reducing their risk of complications and their partner's infection risk, respectively. Removing testing barriers is particularly relevant for chlamydia and gonorrhea, often asymptomatic or minimally symptomatic. If untreated, they present unacceptable threats to the individual's health and wellbeing due to long-term sequelae (infertility, increased HIV risk, other adverse outcomes) and to population-level transmission rates. CDC considers antimicrobial resistance (AMR) of *Neisseria gonorrhoeae* an urgent threat. The organism has eventually developed resistance to all previously employed drug classes; therefore, detection and treatment are essential countermeasures to curb rates and prevent emerging novel resistance.

The new test system hardly constitutes a groundbreaking biomedical invention. Rather, for laboratory technology, it uses the Aptima Combo 2® Assay (AC2®; Hologic Inc., San Diego, CA) a nucleic acid amplification test (NAAT) employing transcription mediated amplification. It runs on Panther® systems, fully automated platforms often found in high-throughput clinical laboratories. The AC2®'s intended use has long included urine and patient-collected vaginal specimens as do many other NAATs, albeit only in clinical settings. LetsGetChecked®'s innovation is that the test is embedded in a telehealth platform that encompasses patient-initiated test ordering, a home collection kit, result receipt and linkage to some health services.

The following public health aspects are noteworthy: First, the market authorization could end the proliferation of unauthorized virtual offerings by major retailers that have raised quality and consumer protection concerns[5]. Concerns centered on the potential for medical or financial harm due to non-recommended test selection and performance after specimen transport, among others.

Second, along with the *De Novo* authorization, the FDA is establishing special controls to assure safety and effectiveness for this test type, described publicly in the decision letter to LetsGetChecked® (DEN200070.Letter.DENG.pdf (fda.gov)). Future publication in the Federal Register is expected. Mitigation measures for health risks are described, i.e., false results, failure to correctly interpret test results or to correctly operate the device. Inaccurate results could lead to missed diagnoses or unnecessary anxiety. Special controls include, among others, requirements for the collection device, labeling, instructions for use, materials on the hyperlinked manufacturer's website and performance testing.

Third, future improvements to STI testing will hopefully follow. WHO recommended same-day treatment of urethritis cases in settings with quality-assured molecular testing and with same-day results available to confirm or exclude gonorrhea and chlamydia[6]. However, test results are rarely available on the day of a clinic visit in the US. Most urethritis cases still receive presumptive antibiotic treatment even though this can cause overtreatment or

necessitate return visits to administer the pathogen-specific recommended antibiotic. Mail-in testing has the potential to allow treatment with the correct antibiotic at initial clinic visit and brings us closer to these recommendations. However, an urgent need remains for faster tests, including high-quality self-tests and more available, implemented point-of-care tests for more specimen types with results in 20 minutes, not 2 to 5 days.

Post market introduction, it is essential to ensure the test works as intended, i.e., performs with acceptable sensitivity and specificity and patients are linked to care and can make their test results accessible to providers. Concerted efforts are needed to ensure equitable accessibility and affordability of the new virtual test system. The LetsGetChecked® website (accessed 12/20/2023) offers the test for $99 and a virtual consultation for $39 which may not be affordable for all. Special offers may be available and reimbursement is possible through flexible spending or health savings accounts. Without more public health efforts patients will likely have to bear the cost and handle payments, potentially excluding low-income individuals. Many health care providers have implemented testing models that prioritize service affordability with minimal or no out-of-pocket patient costs. Offering low-cost clinic testing is possible due to free screenings under the Affordable Care Act or other subsidies managed by clinics. Future market authorizations may include prescription-based tests which may help with billing and integration. Of note, Simple 2 is authorized for ages 18 and up, leaving a gap for younger teenagers. Work is also needed to overcome barriers such as internet access to realize the potential of internet-based testing and ensure equity in testing access[7]. Lastly, the new approach still relies on a (virtual) consultation for treatment delivery; sensitive and inclusive healthcare practices are needed via internet delivery just like in clinics.

In summary, the authorization is an exciting and welcome step in the right direction towards accessible, equitable, faster, affordable and user-friendly STI testing that retains high quality and protects the consumer from harm. Continued research into faster, more cost-effective testing methods is essential, particularly those offering immediate results.

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